

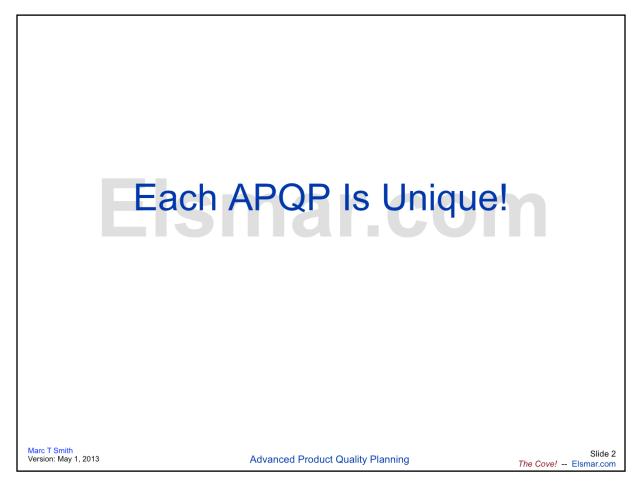
Advanced Product Quality Planning

In Consonance with the AIAG's (TS 16949) APQP Manual

Marc T Smith Version: May 1, 2013

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What Is APQP?

- APQP is a 'defined' process for a product development 'system' for Ford, GM, Chrysler and their suppliers.
- APQP is an attempt to provide a common path and synchronization of product development activities.
- APQP is an attempt to ensure communication both within a company and between a company and their customer.

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	What Is APQP?
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What is the AIAG's APQP Reference Manual?

- It Is General Information
- It Does Not Address Specific Manufacturer Information or Requirements
- It is NOT Auditable
- It Does Attempt To Give Guidance
- It Does NOT Address Any Specific Industry or Manufacturer

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Notes & Commentary

Example Control Plans included in the APQP Manual (starting on page 47):

- Equipment
 - Set-Up Dominant Process
 - Machine Dominant Process
 - Fixture/Pallet Dominant Process
 - Tooling Dominant Process
- People
 - Operator Dominant Process
- Material
 - Material or Component Dominant Process
- Methods
 - Preventive Maintenance Dominant Process
- Environment
 - Climate Dominant Process

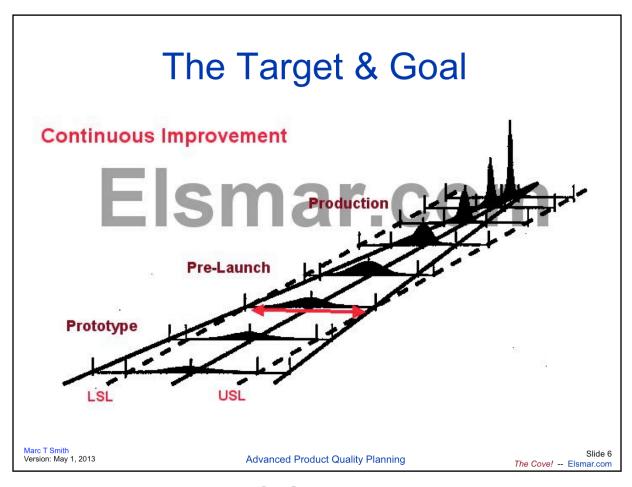
Basics

- Do NOT try to write a procedure just like the APQP reference manual.
- Look at what YOU are doing and relate it to the APQP process described by the reference manual.
- Be ready to explain 'Equivalencies' Where and How and What your system
 does which fulfills APQP timeline
 elements.

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In Consonance with the AIAG's (TS 16949) APQP Manual

This presentation is formatted to be read and printed in the 'Notes' view. Explanations and detail are contained in the 'Notes' portion of the presentation. While not all slides have text in their Notes' window, most have some relevant info. If you do not see the notes below this slide you are not using the 'notes' view.

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Notes & Commentary

When reading the APQP and Control Plan manual, bear in mind that it is written as if you are starting a new product rather than that which is most common - variations on an existing product.

One of the reasons I stress that every APQP is unique is that the fact that a company is typically going through a process they have gone through before. This means that the APQP Team will be drawing on 'old' data and information. For example, most companies do not empanel an entire FMEA team and start their FMEA (process or design) from 'scratch'. More typically someone takes a copy of an FMEA for a similar existing product and reviews it. Many times few , if any, changes have to be made.

The probable failure modes will most often not change for a product 'type' or 'family'. If you' re making a foundation brake currently, the probability is very high that the FMEA will not change, and if it does it will be based upon feedback from the customer in one way or another. There is a higher probability that current production will evoke changes to the FMEA in response to an engineering change arising out of one 'problem' or another during 'this years' production than a need for change being identified during the APQP process.

Meeting the Intent

- It is important to interpret APQP requirements in terms of the documentation and systems within your company. You also have to understand that when the APQP manual talks about a link via a process operation number on the control plan to the process number on the process flow diagram it may be that the control plan and the process flow diagram within your company is one and the same - a single, discrete document.
- It is important to look at what they are attempting to do. In this case they are using the process number as a linkage between two or more documents as a way to ensure that 'counterpart information' is easily visible. This control is for this process step in the process flow which was evaluated for risk in this process FMEA line item.
- In this presentation we will first be looking at the base requirements mainly inputs and outputs to and from 'Phases' of the APQP process. From there we will go to looking closely at the control plan and related 'required' documentation. You will find that a number of times within this presentation I will be reinforcing the fact that there is as low probability that your company's systems and documentation will exactly reflect what is in the APQP and Control Plan manual text. You have to look at the intent and you must identify 'equivalencies' within your company's systems and documentation.

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Notes & Commentary

My intent in the first couple of slides is to begin to acclimate you to the fact that many of the relationships between what your company does and the wording of the APQP and Control Plan manual require not only an understanding of the APQP and Control Plan manual but also of what they are trying to achieve. *Laundry lists* are provided, for example, of inputs and outputs. The fact that something such as DFA is on a laundry list does not mean it specifically is required. On the other hand, the requirement for a control plan is not negotiable - except for the format. As they talk about a control plan, the requirement is really the content. So - you may have the required content spread between multiple documents. Or - you may have the content of several documents (e.g.: the control plan and the process flow diagram) in one document instead of many.

In part because of this it is not always immediately evident, particularly within any given company, of what outputs are the result of what inputs. You have to look closely at the APQP manual and then at your company's systems and documentation. This is where equivalencies come into play. For example, ask yourself: "How does our company come up with design goals (a Phase 1 output)?" Where are they documented? Some of your sources should be from the Phase 1 inputs laundry list.

What Is APQP?

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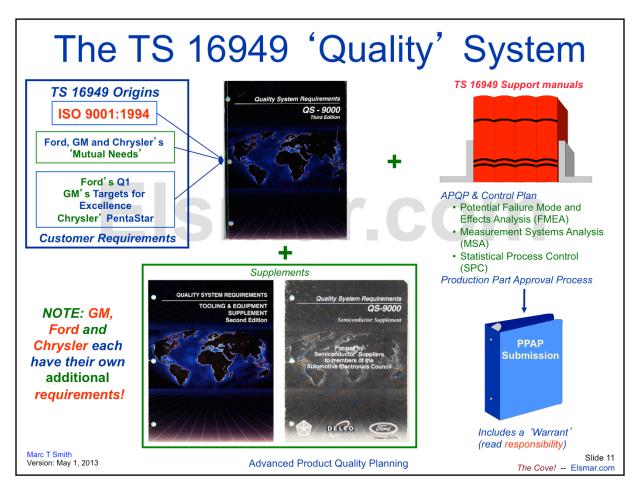
Notes & Commentary

If you are an engineer or a manager from a company which has not before had to address the system Ford, GM and Chrysler uses for product development and introduction, you will find the APQP process to be a structured system. TS 16949 and the related manuals such as the APQP manual were developed by the AIAG (Automotive Industry Action Group). The AIAG its self was formed by 'the big three' to try to standardize this process.

If you worked in an automotive supplier environment other than as a supplier to Ford, GM and/or Chrysler you will probably understand some of the mechanisms but not the specifics required by APQP - such as the part submission process (including the 'warrant').

In this presentation I will try to explain the relationships of the APQP 'Phases' as well as the required standard documentation (such as the control plan and the PPAP Warrant). In addition I will try to address some specific documentation requirements including the FMEAs, the process flow diagram and the process control chart.

You should also be aware of the other manuals: the MSA (Measurement Systems Analysis) manual, the FMEA manual, the SPC (Statistical Process Control) manual and the PPAP (Production Process Approval Process) manual.



Before we go any further with this discussion, if you are new to automotive you should know that the APQP and Control Plan manual is a 'reference' manual. It is a part of Ford, GM and Chrysler's TS 16949 'quality' systems requirements. TS 16949 is a 'standard' but not in the usual sense. When I think of what I call a standard I think of something more or less world wide. Bottom line it is a 'standard' containing 'quality' system requirements of Ford, GM and Chrysler which was derived from their individual requirements. GM's old Targets for Excellence, for example, included their GP's (General Procedures - now called the GM-9000) and general quality systems requirements for suppliers. Ford has their Q1. Chrysler had their PentaStar requirements. This discussion is focused on one support manual of this system - the *APQP and Control Plan* manual. Note that the FMEA, MSA, and SPC support manuals are 'sub-' manuals of the APQP manual in that they further define output parameters (e.g.: your MSA analysis has to include analysis of Bias, linearity and R&R as a minimum).

As much as anything else, the APQP manual is a set of data requirements. Proof your process is capable. Proof (through an FMEA) that you have made certain risk evaluations. Proof you know you can actually produce a part and in the expected

What is the AIAG's APQP Reference Manual?

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The APQP and Control Plan manual is controlled by the AIAG (Automotive Industry Action Group). The AIAG is an organization set up to 'coordinate' certain aspects of the 'big three's' needs. For the best understanding of the full role of the AIAG in this play, go to their web site: http://www.aiag.org/interest_areas.html

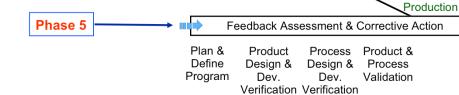
As a reminder, the APQP methodology is a Ford, GM and Chrysler requirement. Although Honda, Toyota, BMW, and other car makers have a similar process which they employ to ensure the same goals, the APQP and Control Plan manual has nothing to do with their systems.

Toyota is an example of a company which uses a somewhat different process to achieve the same goals. It is called the Toyota Production System and companies world wide have adopted Toyota's approach. I see advertisements for employees regularly which cite a requirement for, or a preference for, Toyota Production System experience.

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Validation Product - Proces



This is how the APQP and Control Plan manual graphically represents the process it describes. To a large degree, this can be looked at as Critical Paths in the process. You have to do planing before you do product and process design and development. You have to do product and process design and development before you can do product and process validation. Another way of saying this is to say the phases are **Dependent**. Each phase (except Phase 1) is dependent upon elements of (outputs from) the previous phase.

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Phase 4

Phase 3

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Let's take a close look at what APQP is. Note that it is not specific to product and process development and introduction alone. The last 'Phase' is ongoing production. This said, it is evident that despite the insinuation in the name (advanced planning) the APQP process addresses a continuous system from RFQ (Request for Quote) to the end of product life. It does *not* address 'service' parts. A large part of the APQP manual is devoted to lists of **potential** inputs and expected outputs. From phase to phase there are specified inputs and outputs. The output from Phase 1 is an input to Phase 2. The output from Phase 2 is an input to Phase 3 (etc.). A guick browse through the APQP and Control Plan manual reveals that at the beginning of each Phase these inputs and outputs are defined.

In order to address the issues of suppliers having different parts, different processes and thus often quite dissimilar systems, the APQP manual provides what are in essence 'laundry lists' of **potential** information sources for inputs. For example, in Phase 1 there is a required input of Voice of the Customer (APQP manual, page 7). The 'laundry list' for Voice of the Customer is on the bottom of page 7 (1.1 Voice of the Customer). You may have noticed that they give suggestions (inputs) of where to obtain this **potential** information sources (complaints, recommendations, various

APQP Phases

Think Critical Paths

- Phase 1: Plan & Define Program
 - ° Where do we want to go?
- Phase 2: Product Design & Development Verification
 - Can we design one?
- Phase 3: Process Design & Development Verification
 - Can we make one?
- Phase 4: Product & Process Validation
 - Proof of Phases 2 and 3.
- Phase 5: Feedback Assessment & Corrective Action
 - Production, Continuous Improvement, Prevent Recurrence

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Notes & Commentary

The 5 Phases of APQP are listed above. As you can see they are the logical steps one would take in almost any business situation. I use the word business as this is just as applicable to a service company as a manufacturing company if you think about it. For that matter, these phases or 'steps' make 'good business sense' for companies which do NOT supply automotive.

What matters is what sources of information there are and the specifics. For example, outside the automotive industry one would not expect to see a PPAP submission warrant. However, the process they use for product approval may to some degree reflect parts of the APQP process.

Bear in mind that the APQP and Control Plan manual does not address manufacturer (customer) specific requirements. *The APQP and Control Plan manual only addresses the general requirements*.

Don't over complicate what is required by the APQP system.

APQP Team

Internal (Company) Coordination and Tracking

In this example, you can see the company has defined sequential steps in a spreadsheet. Line items can be broken out and aligned with inputs / outputs of the APQP Phases as defined in the APQP and Control Plan manual. Note that each line item carries a defined responsibility as well as "input", assistance and coordination responsibilities. There is no exact indication of critical path in this example, however in general the line items are sequential.

This said, one should also understand that *many of these items* will be proceeding in parallel. The design FMEA, the process flow diagram, the process FMEA and the control plan will probably all be 'in process' at the same time.

Most of the critical path links are going to be self-evident. For example, you cannot finish your control plan until your process FMEA and Flow diagram are complete. If you do not know why this is true, you may need specialized training.

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नानानानानानानाना	(Timing Templates)	Element
R I	0 X	Business Plan / Marketing Strategy
	1	Contract Review - Initial Feasibility Review
	2	Initial Layout (Prior to Formal Kick-off))
	3 4 X X	Market Research Information Confirm All Customer Requirements
CRITITITITI	4 A A	
- R	5 X	(Including Engineering Research Data) Design Analysis
	6 X	Preliminary Product (Detail) Design
C R A A -	7	Design for Manufacture Review
- R	8 X	Planning Release
	9 X X	Design FMEA
	10 X	Manufacturing Concept
	11 X X	Significant Characteristics Preliminary Process Design & Flow Chart
	12 X X X	Quality History Review
	14	Prototype Build Control Plan
C R - I I 1	15 X X	Prototype Build
	16 X X X	Process FMEA
	17 X X	DVP&R Testing
	18 X X X 19 X X	Feasibility Sign-Off
	19 X X	Contract & Investment Approval Final Product Design
	21 X X	Production Level Drawings & BOM; Eng. Change Date
	22 X X X	OK to Tool Date (Design Freeze)
	23 X	Select, Review, Rate Suppliers
	24 X X	Production Equipment Specifications
	25 X	Process Control Plan (including Pre-Launch version) Kick Off Suppliers (Pre-Award meeting)
	27 X X	Production Equipment Sourcing
	28 A X	Mfg. Equipment/Process Design Approvals
C - I - R 2	29 X	Order Production Tooling, Gages, Test Equipment
C - R 3	30 X X	Production Tooling Complete
	31 X	Approve Suppliers
	32 X X	Audit and QA Work Instructions Equipment Construction
	34 A X	Equipment Pass Off Run
C R I - 3	35 X X	Ship, Install, Debug & Test
	36	Work Instructions (Manufacturing)
	37 X X	Valve Freeze Date Develop Product Training Plan
	38 39 X X	Supplier (Component) PSW Review & Sign-Off
	60 X X X	Preliminary Capability Studies For Production Processes
	41	Final Process Design
R - A A - 4	42	Process Optimization
	43 X X	Establish BOM & Routings
	44 45 X	Product Training Select & Train Quality Personnel
	46 X X	Process Review (PFMEA Walk Through - QA Sys. Review)
- A R - A A - 4	67 X	PPAP - Production Run
C - R 4	48 X	Finalize Supplier Contracts
	49 X X	Define Packaging
	50 51 X X X X	Source Packaging IES Testing
		PPAP - Part Sample Warrant Submission
CA-AAAAA	32 X X X X	
CA-AAAARA	WHERE DO W	
Do we, if if so,	WHERE DO W	E WANT TO FIT THESE (Below) IN?
Do we, if if so,		E WANT TO FIT THESE (Below) IN? M&TE Needs, Costs, Procurement
Do we, if if so,	WHERE DO W	E WANT TO FIT THESE (Below) IN?
Do we, if if so,	WHERE DO W	E WANT TO FIT THESE (Below) IN? M&TE Needs, Costs, Procurement Measurement and Test Equipment Verification
Do we, if if so.	WHERE DO W	E WANT TO FIT THESE (Below) IN? M&TE Needs, Costs, Procurement Measurement and Test Equipment Verification Ridework (Ongoing) A = Assistance
Do we, if if so.	WHERE DO W	E WANT TO FIT THESE (Below) IN? MATE Needs, Costs, Procurement Measurement and Test Equipment Verification Ridework (Ongoing) A = Assistance C = Coordination
Do we, if if so.	WHERE DO W	E WANT TO FIT THESE (Below) IN? MATE Needs, Cods, Procurement Measurement and Test Equipment Verification Ridework (Orgoing) A = Assistance C = Coordination I = Input (Information)
Do we, if if so.	WHERE DO W	E WANT TO FIT THESE (Below) IN? MATE Needs, Costs, Procurement Measurement and Test Equipment Verification Ridework (Ongoing) A = Assistance C = Coordination
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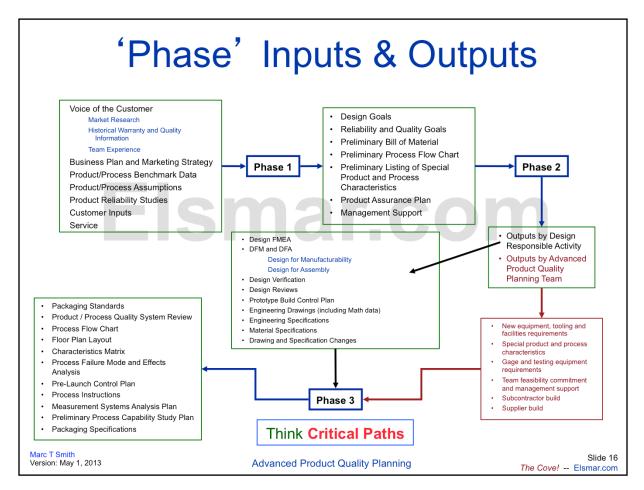
Slide 1

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Notes & Commentary

Each company has their own way of defining and tracking an APQP project. A very important part of all this is **defining responsibilities**. In the example above, a simple Excel spreadsheet is used. Many companies use MS Project or other project management software. An APQP project is just that - a project. There are a number of companies which make APQP project management software (essentially databases). I am not a proponent of 'canned' software, but for some companies it has it's place. Remember, each company is unique in how they assign responsibilities.

Each APQP Team member is representing their department. If you're from manufacturing, you will be bringing back to your department certain requirements which (depending on how your company and team is structured) will have to be carried out at certain times. Sales is generally in the action arena early in the game and will be providing some information such as contributions to the identification of certain customer requirements. Manufacturing, at some point, will have to do capability studies and a run-off. Typically manufacturing is in up to their necks from the beginning while sales is for the most part out of the picture early on. Design is involved early on and then typically fades back until / unless a problem occurs (we're



Let's take a look at the above inputs and outputs. Remember that the outputs from one stage are necessarily inputs to the next phase. That does not mean that in your company you will be able to look at the APQP and Control Plan manual requirements and immediately be able to literally translate the requirements. An example would be the *characteristics matrix*. Some companies do not have a discreet, stand alone characteristics matrix. So when you are reading through the APQP and Control Plan manual and you come to a place where it refers to a characteristics matrix you have to look at where *your* company documents critical / special characteristics.

When looking at the inputs and outputs one has to use their understanding of how their company systems are set up. Design goals are an output of Phase 1. What inputs will determine, at least in part, the design goals are mixed. You would probably use various inputs from the customer, including Voice of the Customer, and the Business Plan (to name a couple of information inputs for determining design goals). Reliability (MTBF) may a design characteristic goal. Some are relatively evident. Some may not be so evident. Let us again step back and remember that the lists of inputs and outputs may contain 'requirements' not applicable to your product. An example is DFA. Although listed as an output from Phase 2 in the manual, your

Inputs / Outputs - Phase 1

Phase 1

Phase 1 Inputs

- Voice of the Customer
 - Market Research
 - Historical Warranty and Quality Information
 - Team Experience
- Business Plan and Marketing Strategy
- Product/Process Benchmark Data
- Product/Process Assumptions
- Product Reliability Studies
- Customer Inputs
- Service

Phase 1 Outputs (= Phase 2 Inputs)

- Design Goals
- · Reliability and Quality Goals
- Preliminary Bill of Material
- Preliminary Process Flow Chart
- Preliminary Listing of Special
 Product and Process Characteristics
- Product Assurance Plan
- Management Support

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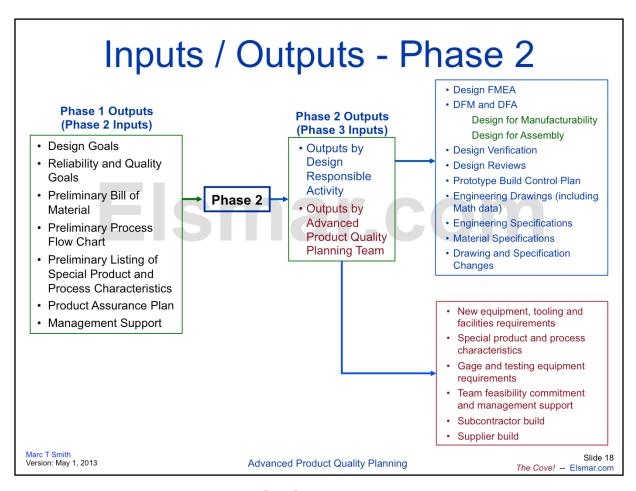
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Notes & Commentary

On the previous page I displayed inputs and outputs from Phase 1 through Phase 3 to illustrate the over all flow through. On the next 5 pages each phase is addressed individually. It is always the case that the output from one phase is an input to the next except for Phase 5 which technically has no phase to input to. However, while the APQP manual does not list it, the data and such from ongoing production will be used if later you do an APQP project on a similar or family part.

The APQP and Control Plan manual discusses each input and output individually on pages 7 through 30. We earlier looked at Voice of the Customer as an example input to Phase 1. On page 7 of the APQP manual there is the following: "The "Voice of the Customer" encompasses complaints, recommendations, data and information obtained from internal and/or external customers. Some methods for gathering information appear in the following paragraphs." It should be evident that this is guidance for compliance.

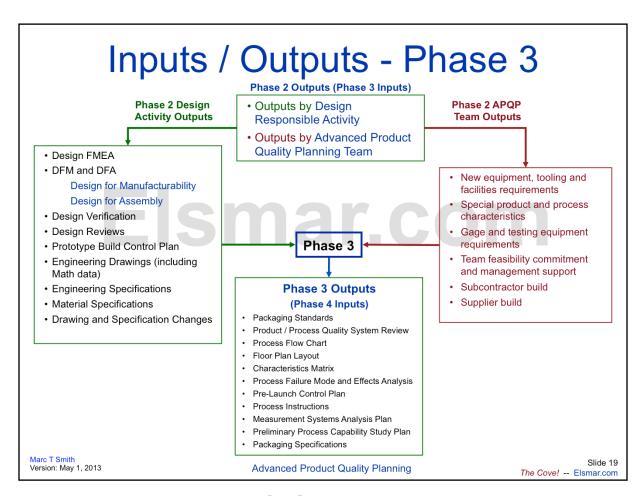
For the most part, the APQP and Control Plan manual will only be relevant as you set up your system. This is because most companies use project planning software and they make a template which addresses each of the required items. Once the system is defined and proven changes are typically rare.



As noted earlier, one should not look at this entirely in a linear fashion. However, to some degree one may look at the phases with an eye to critical paths. For example, design goals, a Phase 1 output, is necessary for completion of certain Phase 2 outputs (for example the Design FMEA).

Step back and ask yourself: "...What do I need before I can complete my Control Plan?..." There may be inputs your company utilizes which are not listed in the APQP manual.

If you try to draw a direct line from an input to an output (such as from design goals to design FMEA above), you will not always have a clear 1 to 1 relationship. As an example, when design goals are established and documented they will probably have an effect on a number of the outputs. In this case design goals *may* affect the design FMEA, design verification test design, certain engineering and material specifications, and the prototype build control plan.





Inputs / Outputs - Phase 4

Phase 3 Outputs (Phase 4 Inputs)

- · Packaging Standards
- Product / Process Quality System Review
- · Process Flow Chart
- Floor Plan Lavout
- · Characteristics Matrix
- Process Failure Mode and Effects Analysis
- · Pre-Launch Control Plan
- Process Instructions
- Measurement Systems Analysis Plan
- Preliminary Process Capability Study Plan
- Packaging Specifications

Phase 4 Outputs (Phase 5 Inputs)

- Production Trial Run
- Measurement Systems Evaluation
- Preliminary Process Capability Study
- Production Part Approval (PPAP)
- Production Validation Testing
- Packaging Evaluation
- Production Control Plan
- · Quality Planning Sign-off

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Phase 4

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Inputs / Outputs - Phase 5

Phase 4 Outputs (Phase 5 Inputs)

- · Production Trial Run
- Measurement Systems Evaluation
- Preliminary Process Capability Study
- Production Part Approval (PPAP)
- Production Validation Testing
- Packaging Evaluation
- Production Control Plan
- · Quality Planning Sign-off

Phase 5 Outputs

- Reduced Variation
- · Customer Satisfaction
- Delivery and Service

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Phase 5

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Phase 1 Inputs

Voice of the Customer

Market Research
Historical Warranty and Quality Information
Team Experience

- Business Plan and Marketing Strategy
- Product/Process Benchmark Data
- Product/Process Assumptions
- Product Reliability Studies
- Customer Inputs
- Service

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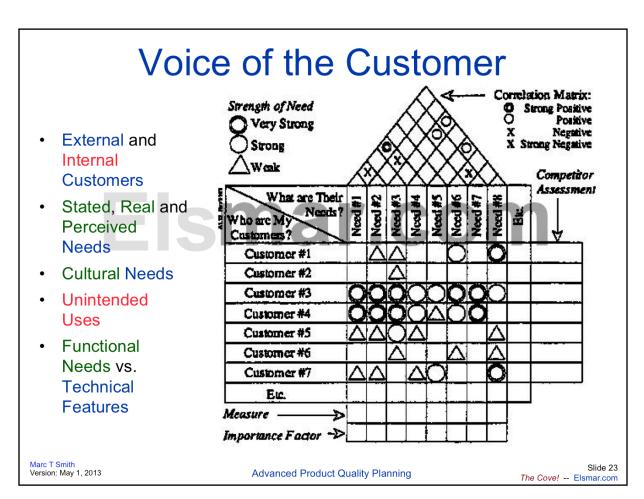
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Notes & Commentary

Some aspects are not always abundantly clear. Let's take a look at Team Experience under Voice of the Customer. This has little to do with team experience as one might expect from the title, but rather is a list of information sources.

I earlier referred to 'Laundry Lists' - this is an example. Why? Because is the expectation is that each company look at this list and determine which of these is appropriate for their product. Not every company will be able to obtain information from 'fleet' operators, for example (1.1.3 Team Experience, page 9, "Fleet Operator's comments"). But if you do have access to fleet information you' re supposed to utilize it! This said, it is true that each company will have, as a minimum, a sub-set of the information resources listed to draw upon. For example, every company will have customer letters and suggestions (1.1.3 Team Experience, page 8, "Customer letters and suggestions"). If not actual letters, e-mail or other customer 'input' /feedback.

It should also be pointed out that some companies have information resources that fit the category (will provide information relative to the intent of gaining insight on the Voice of the Customer) which may not specifically be on the list. Exclusion from the 'laundry list' does not negate the importance of such inputs and the expectation that

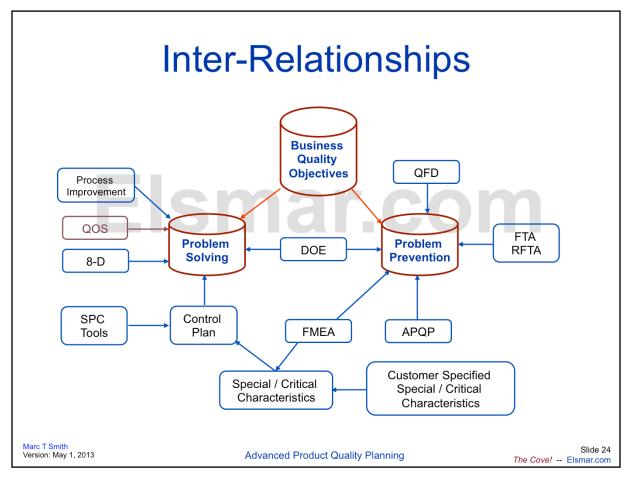


Above is an example of one method (you need more than 1 so don't misunderstand this as 'the sole source') of determining the Voice of the Customer. When the auditor looks for compliance, they are simply looking to see that your company has defined some 'minimums'. These may or may not be in a listing but are typically at least addressed in a procedure or policy.

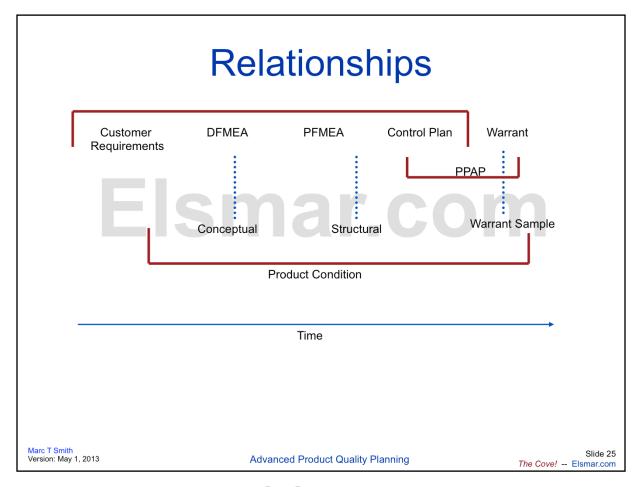
In addition, one should note that different aspects of Voice of the Customer can come from various departments. This is the reason that that the APQP Team is the entity which gathers the information, parses it and interprets it. We do not simply go to (for example) sales and get what they have.

Most companies use some sort of check list as they define how, within their company, APQP requirements are met. Since each company is different, each company will have a different approach on what information they gather, how it is gathered and how it is interpreted.

There is nothing precise in this. Relating customer needs to technical features, for example, plays a part (and outwardly appears quite clear), while determining/ forecasting possible/probably 'unintended uses' is quite a bit less clear.

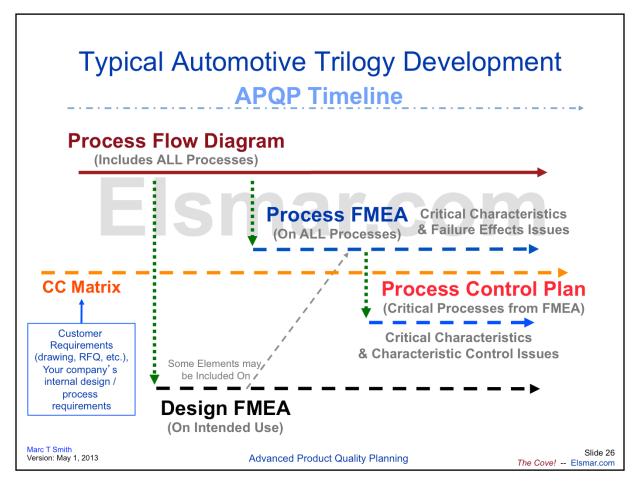


This is one illustration of APQP document relationships. While I find this type of chart somewhat confusing (it is a bit more abstract than a timeline), I include it as some folks like this type of association. It does give a sense of what are inputs and what are outputs on a high level.



In a recent course I was asked to explain 'what feeds what' and 'how this all fits together'. This sounds simpler than is is as while some relationships are quite clear, such as the control plan deriving its contents from the product and process FMEAs, other aspects are less clear. It is one thing to say that one phase feeds another. It is another thing to attempt to show each and every 'this leads to that'. In part this is because many times there is nothing quantifiable or there is a lack of an equivalent. An example would be customer questionnaires and surveys as a part of Market Research. From the laundry list in 1.1.1 Market Research, your company has to have a methodology of taking the items and translating them into some type of measurables.

The above diagram is meant to illustrate the sequence of the required documentation. This is one way of looking at the relationships. Here we see the sequence of a sub-set of required documents. It is evident that the Design FMEA precedes the Process FMEA. But here we must pause to consider reality. More often than not these documents are actually being developed concurrently. Knowing this we can only say that the sequence above, as in the APQP manual, is 'preferred'. In truth, the Design FMEA should, for example, be completed prior to the completion of

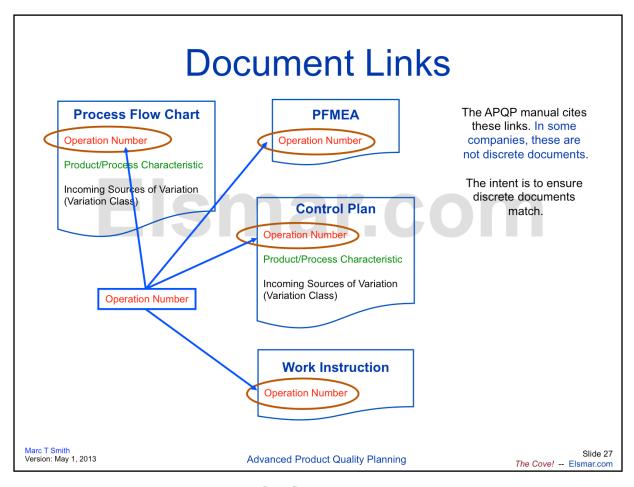


The above is another way of illustrating how each document 'feeds' another. This is quite clear when you understand the requirements of each document.

It should be noted here that while there is a reference to a characteristics matrix, some companies put 'critical' (or 'special' characteristics, or whatever your terminology is) on their drawing or somewhere other than a 'stand-alone' characteristics matrix. This is an example of 'meeting the intent'. You can start all of your documents at the same time, technically, but 'critical path' comes into play.

From this illustration we can see several factors.

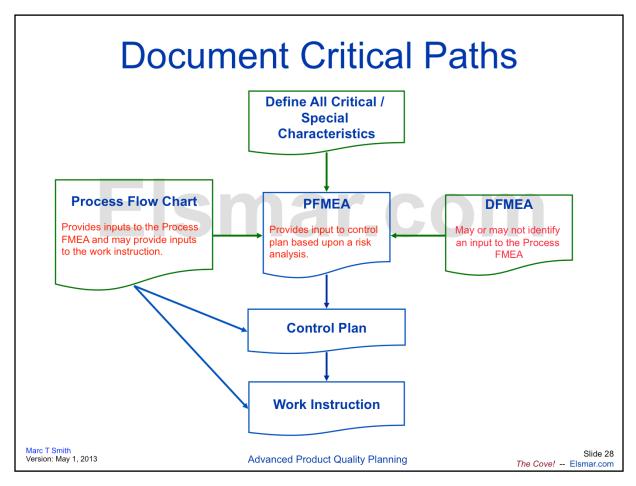
Determining / defining 'critical' or 'special' characteristics (customer and internal) must be started early. If you do not know what these are you cannot complete either of your FMEAs. If you do not complete your design FMEA you cannot complete your process FMEA as sometimes your design FMEA will contain inputs to your process FMEA. You cannot complete your process FMEA until your process flow diagram is complete. If you cannot complete your process FMEA, you cannot complete your process control plan. In the same vein, you cannot complete your characteristics matrix until you know your customer requirements.



As we started to look at on the previous page, it is evident that the process flow diagram be 'completed' early. This is because it serves to identify all processes involved from which internal critical (special, whatever) characteristics are derived. I have only seen a couple of companies which got through a QS audit with NO internal critical / special characteristic.

The above illustration shows the internal links in these documents which key each to the other. Note that the design FMEA does not have an internal link to the process FMEA because the design FMEA addresses intended use as opposed th the process FMEA which addresses processes.

Note that on this example the PFMEA, the control plan and the process flow diagram have 'links' (in this example the Operation Number). Later in this presentation we will address situations where these documents are looked at as 'elements' as opposed to discrete documents. Looking at each of these as discrete documents is the classical way of representing the requirements, however in many cases, such as companies which use Ford's DCE methodology (Dynamic Control Plan), two or more 'elements' may be in one document. From this it is obvious that there is no intradocument linkage as illustrated above. Meeting the intent is that separate documents



This diagram illustrates several critical paths in the documentation. I again want to stress that these documents may all be started at the same time and, in fact, typically are. However, the PFMEA cannot be signed off on as complete until the 3 input sources are completed. The control plan cannot be signed off on until the PFMEA is complete. The reason the control plan cannot be signed off on as it cannot be complete until the PFMEA contains all known possible issues.

Remember that the control plan will not necessarily contain every item from the PFMEA. That is in part the function of the process FMEA - to determine what 'should' or 'must' be controlled. It is a risk analysis.

At times this can become confusing because, for example, design validation may provide evidence that an issue not previously considered 'should' be addressed in the DFMEA and/or the PFMEA. Often by the time the design validation is started the DFMEA has been 'finished'.

Process validation may in the same way reveal something which should be on the process FMEA (and probably on the control plan as well). As you can see, everything is not always consecutive and simple.

Automotive Process FMEA

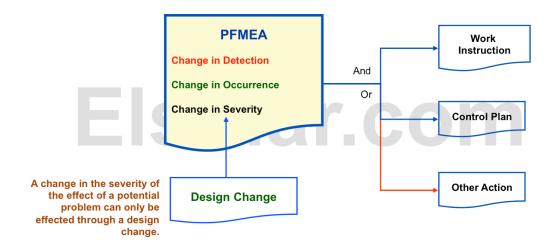
Process: Primary P	rocess Responsibility:		-	Outside Suppliers Affected Model Year/Vehicle(s)						Part Number:					1 - 10
Other Div	v. Or People Involved:			Scheduled Production Released						PFMEA Date:			Rev		
Approvals:	ovals: Quality Assurance Manager Quality Assurance Engineer Senior Advisor														
Part Name Operation Number	Process Function	Potential Failure Mode	Potential Effects Of Failure	Potential Cause Of Failure	Current Controls	Occured	Severity	Detection	RPN	Recommended Actions And Status	Actions Taken	Occured	Severity	RPN	Responsit Activity
SIR Container 1	Take TPPE Material Held In Storage Area	Wrong Material	Fragmented Container Unpredictable Deployment	Insufficient Supplier Control Improper Handling Misidentified Material	Material Certification Required With Each Shipment Release Verification	1	9	2							
		Out Of Spec Material	Fragmented Container Unpredictable Deployment Fragmented Container	Supplier Process Control Open Boxes	Periodic Audit Of Supplier Material Visual Inspection	3	10		90				4		
		Material Material Composition Change	Unpredictable Deployment Fragmented Container Unpredictable Deployment	Engineering Change Supplier Change	Release Verification Green "OK" Tag Customer Notification	1	10	7	70					+	
2	Move To Approved Storage	Unreleased	Fragmentation	Untrained LTO Untrained Personnel	Check For Green "OK" Tag At Press Trace Card Check List Training	5	10	1	50						
3	Hold In Approved Storage Until Needed	Contamination	Fragmentation Process Problems	Open Containers Housekeeping Area Maintenance	Boxes Kept In Sealed Storage Area Until Needed Boxes Lined With Plastic Liner On Pallets Inside Storage P. M. Facility	1	10	3	30						

Notes & Commentary

This is a process FMEA I participated in as the Project Quality Engineer some years back to give you an idea of the automotive approach. It is a predictor of problems in the form of a risk analysis.

The details involved in producing an FMEA (process or design) are beyond the scope of this presentation. For details, please see the AIAG's FMEA Manual.

Effects of Changing the Process FMEA



When making a change to a document, it is important to consider the effects of that change on other documents. Typically the engineering change system in a company and/or corrective action system ensures these occur. But this is not always the case. Review your company engineering change procedure / system and see if it does so.

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Notes & Commentary

When you change your process FMEA there are several documents which should be reviewed and, often, one or more will require changes. For example, if you add a potential problem to the FMEA for evaluation, after the evaluation it may or may not lead to an addition to the control plan. The same is true of the work instruction.

It should be noted that a change in a 'severity' on an FMEA can only be accomplished through a design change. Why is this so? This is because a change in the severity of the effect of a potential problem will not change by changing how often it occurs nor will it change by changing the probability of detection. These two issues do not change the effect(s) of the problem in any way, shape or form.

It should be evident that a change in detection on the process FMEA necessarily causes a change in the either the related work instruction (it may in fact cause the initiation of a new work instruction) and/or the control plan. In some cases another action may be initiated or changed in response to a change in detection. An example would be where a change in the process (driving the process flow diagram to change) is effected in response to an FMEA. The same is true with respect to a change in the occurrence. Changing the occurrence may, for example, change the sampling method, frequency, etc. on the control plan.

A Corrective Action System Nonconformance & Corrective Action Database Data Entry Base Record Hold Tag No.: Customer Part No.: Date Code: Hold Tag Issued By: (If Applicable) Product: Hold Tag Issue Date: _ Initial Disposition: Part Description: Qty. On HOLD: If Rework, Rework Instruction No. No. Of Carriers: Defect Code: If Use-As-Is, Deviation/Waiver No. Material Location: Qty. Checked: Number Good: Nonconformance (Reason): These are some typical Response Team Members: 'checks' in the automotive world in Process Adequate? O Yes O No O Revised O N/A instruction Reviewed By: response to a corrective action. A ction Instruction Adequate? O Yes O No O Revised O N/A change to any one document typically Prior History Brief: PFMEA Adequate? O Yes O No D Revised O N/A drives an Engineering rocess Control Plan Reviewed By: Process Control Plan Adequate? O Yes O No O Revised O N/A Change where the ess Flow Diagram Reviewed By: engineering change system is used to Defect Code Tooling/Gaging Reviewed By: ensure that changes to Defective Component Name Tooling/Gaging Adequate? O Yes O No O Revised O N/A any one document Stock Purged? ensures appropriate Print(s) Adequate? O Yes O No O Revised O N/A changes to others.

Notes & Commentary

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This is an example of a nonconformance database written in Filemaker Pro. Notice the 'Analysis' section. This is where one ensures each relevant associated document is reviewed.

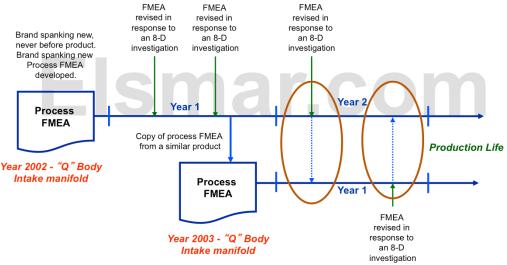
Typically each company's Engineering Change System will address the update of relevant documents and is typically more precise in how this is done.

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I do NOT recommend product specific FMEAs unless you really cannot segregate your products into families for some reason.

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Notes & Commentary

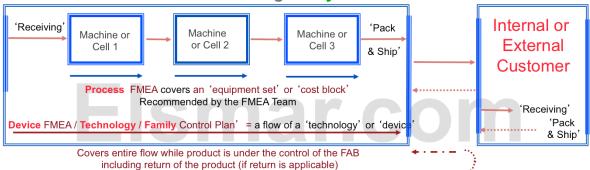
Understand there are different ways companies address FMEAs (and control plans, etc.). Some take a generic approach for a product family (in the case of Design FMEAs) and process (machine) specific Process FMEAs. Other companies have product specific FMEAs.

The above diagram represents a product specific approach where each product has its own FMEA. It is probable that when a new contract is agreed to the control plan from the similar product will simply be copied. Changes driven by engineering changes (often in response to an 8-D investigation / customer complaint) up to that point will probably have addressed all known issues. Note that one of the failures or downsides in a product specific system like this is that typically a change to the FMEA in response to a customer problem have to be addressed in the FMEAs for similar products. The problem is the trigger for a change in one to cause other FMEAs for similar products to be appropriately updated.

In the case of part family DFMEAs and machine specific PFMEAs, the same FMEA is used for a 'new' product .**Control plans will almost always change because of 'slight' product differences. On the other hand I have seen control plans which were relatively static because the company used a matrix which defined specific tolerances (for example). The control plan process / product specification / tolerance column

Current Control Plans & FMEAs

FAB or Other Manufacturing Entity



A Technology/Family Control Plan / Device FMEA follows an entire flow for a 'technology' through a defined entity. This is in contrast with a 'process' flow where there is an individual Control Plan for each piece of equipment or a manufacturing 'cell' (company definition). A 'Technology' consists of many *similar* devices.

'Receiving' in FAB FMEAs consists of what the FAB looks at when materials arrive. Received materials, such as gasses, liquid chemicals and related materials must be addressed. Registrar interpretation Q5 1/12 (AEC-A100): "...So in effect, supplier's control plans will include wafers, gases, and chemicals..."

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Notes & Commentary

This is a discussion of one methodology for control plans and FMEAs, etc. The intent is to provide coverage in a way which is minimally complex and simplifies the required documentation.

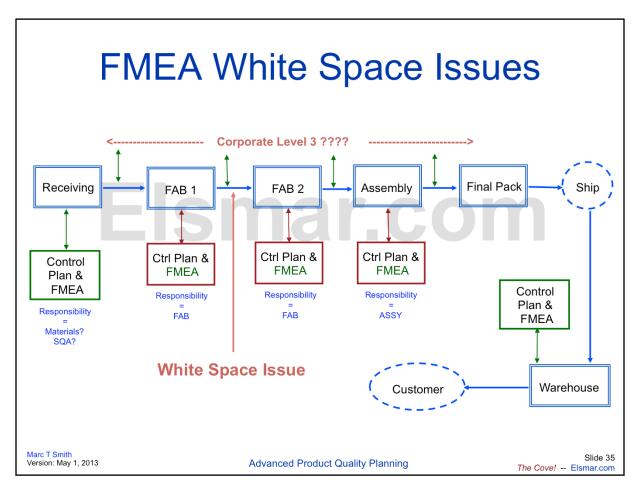
In this system, 'like' devices or 'families' have common documents reducing the total number of documents.

FAB or Other Manufacturing Entity Process Control Plan / FMEA covers an 'equipment set' (cell) or individual equipment 'Receiving' Machine or Cell 2 Machine or Cell 2 Technology Control Plan / FMEA - applies to devices, families

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Discrete Documents

- Early on I stressed that each APQP is unique both between companies and within a company. The same is true of document changes. On the previous page I discussed some of the expected effects of a change to the process FMEA. Because of the differences in how companies structure their documentation it is only possible in a course document such as this to address the effect of changing one document on another. Another reason this is true is because every change to a process FMEA does not automatically require a change to, for example, the control plan. When the evaluation is made it may turn out that the 'risk' number (the RPN) may be low and thus may not require a control.
- In speaking of differences in company documentation, there are companies which (for example) combine their control plan and their process flow diagram into one document. This said, there is no process flow diagram per se to change. Because of the possible permutations of how a document system is set up, it is next to impossible in a course to 'predict' how a company will react within their documentation to a change in any given document.
- Another example is where a company uses the Ford Dynamic Control Plan (APQP and Control Plan manual, page 100) methodology where the control plan is combined with the process FMEA.
- As we proceed through this presentation, keep in mind that where we discuss the changes in one document and its effects on another you will have to look at your company's documentation structure and determine equivalencies.

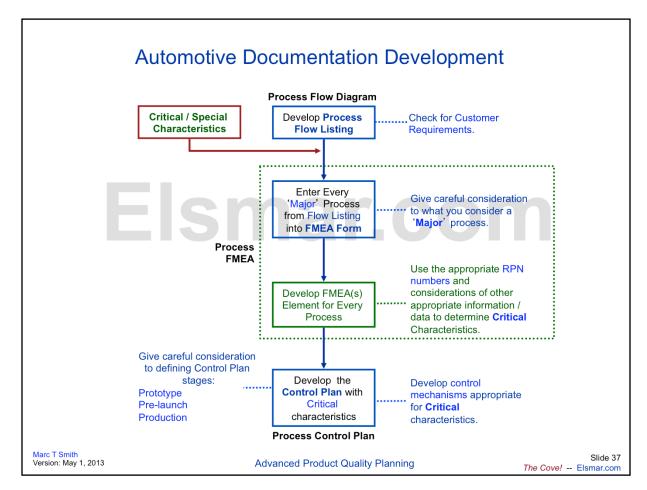
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Notes & Commentary

The differences in documents within a company with respect to the the changes in one driving a change in another is only one aspect to consider as you go through this presentation. There is also the time line for documentation. If, for example, you are using Ford's Dynamic Control Plan methodology, you have two documents in one. In this presentation if we discuss how a change to the process FMEA may affect the process control plan, we are talking about the same document. None the less, the underlying theory is still true. You just have to look at the situation from the perspective of the elements contained in the document. For example, a change to the FMEA part of the DCP (Dynamic Control Plan - APQP and Control Plan manual, page 100) may affect the process control plan element. A DCP is one document with 2 elements within it.



This diagram is another way to illustrate several developmental / critical paths of the main documentation requirements.

As we discussed earlier, the APQP and Control Plan manual represents these as different, discrete documents. However, one should look at them as 'element' requirements. In the Ford DCP the process control plan 'element' is in the same document as the process FMEA 'element'. None the less, the critical path rules still hold true. For example, in the DCP the control plan 'part' cannot be completed until the FMEA 'part' is completed.

Base Documentation

- Critical Characteristics Matrix
- Process Flow Diagram
- Design FMEA
- Process FMEA
- Control Plan

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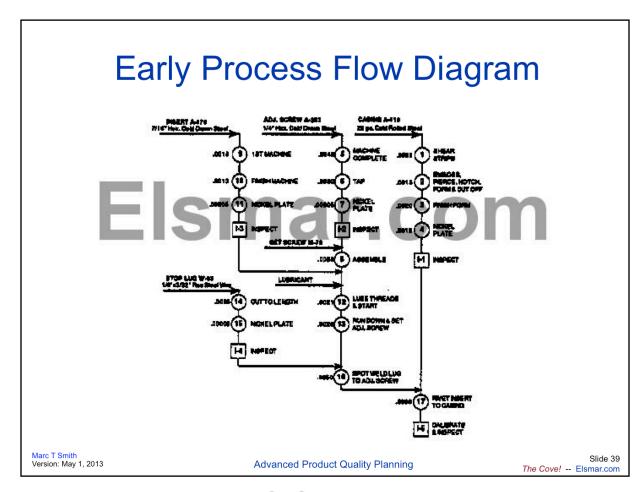
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Notes & Commentary

From the APQP and Control Plan manual, and from our discussion thus far, we know that these four 'documents' are required. We should also by now understand that these can be looked at as 'elements' where each is not a discrete document.

When looking at one of these required 'documents' in terms of it being an element (as opposed to a discrete document) we have to look at each and determine what the specific requirements are for it. As with the control plan example on the next slide, there is a 'minimum' content required for each element.



Before TS 16949 made the scene many companies had control plans which did not contain all the 'elements' that the APQP and Control Plan manual examples contained. In others, there were combined documents such as this combination control plan and process flow diagram. In this example you can see that there is not enough information to satisfy the control plan requirements. In the past, some companies would initiate separate documents to supplement their existing process documents to fulfill the requirements. Today the expectation is that a company use a format similar to that defined within the APQP and Control Plan manual.

In the APQP and Control Plan manual, pages 37 through 47 lists each expected 'item' and includes a brief explanation of the expected contents. You may have additional information on your control plan, but these 26 listed items are each required as a minimum. For example, a reaction plan MUST be included. No debate. No opinions. No stories. In one way or another a reaction plan has to exist.

The Control Plan

A Control Plan is a written description of systems for parts and processes

r.con

- · It is Process Dominated
- Three 'Types' or Phases

Prototype *A Design Output

- Used During Prototype Build
- Dimensional Measurements
- Material and Performance Tests

Pre-Launch

• Update After Prototype and Before Production

Production

- Comprehensive
- Process Controls
- Test and Measurement Systems Used
- Reaction Plan
- Sampling Plans
- SPC Requirements

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Notes & Commentary

Let's look at the control plan. Three control plans are 'required'. The first thing to remember is that the control plan evolves. This said, sometimes the control plan at the pre-launch stage may be exactly the same as that of the production stage. It depends upon the product and the processes.

Example Control Plans

Example Control Plans included in the APQP Manual (starting on page 47):

Equipment

Set-Up Dominant Process

Machine Dominant Process

Fixture/Pallet Dominant Process
Tooling Dominant Process

People

Operator Dominant Process

Material

Material or Component Dominant Process

Methods

Preventive Maintenance Dominant Process

Environment

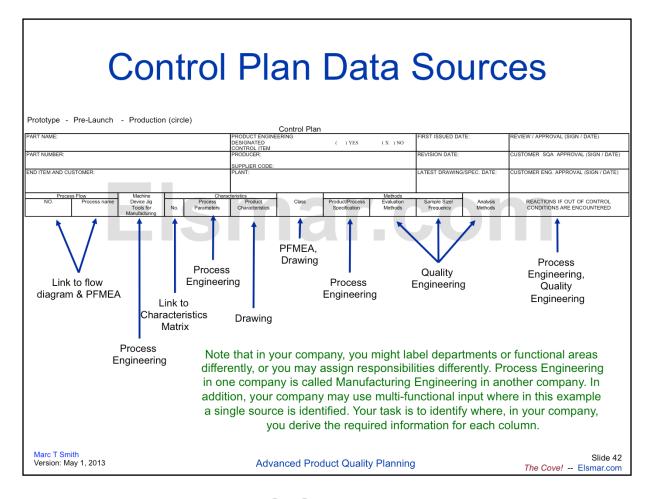
Climate Dominant Process

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As is evident, there are a number of different 'recognized' control plans. If you take a minute and browse through the APQP and Control Plan manual you will see the content is similar - each have the same items detailed in the listings in pages 37 through 47.



This is an example of a control plan header. I suggest that you peruse the APQP and Control Plan manual you have (pages 37 through 47) and review their examples and their explanations of what goes in each column. While items 1 through 14 are important, they are self evident for the most part. Items 15 through 26 are what you should focus on (as numbered in the APQP and Control Plan manual).

Making the control plan is not particularly difficult, but remember it's place and it's relationships to other documents.

End Advanced APQP Section

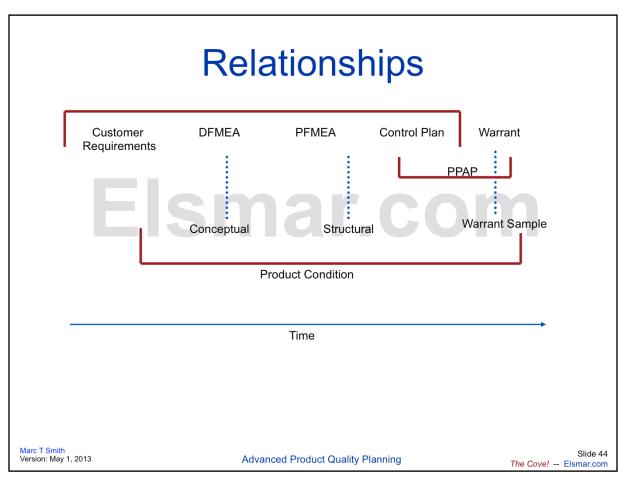
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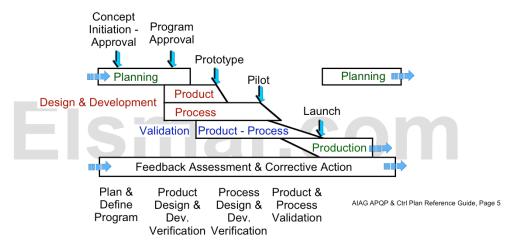
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Advanced Product Quality Planning



- A structured method of defining the steps (process) necessary to assure that a product satisfies the customer
- The goal of APQP is to facilitate communication with everyone involved to ensure that all required steps are completed on time.
- Effective APQP depends upon top management commitment and support to assure that customer satisfaction is achieved

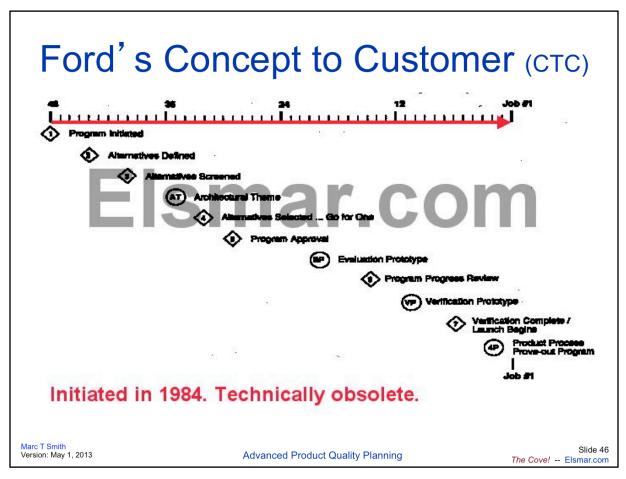
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Notes & Commentary

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Simplicity

- Do not make your system overly complex
- Don't try to copy the APQP manual, just Meet the intent with your system

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Responsibility Responsibility

Notes & Commentary

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T = Sachs - Troy

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QS 9000

APQP Involves:

- 4.1 Management Responsibility
- 4.2 Quality System
- 4.3 Contract Review
- 4.4 Design Control
- 4.5 Document and Data Control
- 4.9 Process Control
- 4.10 Receiving (Incoming)
- 4.11 Inspection, Measuring and Test Equipment
- 4.12 Inspection and Test Status
- 4.13 Control of Nonconforming Product
- 4.14 Corrective Action
- 4.15 Handling, Storage, Packaging and Delivery
- 4.16 Quality Records
- 4.18 Training
- 4.19 Servicing
- 4.20 Statistical Techniques

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E	Explain how APQP affects each element of TS 16949.					

A Word About Design



If you design it in, it's there to stay!

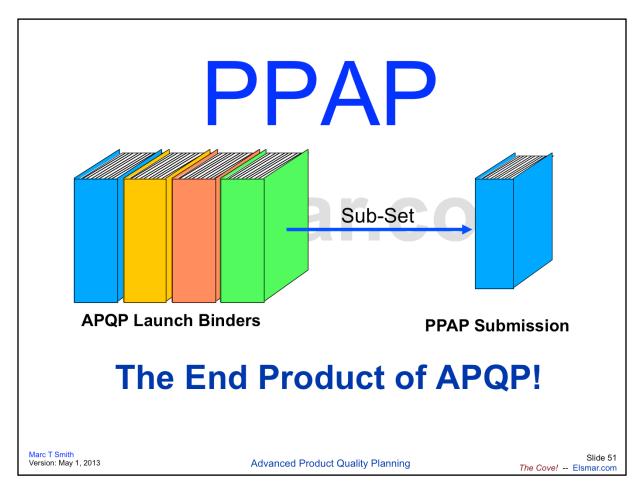
You will constantly be waiting for the next problem to surface!

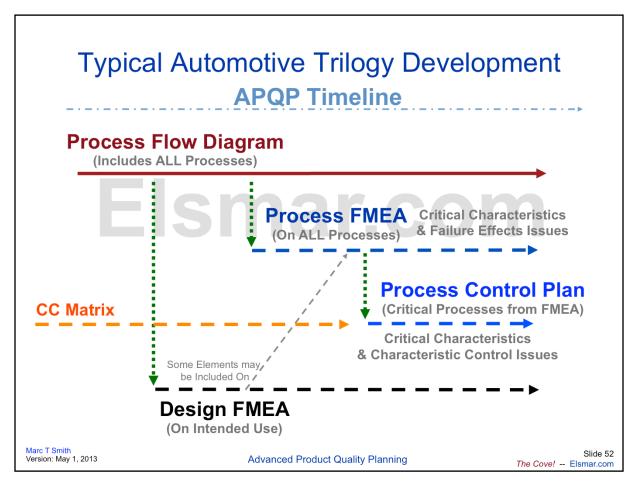
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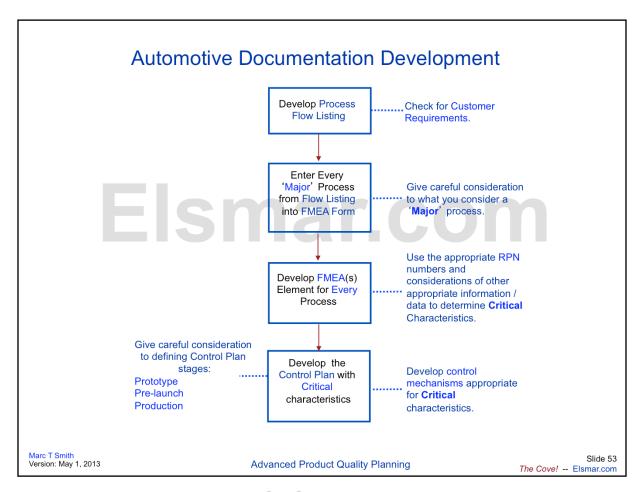
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APQP Design & Process Controls

- Design Reviews
- Design Verification
- Design ValidationProcess Validation
- Design FMEA
- Process FMEA
- Prototype Validation

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Product Quality Planning Responsibility Matrix

APQP Phases	Design	Manufacturing	Service Supplier
Define the Scope	Х	X	X
Plan and Define (Section 1.0)	Х		
Product Design and Development (Section 2.0)	X		
Feasibility (Section 2.13)	Х	X	X
Process Design & Development (Section 3.0)	X	X	X
Product and Process Validation (Section 4.0)	Х	X	Х
Feedback, Assessment and Corrective Action (Section 5.0)	Х	Х	Х
Control Plan Methodology (Section 6.0)	Х	х	Х

AIAG APQP & Ctrl Plan Reference Guide, Page 2

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Product Quality Planning Checklists

- Design FMEA
- · Design Information
- New Equipment, Tooling and Test Equipment
- Product/Process Quality
- Flow Plan
- Process Flow Chart
- Process FMEA
- Control Plan

Check Lists for these line items are in the AIAG's APQP & Control Plan reference manual contained as a group - Appendix A starting on page 63. Use them!

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Benefits of APQP

- Ensures early planning takes place
- Directs resources to the customer
- Identifies required changes early in the process
- Provides quality product on time and at lowest cost
- Enables cross-functional inputs and outputs
- Addresses potential problems early in Design Manufacturing

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Each APQP is Unique

- Because of product and program differences
- Timing and sequence are dependent upon customer needs and expectations
- Product complexity

Stamping

Sub-assembly

- New
- Modification

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Progressive Fundamentals

- KEY** Organize a Cross-Functional TEAM
- Define the scope
- Team-to-team communications
- Training
- · Simultaneous (concurrent) engineering
- Control Plan Phases

Prototype

Pre-Launch

Production

Concern resolution

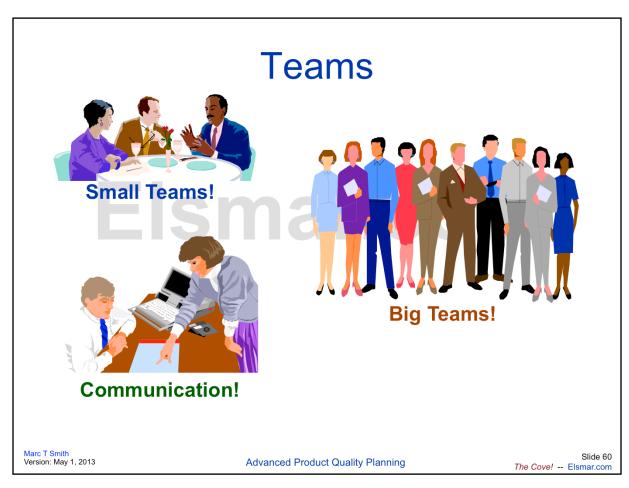
Includes analytical techniques

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Team Organization

Cross-functional

- Engineering (Typically the leader)
- Quality Assurance
- Purchasing
- Manufacturing Engineering
 Material Control
- Material Control
- Sales/Marketing
- Etc.
- · Participation appropriate for phase being conducted
- Resources Team defines 'Needs'
- *Should* involve customer or subcontractor participation (not always feasible)

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Natural Work Group vs. Team

Two Types of Team Structures

Natural	Work	Grou	p ⁻	Γask ⁻	Геат

Work area or unit. Representatives who have key Membership Representatives from support information or are froups on as-needed basis. stakeholdrs. Assigned by steering **Member Selection** Participation is necessary. committee or upper management. Assigned by, or negotiated Assigned by management or **Project Identification** identified by team and within its with, steering committee or authority. upper management. Disbands when task is **Team Life Span** Ongoing. complete.

Leadership

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Leadership shared or

delegated by members.

Notes & Commentary

Leader appointed by

management.

Roles In A Team

Several roles need to be established for the team. These roles are: Leader, Champion, Record Keeper (Recorder), Participants and (if needed) Facilitator.

Leader

Group member who ensures the group performs its duties and responsibilities. Spokesperson, calls meetings, establishes meeting time/duration and sets/directs agenda. Day-to-day authority, responsible for overall coordination and assists the team in setting goals and objectives.

Record Keeper

Writes and publishes minutes.

Champion

Guide, direct, motivate, train, coach, advocate to upper management.

Participants

Respect each others ideas.

Keep an open mind.

Be receptive to consensus decision making.

Understand assignments and accept them willingly.

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Team Experience

- Input from higher system level or past QFD projects
- Media commentary and analysis
- Customer letters and suggestions
- Things gone Right/Wrong reports
- Dealer comments
- Fleet operator comments

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Team Experience (continued)

- Field service reports
- Problems and issues reported from Internal customers
- Internal evaluations using surrogate customers
- Road trips (e.g.: Struts)
- · Management comments and/or direction
- Government requirements and/or regulations
- Contract review

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Team-to-Team Communication

- Manage using the APQP process
- Understanding of 'How We Work As A Team'
- Should have a Focus Person & Distributed Minutes
- Customer teams
- Internal teams
- Supplier teams
- Sub-Teams
- Subcontractors should be encouraged to embrace APQP and QS 9000

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Define Project Scope

- Select team members and functions
- Define roles and responsibilities
- Identify external customer needs, expectations and requirements
- Identify internal customer needs, expectations and requirements
- Complete preliminary feasibility study
- · Identify costs, timing and constraints
- Identify documentation process and method
- Develop program plan (if project is a go)

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Responsibility	
' '	
oesign Engineering Aanufacturing Engineering Aaterials rogram Manager roduction vurchasing	Simple Responsibilities Matrix Example
aring Engin	
Design Engineering Manufacturing Engin Materials Program Manager Production Purchasing Quality Assurance	
esign Eng anufactur aterials rogram M roduction urchasing	THE L
hesign En, flanufactur flaterials frogram M roduction vurchasing	Customer
	T Element
	R A Market Research Information
I A I A R	A Quality History Review
RIAAI	A Engineering Research Data
	A Advanced Quality Planning Schedule
RRIIIA	Preliminary Product/Process Design
R A I I A	A Feasibility Analysis
I R A I A A	Design FMEA Process FMEA
RAIIAIA	A Prototype Build and Verification
AAIIIR	A Significant Characteristics
RRIIIIA	Final Product and Process Design
A A I R	Measurement and Test Equipment Needs & Costs
I A I I I R	A Process Control Plan
RIIIA	I Process Flow Chart
A I A R A	Audit and QA Work Instructions Order Production Tooling, Gages, Test Equipment
AII	Select & Rate Suppliers
R	Train Quality Personnel
R	Supplier PSW Review & Sign-Off
	Set-Up & De-Bug Production and Inspection Equipment
	Preliminary Capability Studies For Production Processes Process Optimization (Design Of Experiments)
	I Process Review (PFMEA Walk Through)
R	Product Training
I R A I A	Work Instructions (Manufacturing)
	Measurment and Test Equipment Verification
	I Packaging A A Part Sample Warrant
LA I A I I I A I A I I I I A	A A Part Sample Warrant A = Assistance
	A = Assistance I = Input
	R = Responsibility
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APQP Documents and Elements

- Action Plan
- · Product / Process Assumptions
- · Product Reliability studies
- Product / Process Characteristics
- · Cross Functional Team Members
- Design FMEA
- Design Verification Plan and Report
- Design FMEA checklist
- Design Information Checklist
- · New equipment tooling and Equipment checklist
- · Team feasibility Commitment
- · Process Flow
- Manufacturing Process Flow Chart Checklist
- · Process FMEA
- Control Plan
- Product / Process Quality checklist
- · Floor plan checklist
- · Process Flow Chart checklist
- Process FMEA checklist

- · Control Plan checklist
- · Characteristics Matrix
- · Packaging standards
- · Product and Process Validation
- · Summary and sign-off
- Process Verification Run
- Corrective Action
- APQP Status Report
- PAPP- Warrant
- Appearance Evaluation
- · Dimensional Results
- · Material Results
- · Function Results
- 8 D Report
- Tooling instructions
- Gages Instructions
- · Preventive Maintenance Checklist
 - Housekeeping Checklist

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Training

Customer Needs and Expectations

Working as a Team

Group process skills

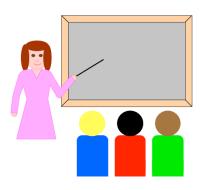
Development skills

Requirements of APQP

FMEA

APQP

PPAP

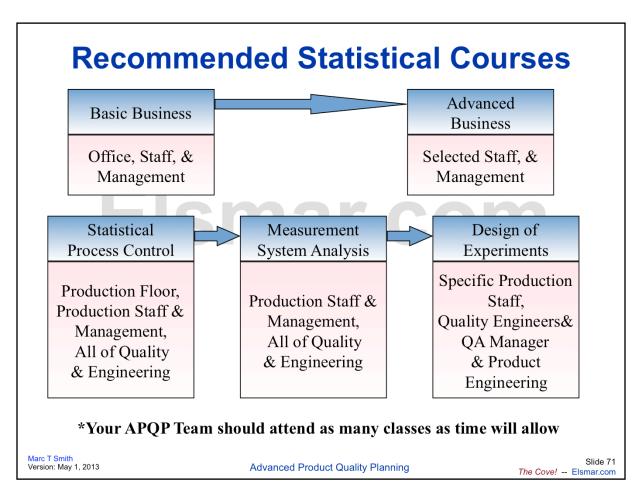


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Customer and Supplier Involvement

Customer may initiate the planning process

Supplier has the obligation to establish cross-functional team to manage process

Supplier should expect the same performance from their subcontractors

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Simultaneous (Concurrent) Engineering

- · Requires cross-functional team participation
- Replaces prior system of sequential phases and pass-off (old method)
- APQP team ensures that other functions and teams plan and execute support activities

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Customer Requirements

Ways to Determine Customer Requirements

- Print
- Purchase Request or Request for Quotation
- QFD Quality Function Deployment
- Service Engineers
- Verbal Communications
- Development Engineers
- Product Check List
- Customer's Customer Requirements Review

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Base Documentation

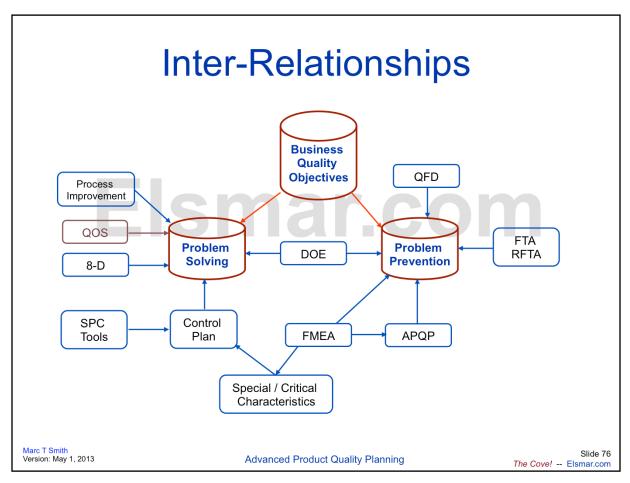
- Critical Characteristics Matrix
- Process Flow Diagram
- Design FMEA
- Process FMEA
- Control Plan

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Chicken or Egg

Which is First? Second? Third?

Control Plan?

Process Flow Diagram? lar.com

Project Plan?

Design FMEA?

Process FMEA?

Process Documentation ('Work' Instructions)?

Why Does it Matter?

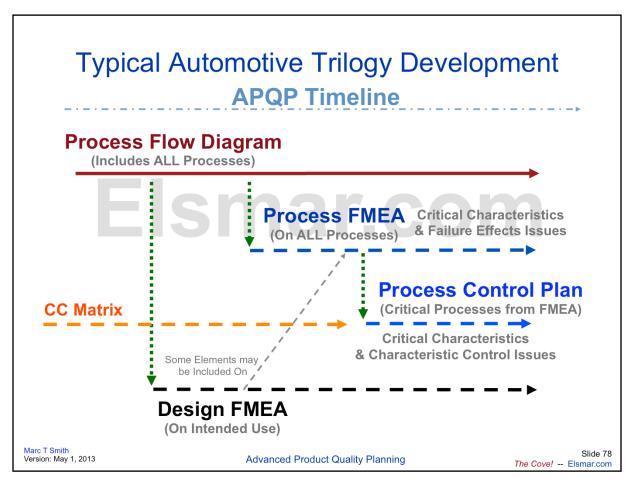
Relationship to Product Planning

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Explain the role of the project plan and why it is so important.



The Links

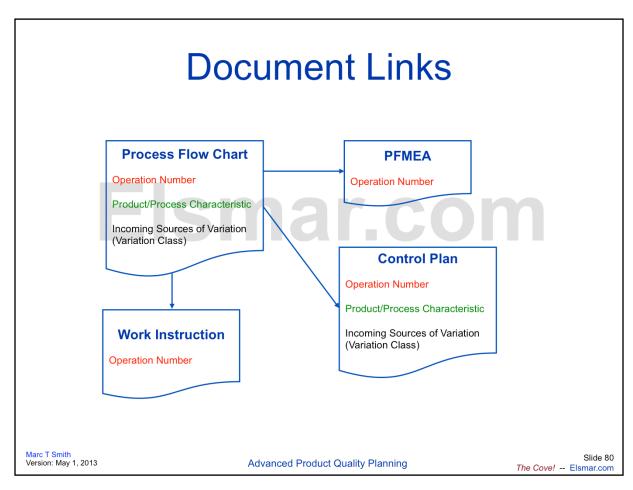
- Each Flow Chart 'element' must have a matching FMEA element. As a 'trilogy', remember - the links must all match.
- The 'trilogy' documents must precisely link to your process documentation (work instructions or however your company addresses this issue)

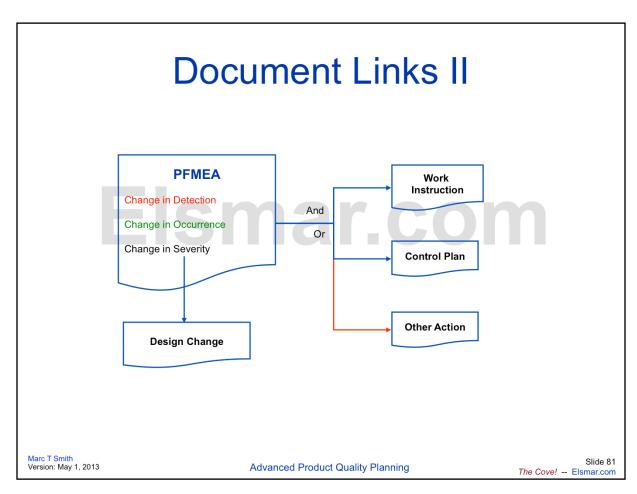
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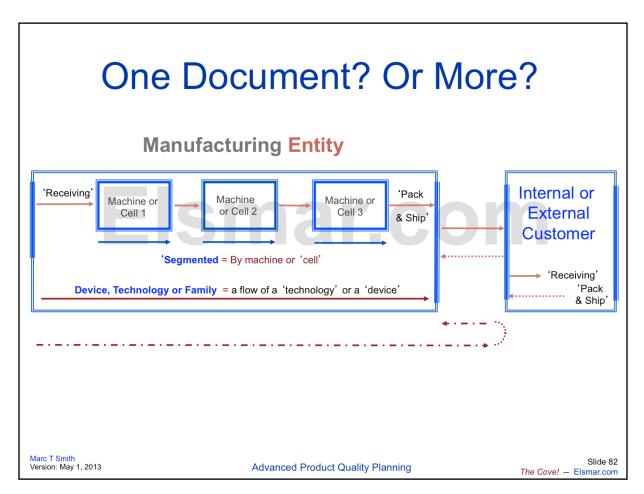
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Example Discussion

Issues in the interpretation of QS 9000 and the Semiconductor Supplement:

- 1. Control Plans must address the flow of received materials and parts from receiving, through manufacturing and on to shipping and to warehouses.
- Control Plan content must contain as a minimum all customer and Company X 'critical' characteristics.
- 3. Impact of Flow Diagram being incorporated into the Control Plan, if any.

The questions are:

- 1. What must be on a Control Plan (content)? --> Every process in accordance with corporate procedure?
- 2. Does each 'responsibility' have to have * both * Control Plan(s) and FMEA(s)??? (e.g.: Receiving has only Control Plans)
- 3. What must be on an FMEA (content)? Every process that is on the Control Plan?
- 4. White Space Does every move have to be on the Control Plan &/or FMEA?

Terminology!

- ° Technology Control Plan (Language used in FABs) vs. Device FMEA
- ° Process Control Plan (Various places) vs. Process FMEA
- Machine/Equipment FMEA (Definition from corporate procedure)
- ° Family Control Plan (See Definition for Control Plan in company procedure)

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Registrar Responses

- 1. QUESTION: What must be on a Control Plan? -- Every process?
 ANSWER: Only the major processes are required on the control plan. Critical processes alone are not sufficient.
- 2. QUESTION: Does each 'responsibility" have to have *both* Control Plan(s) and FMEA(s)? (e.g.: Receiving has only Control Plans).
 ANSWER: Yes, both the Control Plan(s) and FMEA(s) are required.
- 3. QUESTION: What must be on an FMEA? Every process that is on the Control Plan?
 ANSWER: Only the major processes are required on the FMEA. (technology)
- 4. QUESTION: White Space Does every move have to be on the Control Plan &/or FMEA?

ANSWER: Yes, there should be a block on the Control Plan to indicate a transfer.

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based)

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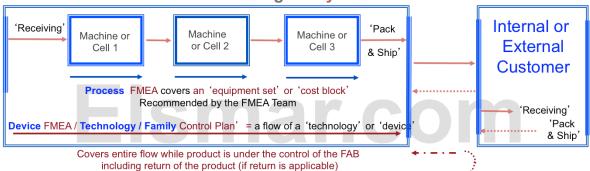
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Current Control Plans & FMEAs

FAB or Other Manufacturing Entity



A Technology/Family Control Plan / Device FMEA follows an entire flow for a 'technology' through a defined entity. This is in contrast with a 'process' flow where there is an individual Control Plan for each piece of equipment or a manufacturing 'cell' (company definition). A 'Technology' consists of many similar devices.

'Receiving' in FAB FMEAs consists of what the FAB looks at when materials arrive. Received materials, such as gasses, liquid chemicals and related materials must be addressed. Registrar interpretation Q5 1/12 (AEC-A100): "So in effect, supplier's control plans will include wafers, gases, and chemicals."

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Cone Proposed Terminology FAB or Other Manufacturing Entity Process Control Plan / FMEA covers an equipment set (cell) or individual equipment Receiving Machine or Cell 2 Machine or Cell 2 Technology Control Plan / FMEA - applies to devices, families

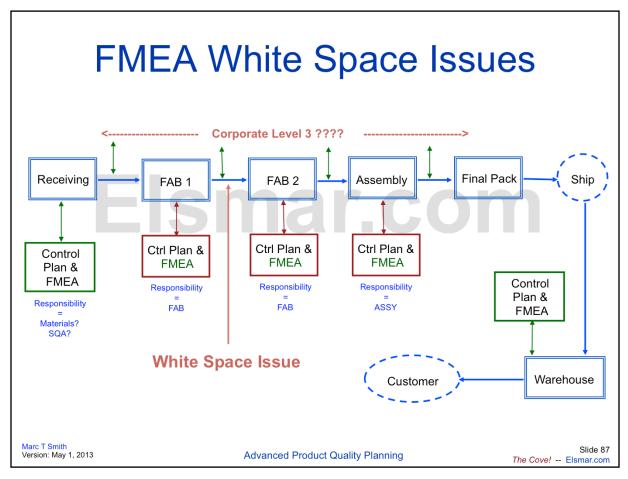


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Example Discussion I

- Each functional area is responsible for detailing on their FMEA all elements of their responsibilities.
- If a functional area transports product to another functional area, that transportation must be considered for inclusion in the FMEA. If it is not addressed, the functional area must be ready to discuss why it is not.
- Control Plans must cover the actual processes.
- We have to go by the rule of:

First touch to last touch - Check with your 'touches' to ensure they have the Control Plans and FMEAs.

We know:

Receiving has Control Plans, no FMEAs.

Fabs have Control Plans and FMEAs

Warehouses have ????

** What other areas are there?? **

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Example Discussion II

Meeting Objective:

 Develop Recommendation for a "Standard FMEA Approach"

The team defined two different types of Process FMEAs as defined below:

Device FMEA (a single FMEA that defines a single Device Flow (from start to completion).

Process FMEA, which defines the process for either an equipment set or a "Cost Block" (e.g., probe).

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Example Discussion IIa

Device FMEA "PRO's":

- Defines a single flow.
- Allows identification of Process Interaction Failure Modes.
- Allows identification of "Critical Processes".
- Opens communication between Device and Process Engineers.

Device FMEA "CON's":

- Less detail on Process Failure Modes.
- Document control is unmanageable.
- Diffuses ownership responsibilities.

Process FMEA "PRO's":

- ° More user friendly.
- More detailed.
- ° More manageable.
- ° TPM/Cross Functional Team Enabler.

Process FMEA "CON's":

- Doesn't exhibit Process Interaction Failure Modes.
- More difficult to identify critical processes.

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Example Discussion IIb

RECOMMENDATIONS

Based on this information the team made the **following recommendations**:

- As a minimum, Process FMEAs should be used.
- Device FMEAs should be used as tool to introduce new Platforms to manufacturing.

CONCERNS

FMEAs must be reviewed and updated as detailed below:

- ° Process Changes.
- ° Customer Incidents (IFAR/EFAR).
- ° Annually.
- ° Whenever the process produces significant line scrap as determined by each manufacturing site.
- Ensure that the FMEAs links with the Control Plans.

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Registrar Interpretations

Q5 1/12 (AEC-A100)

Are control plans developed to the...and/or material....level?

Control plans are required at the system, subsystem, component, and/or material level. Suppliers may not need a separate and distinct control plan for components such as wafers, gases, and chemicals. However, existing control plans must cover receiving through shipment of materials, parts, components, and assemblies. So in effect, supplier's control plans will include wafers, gases, and chemicals. The Semiconductor Supplement supports this!

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Registrar Interpretations

Q8 2/18 (Rev 1) QS9000 Page 13, Production Control Plans:

- "Comprehensive" requires the company to duplicate all inspections and tests already called out in shop orders and specifications into the control plan. Our company document requires inclusion of all customer-identified special characteristics and company identified important characteristics. Other inspections and tests are optional in the control plans.
- Control plans should be comprehensive including all processes, inspection, tests, methods & include special characteristics but can reference existing inspection/ test procedures.

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The Control Plan

- A Control Plan is a written description of systems for parts and processes
- · Process Dominated
- Prototype *A Design Output

Used During Prototype Build

Dimensional Measurements

Material and Performance Tests

Pre-Launch

Update After Prototype and Before Production

Production

Comprehensive

Process Controls

Test and Measurement Systems Used

Reaction Plan

Sampling Plans

SPC Requirements

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TS 16949

4.2.3.1 - Advanced Product Quality Planning

- The supplier shall establish and implement an advanced product quality planning process. The supplier should convene internal multi-disciplinary teams to prepare for production of new or changed products. These teams should use appropriate techniques identified in the Advanced Product Quality Planning and Control Plan reference manual. Similar techniques that accomplish the intent are acceptable.
- · Team actions should include:
 - Development/finalization of special characteristics (see Appendix C)
 - Development and review of FMEAs
 - Establishment of actions to reduce the potential failure modes with high risk priority numbers
 - Development or review of control plans

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TS 16949 - Control Plans

4.2.3.5 - Process Failure Mode and Effects Analysis (Process FMEAs)

 Process FMEAs shall consider all Special Characteristics. Efforts shall be taken to improve the process to achieve defect prevention rather than defect detection. Certain customers have FMEA review and approval requirements that shall be met prior to production part approval (see Section II). Refer to the Potential Failure Mode and Effects Analysis reference manual.

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Semiconductor Supplement

Quality Planning - 4.2.3.S

During the advanced quality planning processes, the supplier shall include all processes from the incoming material through shipping and warehousing

Failure Mode and Effects Analysis and Control Plan documents shall include these processes.

The Intent:

The supplier shall *consider* all processes. But - does it mean that all process shall be included in the FMEA and Control Plan?

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APQP Manual: 1995

6.2 Overview

- "A control plan is a written description of the system for controlling parts and processes"
- "In effect, the Control Plan describes the actions that are required at each phase of the process including receiving, in-process, out-going, and periodic requirements to assure that all process outputs will be in a state of control"

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FMEA Manual

"Process Potential FMEA"

Is "...a summary of engineer' s/team' s thoughts (including an analysis of items that could go wrong based upon experience and past concerns) as a process is developed."

"A process FMEA should begin with a flow chart / risk assessment of the general process. This flow chart should identify the product characteristics associated with each operation."

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Concern Resolution

Design or Process concerns

Responsibility matrix

Disciplined problem solving methods

Use analytical techniques (*as appropriate)
(See AIAG's APQP & Control Plan reference manual page 4 and appendix B, page 81)

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Timing Plan

Depends upon

- Product complexity
- Customer expectations

Team plan for

- Training
- Event
- Action

Framework for tracking

Basis for status reporting

Prepare a timing chart using available project or similar software

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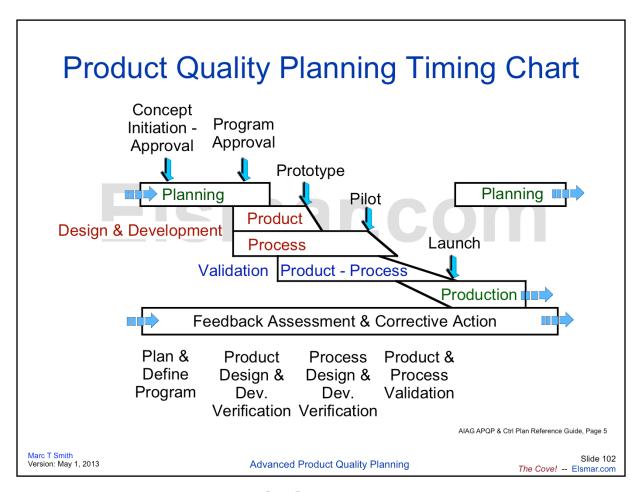
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Do NOT Under Estimate the

Importance of Timing!



Timing Plan Contents

Identify individual tasks

Track resources by task

Establishes dependencies between tasks

Determine critical path

Track specific tasks or groups of tasks

Status reports

					April	May	June	July	August	September
ID	Task Name	Dur	Start	Finish	Apr	May	Jun	Jul	Aug	Sep
1	Visit 1	5 d	4/28/97	5/2/97	\Rightarrow					
2	Plant Tour and Gather Information	2d	4/28/97	4/29/97	100%					
3	Meet with Teams	2d	4/28/97	4/29/97	100%					
4	Feasibility Determination	2d	5/1/97	5/2/97	100%	•				
5	Initial Project Plan Developed	1d	5/2/97	5/2/97		<u> </u>				

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Project Plan Elements

- Mission
- Scope
- Objectives
- Requirements
 - How to measure
- Definitions and specifications
- Market analysis
- Feasibility
 - Time
 - Resources
 - Plant space
 - · Etc.
- Timeline
- Control system
- Team
- Oost Estimate

Consider this a 'laundry list' for an index.

Each item does not, however, have to reside in 'one book'.

You should have (at least) an index of the project plan with the location and owner (responsibility) of each element clearly identified.

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Project Plan Definitions I

- Mission Goal, customer and approach
- Scope What will and will not be included (with consideration to available technology)
- Objectives Technical, profit, performance, quality, etc.
- Requirements Deliverables
- Definition and specification Criteria it must meet
- Market analysis Expected annual production volume, length of run, start (delivery) target date, target price (Japan), key sales points, key competitors, etc.

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Project Plan Definitions II

- Preliminary Feasibility Degree to which current tooling and equipment can be used
- Timeline Major milestones and detail task schedule
- Control system Answers questions such as:

How will progress be measured?

Who will receive reports?

How are changes handled?

What limits are there on authority, responsibility, and accountability?

Team - Who, from where and who is the team leader?

Beware of Turf Wars!

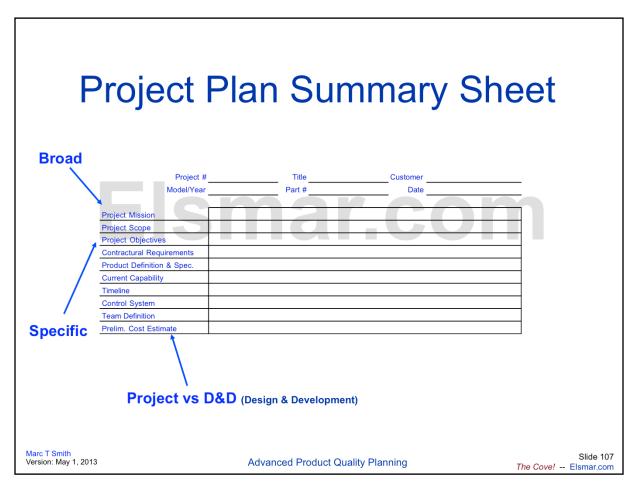
 Cost estimate - Estimate with assumptions. Often 'all' information is not available.

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Analytical Techniques

- · Assembly Build Variation Analysis
- Benchmarking
- · Cause & Effect Diagram
- · Characteristics Matrix
- Critical Path Method
- Design of Experiments (DOE)
- Design for Manufacturability & Assembly (DFM & DFA)
- Design Verification Plan & Report (DVP&R Chrysler & Ford)
- Dimensional (Dynamic) Control Plan (DCP)
- Mistake Proofing (Poka-Yoke)
- Process Flow Charting
- Quality Function Deployment (QFD)
- System Failure Mode & Effects Analysis (SFMEA)

See AIAG's APQP & Control Plan reference manual appendix B, pages 81 thru 85

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APQP Phases

- Phase 1: Plan & Define Program
- Phase 2: Product Design & Development Verification
- Phase 3: Process Design & Development Verification
- Phase 4: Product & Process Validation
- Phase 5: Feedback Assessment & Corrective Action

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APQP Manual Appendix A - Check Lists

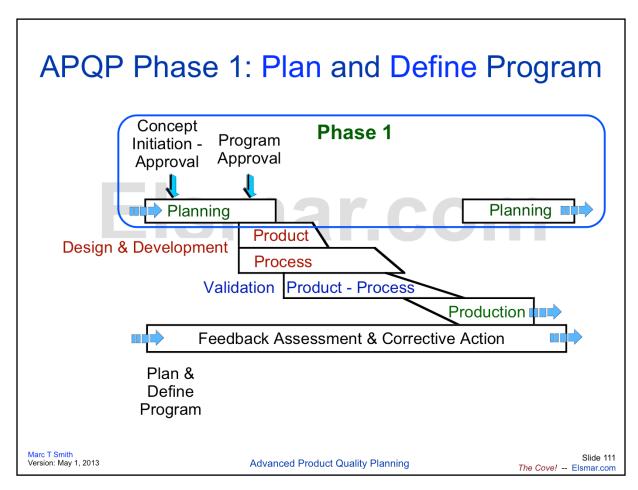
- A-1 Design FMEA Check List
- A-2 Design Information Checklist
- A-3 New Equipment, Tooling and Test Equipment Checklist
- A-4 Product / Process Quality Checklist
- A-5 Floor Plan Check List
- A-6 Process Flow Chart Checklist
- A-7 Process FMEA Checklist
- A-8 Control Plan Checklist

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Phase 1 Inputs

Voice of the Customer

Market Research
Historical Warranty and Quality Information
Team Experience

- Business Plan and Marketing Strategy
- Product/Process Benchmark Data
- Product/Process Assumptions
- Product Reliability Studies
- Customer Inputs
- Service

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Phase 1 Outputs

- Design Goals
- · Reliability and Quality Goals
- Preliminary Bill of Material
- Preliminary Process Flow Chart
- Preliminary Listing of Special Product and Process Characteristics
- Product Assurance Plan
- Management Support

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Voice of the Customer

- · Market research
- · Historical warranty and quality information
- Team experience
- Complaints
- Recommendations
- Data and/or other information





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Voice of the Customer Correlation Matrix: External and Strength of Need Strong Positive Positive Internal O Very Strong X Negative X Strong Negative Customers Strong Weak Stated, Real and Competitor Assessment Perceived What are Their Needs Needs? Who are My Customers? Cultural Needs Customer #1 Unintended Customer #2 Uses Customer #3 **Functional** Customer#4 Needs vs. Customer #5 **Technical** Customer #6 **Features** Customer #7 Ec. Measure -Importance Factor -> Marc T Smith Version: May 1, 2013 Slide 115 Advanced Product Quality Planning The Cove! -- Elsmar.com

Market Research Customer **Things Gone Right** interviews Customer The following is a list of vehicle features. Please read the entire list and place an X next to those features of your new vehicle that you Particularly Like. questionnaires and surveys **Room & Comfort Interior Appearance** Marketing test and Front Room Seat Appearance positioning reports Front Seat Comfort Instrument Panel Entry & Exit from Front Door Panels New product Cargo Capacity Carpeting quality and Cargo loading, unloading reliability studies Competitive Handling Exterior Appearance Front View product quality Handling on Highway Side View Handling in City, Parking studies Rear View Visibility in Rear "Things Gone Paint Steering Right" reports Moldings Brakes Marc T Smith Version: May 1, 2013 Slide 116 **Advanced Product Quality Planning** The Cove! -- Elsmar.com

Historical Warranty and Quality Information **Things Gone Wrong** "Things gone Wrong" reports Tell us about any troubles you have had with the vehicle. Mark a X in each box next to any item you have had trouble with. Warranty reports **Exterior Paint** Capability Paint mist or soray over body finish Chipped paint indicators Color difference between body panels Scratched paint Uneven color on one body panel Sags, runs in paint Supplier plant Paint ot tape stripes coming off, missing Dirt in paint internal quality Rust, corrosion Body paint on moldings, ornaments Other paint troubles. Please describe. reports Problem Steering & Handling resolution reports Steering noisy Steering requires high or uneven effort Customer plant Constant pull to one side returns and Vehicle vibrates at speeds Below 45 MPH Above 45 MPH rejections Steering wheel spokes not correctly positioned when front wheels streight Other steering and handling problems. Please describe. Field return product analysis Marc T Smith Version: May 1, 2013 **Advanced Product Quality Planning** The Cove! -- Elsmar.com

Business Plan - Marketing Strategy

- · Framework for quality plan
- May place constraints on timing, cost, investment, positioning, R&D resources
- Strategy defines target customer, key sales points, key competitors
- SWOT

Strengths

Weaknesses

Opportunities

Threats

Old vs. New

How deep and how far to go

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Product - Process Benchmark Data

- A requirement of QS 9000 para. 4.1
- Provides inputs to establish performance targets
- Must address key process(es)
- Must be measurable
- Methods for successful benchmarking:

Identify appropriate benchmark(s)

Find reason for gap between your status and benchmark

Develop a plan for closing gap, meeting or exceeding benchmark

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Product - Process Assumptions

- **Assumptions**
 - **Features**
 - Design
 - Process concepts
 - Technical innovations

 Advanced materials
 - Advanced materials
 - Reliability assessments
 - New technology
- Document assumptions as part of project plan
- Utilize as inputs to plan
- Consider alternate paths in case assumptions do not play out

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Product Reliability Studies

 Frequency of repairs or replacements within designated time period(s)

Repair or Throw-away?

LRU Level (Line Replaceability Unit)

- Long range reliability and/or durability tests
- · Studies can be VERY costly and lengthy

EDCTP (Environmental Design Criteria Test Plan)







MTBR = Mean Time Between Replacement

MTBO = Mean Time Between Overhaul
MTBF = Mean Time Between Failures

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Product Reliability Studies		

Customer Inputs

- Next users provide information about needs and expectations
- Possibility of previous conducted reviews and studies
- Used to develop measure of customer satisfaction

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Critical Characteristics Matrix

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Notes & Commentary

TS 16949 Appendix C (page 87) Standard and Special Characteristics Symbols Matrix

APQP Manual

- Section 1.11 (page 10) Preliminary Listing of Special Product and Process Characteristics
- Appendix B (starting on page 81) Analytical Techniques --> Characteristics Matrix

PPAP Manual

- Appendix F.6 (starting on page 71) Bulk Materials Example
- Section II.4.6 (Truck) on page 49

Characteristics I

- CHARACTERISTIC: A distinguishing feature, dimension or property of a process or its output (product) on which variable or attribute data can be collected. (P39 APQP)
- CHARACTERISTIC, CRITICAL, CHRYSLER DEFINITION: Characteristics applicable to a component, material, assembly, or vehicle assembly operation which are designated by Chrysler Corporation Engineering as being critical to part function and having particular quality, reliability and/or durability significance. These include characteristics identified by the shield, pentagon, and diamond. (49 PPAP)
- CHARACTERISTIC, CRITICAL (INVERTED DELTA), FORD DEFINITION: Those product requirements (dimensions, performance tests) or process parameters that can affect compliance with government regulations or safe vehicle/product function, and which require specific supplier, assembly, shipping, or monitoring and included on Control Plans. (P49 PPAP)
- CHARACTERISTIC, CRITICAL, GM DEFINITION: See Key Product Characteristic. (P49 PPAP)
- CHARACTERISTIC, KEY CONTROL (KCCs): Those process parameters for which variation must be
 controlled around a target value to ensure that a significant characteristic is maintained at its target value.
 KCCs require ongoing monitoring per an approved Control Plan and should be considered as candidates
 for process improvement. (P49 PPAP)
- CHARACTERISTIC, KEY PRODUCT (KPC): Those product features that affect subsequent operations, product function, or customer satisfaction. KPCs are established by the customer engineer, quality representative, and supplier personnel from a review of the Design and Process FMEA's and must be included in the Control Plan. Any KPCs included in customer-released engineering requirements are provided as a starting point and do not affect the supplier's responsibility to review all aspects of the design, manufacturing process, and customer application and to determine additional KPCs. (P49 PPAP)

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Characteristics II

- CHARACTERISTIC, PROCESS: Core team identified process variables (input variables) that have a
 cause and effect relationship with the identified Product Characteristic(s) which can only be measured at
 the time of occurrence. (6.3 #20 APQP)
- CHARACTERISTIC, PRODUCT: Features or properties of a part, component or assembly that are described on drawings or other primary engineering information. (6.3 #19 APQP)
- CHARACTERISTIC, PRODUCT, CRITICAL (D), CHRYSLER DEFINITION: A defect which is critical to part
 function and having particular quality, reliability, and durability significance. (TS 16949)
- CHARACTERISTIC, PRODUCT, MAJOR, CHRYSLER DEFINITION: A defect not critical to function, but which could materially reduce the expected performance of a product, unfavorably affect customer satisfaction, or reduce production efficiency. (TS 16949)
- CHARACTERISTIC, PRODUCT, MINOR, CHRYSLER DEFINITION: A defect, not classified as critical or major, which reflects a deterioration from established standards. (TS 16949)
- CHARACTERISTIC, PRODUCT, SAFETY/EMISSION/NOISE (S), CHRYSLER DEFINITION: A defect
 which will affect compliance with Chrysler Corporation and Government Vehicle Safety/Emission/Noise
 requirements. (TS 16949)
- CHARACTERISTIC, SAFETY, CHRYSLER DEFINITION "Shield <S>: Specifications of a component, material, assembly or vehicle assembly operation which require special manufacturing control to assure compliance with Chrysler Corporation and government vehicle safety requirements. (TS 16949)

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Characteristics III

- CHARACTERISTIC, SAFETY, CHRYSLER DEFINITION: Specifications which require special manufacturing control to assure compliance with Chrysler or government vehicle safety requirements. (P50 PPAP)
- CHARACTERISTIC, SIGNIFICANT, CHRYSLER DEFINITION: Special characteristics selected by the supplier through knowledge of the product and process. (TS 16949)
- CHARACTERISTIC, SPECIAL: Product and process characteristics designated by the customer, including
 governmental regulatory and safety, and/or selected by the supplier through knowledge of the product and
 process. (P104 APQP)
- CHARACTERISTIC, SPECIAL, CHRYSLER DEFINITION "Diamond" <D>: Specifications of a component, material, assembly or vehicle assembly operation which are designated by Chrysler as being critical to function and having particular quality, reliability and durability significance. (TS 16949)
- CHARACTERISTIC, SPECIAL, CHRYSLER DEFINITION "Diamond" <D>: Specific critical characteristics
 that are process driven (controlled) and therefore require SPC to measure process stability, capability, and
 control for the life of the part. (Appendix C TS 16949) & (Appendix C APQP)
- CHARACTERISTIC, SPECIAL, CHRYSLER DEFINITION "Pentagon" <P>: Limited to highlighting Critical characteristics on (Production) part drawings, tools and fixture, and tooling aid procedures where ongoing process control is not automatically mandated. (Appendix C TS 16949) & (Appendix C APQP)
- CHARACTERISTIC, SPECIAL, CHRYSLER DEFINITION "Shield" <S>: Engineering designated specifications or product requirements applicable to component material, assembly operation(s) which require special manufacturing control to assure compliance with governmental vehicle safety, emissions, noise, or theft prevention requirements. (Appendix C TS 16949) & (Appendix C APQP)

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Characteristics IV

- CHARACTERISTIC, SPECIAL, FORD DEFINITION "Critical Characteristic" <Inverted Delta>: Those
 product requirements (Dimensions, Specifications, Tests) or process parameters which can affect
 compliance with government regulations or safe Vehicle/Product Function and which require specific
 producer, assembly, shipping or monitoring actions and inclusion on the Control Plan. (Appendix C TS
 16949) & (Appendix C APQP)
- CHARACTERISTIC, SPECIAL, FORD DEFINITION "Significant Characteristic SC" <None>: Those
 product, process, and test requirements that are important to customer satisfaction and for which quality
 planning actions shall be included in the Control Plan. (Appendix C TS 16949)
- CHARACTERISTIC, SPECIAL, FORD DEFINITION "Significant/Characteristic S/C" <None>:
 Characteristics that are important to the customer and that must be included on the Control Plan.
 (Appendix C APQP)
- CHARACTERISTIC, SPECIAL, GM DEFINITION "Fit/Function" <F/F>: Product characteristic for which
 reasonably anticipated variation is likely to significantly affect customer satisfaction with a product (other
 than S/C) such as its fits, function, mounting or appearance, or the ability to process or build the product.
 (Appendix C TS 16949) & (Appendix C APQP)
- CHARACTERISTIC, SPECIAL, GM DEFINITION "Safety/Compliance" <S/C>: Product characteristic for
 which reasonably anticipated variation could significantly affect customer the product's safety or its
 compliance with government regulations (such as: flammability, occupant protection, steering control,
 braking, etc. . .), emissions, noise, radio frequency interference, etc. . . (Appendix C TS 16949)
- CHARACTERISTIC, SPECIAL, GM DEFINITION "Safety/Compliance" <S>: Product characteristic for
 which reasonably anticipated variation could significantly affect customer the product's safety or its
 compliance with government regulations (such as: flammability, occupant protection, steering control,
 braking, etc...), emissions, noise, radio frequency interference, etc... (Appendix C APQP)

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Characteristics V

- CHARACTERISTIC, SPECIAL, GM DEFINITION "Standard" <None>: Product characteristic for which
 reasonably anticipated variation is unlikely to significantly affect a product's safety, compliance with
 governmental regulations, fit/function. (Appendix C TS 16949) & (Appendix C APQP)
- CHARACTERISTIC, SPECIAL, PROCESS (e.g., CRITICAL, KEY, MAJOR, SIGNIFICANT): A process
 characteristic for which variation must be controlled to some target value to ensure that variation in a
 special product characteristic is maintained to its target value during manufacturing and assembly. (P57
 FMEA)
- CHARACTERISTIC, SPECIAL, PRODUCT: Core team compilation of important product characteristics from all sources. All Special Characteristics must be listed on the Control Plan. (6.3 #19 APQP)
- CHARACTERISTIC, SPECIAL, PRODUCT (e.g., CRITICAL, KEY, MAJOR, SIGNIFICANT): A product
 characteristic for which reasonably anticipated variation could significantly affect a product's safety or
 compliance with governmental standards or regulations, or is likely to significantly affect customer
 satisfaction with a product. (P55 FMEA)
- CHARACTERISTIC, SPECIAL, TOOLING, CHRYSLER DEFINITION "Pentagon" <P>: Critical tooling symbol used to identify special characteristics of fixtures, gages, developmental parts, and initial product parts. (TS 16949)
- CONTROL ITEM PART, FORD DEFINITION: Product drawings/specifications containing Critical Characteristics. Ford Design and Quality Engineering approval is required for changes to Control Item FMEA's and Control Plans. (TS 16949)

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Design Verification Plan and Report

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Notes & Commentary

APQP Manual, Appendix B, page 83.

Phase 1 Project Review

Project #	Title Part #	Customer Date	
Model/Year	Part #	Date	
	of our APQP process. The docume the ability to meet all specified req	am has considered the following questions in Phase ents provided have been used as a basis for analyzing price with attact as a basis for analyzing the action of the proposed changes to enable us to meet	ng
	Yes No Checklist Item		
1.		d experience concerning customer needs been cons	
2.		been given to the overall business plan and marketing	ng strategy?
3.		benchmark data been considered?	
4. 5.		cess assumptions been identified and challanged? y studies been conducted?	
6.		priate customer inputs into the process?	
7.		reflect the data generated?	
8.		iability goals reflect appropriate standards?	
9.		of materials sufficiently thorough?	
10.		process flow chart relate to the primary BOM and	
11.	Are all special product	t and process characteristics lited?	
12.		surance plan include and outline of program requirem the program at risk, FMEA, and preliminary enginerints?	
		n be produced as specified with no revisions.	
		ision required to produce product within specified req	uirements
	Team Member/Title/Date	Team Member/Title/Date	
	Team Member/Title/Date	Team Member/Title/Date	



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Phase 1 Responsibility Matrix

Phase 1: Plan and Define Program	Management	Purchasing	Engineering	Quality	Laboratory	Sales	Production	HR	Maintenance	Materials	MIS
Output				5							
Design Goals											
Reliability and Quality Goals											
Preliminary BOM											
Preliminary process flow chart											
Preliminary list of special product and											
process characteristics.											
Product assurance plan											
Management Support											

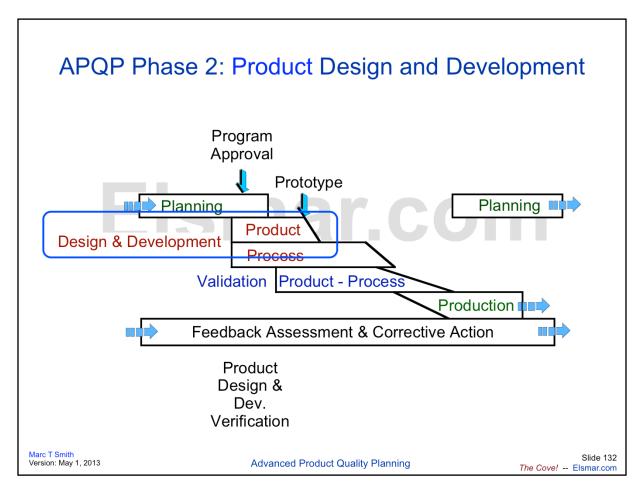
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Notes & Commentary

Discuss the difference between:

Process

How you make it.

Product
What it is and what is is supposed to do.

Phase 2 Outputs

- Outputs by Design Responsible Activity
- Outputs by Advanced Product Quality
 Planning Team

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Outputs by Design Responsible Activity

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- Design FMEA
- DFM and DFA

Design for Manufacturability

Design for Assembly

- Design Verification
- Design Reviews
- Prototype Build Control Plan
- Engineering Drawings (including Math data)
- · Engineering Specifications
- · Material Specifications
- Drawing and Specification Changes

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Additional Outputs by Design Responsible Activity

- · Updated special characteristics list
- Prototype parts build

Make - Buy decisions

Parts inspection

Assembly of prototype(s)

Preferably manufacturing, not model shop

Inspection layout

Prototype validation testing

- · Redesign as required and design review
- Update DFMEA (and System Level FMEA if appropriate)
- Feasibility report

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FMEAs

System: Plan	X101 clary Group clam Apple 910228	teral Damage Seriousness Probability]		-	very low not low mit medium sig high big	S P ne in t0 nor =3 in 10 ndfleant 50-50 h =7 in 10 natrophic>9 in 10		
Component (Part #)	Potential Fallure	Cause of Failure				Effect of Failure	Corrective Action		
Gear, Hub Part # xxxxx	Grooved external spline teeth	Wear, case crunching	2	5	3	Will not transmit power	Heat treat splines		
Plate, Reaction Pan # xxxxx	Warped	Not made flat Excessive heat, slippage	1	4	2	Clutch slippage Clutch slippage	Provide straightening Increase engaging force		
	Worn or smeared	Lack of lube	1	4	2	Clutch slippage	Increase lube oil		
Disc Assembly Part # xxxxx	Warped	Excessive heat, slippage	1	5	3	Chach slippage	Increase lube oil		
	Loss of friction material	Bond failure	1	4	2	Clutch slippage	Develop better bonding		
Spring	Broken	Fatigue	2	3	2	No plate separation	Design for lower stress		
Part # xxxxx		Improper assembly	132			No plate separation	Provide assembly instructions		

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DFMEA

· Disciplined analytical tool

Assess probability of failure Effect of failure

- Must be continually updated
- Causes changes and/or additions to previously selected special product and/or process characteristics
- If you do not have design control, you MUST (should) have customer DFMEA
- Check list (AIAG APQP Manual Appendix A-1)

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DFM and **DFA**

- Design, concept, function and sensitivity (tolerancing) to manufacturing variation
- Manufacturing and/or assembly process
- Dimensional tolerances
- Performance requirements
- Number of components (complexity)
- Process adjustments
- Material handling

ASSEMBLEABILITY EVALUATION CALCULATION FORM

-	bool				# of			8	Summation method				
(P		MVA	1	Parl name	Parte	ayrribe)	opments Op	Σ,	Σ, 100+Σ,	C(100+E)	т-,		
1	-	3	÷	CABINET CABE	1	- PR	2	BO .			207		
	9/	•	1					250					
2				CHASSIS BOARD	•	PAPPEPAPHA	10	80			823		
	2			DRUM	7	N ₄ H	3	0			234		
	3			WASHER	1	+	1	30		i i	100		
	4			SCREW	1	+ 1	2	40			150		
	5	1		BUTTON BRACKET	1	F-	1	0			140		
	8	2		BUTTON	. 8	+	1	30			80		
1		3		BCREW	8	4.3	2	60			280		
	•		_	DISPLAY BRACKET	1	Ę	2	30		120	184		
- 1	7			BCREW	1	71	2	80			180		
٨	-	nt.	-4	ByRading N=∑n=	18	Assurably Coul. Ratio		Æ	nombly	ET·n=	3087		
Ę	<u>. P</u>	111	(0)	- 1800 50.8 - 58.44		K = AT = 30.8	7	AT	- IT.	<u>n</u> = 50.8			

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Design Verification

- Inspection methods
- Testing methods
- Ensure that all design outputs meet design input requirements

Alternate calculations

CAD/math data

Review design stage documents before release

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Design Reviews - Evaluations

- Design/functional requirement(s) and considerations
- · Formal reliability and confidence goals
- Component/subsystem/system duty cycles
- · Computer simulation and bench test results
- DFMEA(s)
- · Review of the DFM and DFA
- Design of experiments (DOE) and assembly build variation results
- Test failures
- Design verification progress
- Max/Min builds

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Design Review Tracking

- Track verification progress using a design verification plan and report (DVP&R - Ford & Chrysler)
- Product/process validation of components



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Process Flow Diagram Example **Process Flow Diagram** Approved By: Date: 4/5/93 Rev. : C Part Number: Part Description: Operations Manager Prepared By: Senior Advisor QA Enginee Key Product Characteristic Key Control Characteristic Move "OK" Vinyl Material Material Specs Material Certification Tag From Storage Area and Load Into Press. Tearstrip In Cover 2 Auto Injection Mold Cover 2.0 2.1 Tool Setup In Tool # 2.2 Machine Setup Hole Diameter In Cover Tool Setup 2.2 Flange Thickness In Cover Tool Setup Pressure Control Protrusions 5.0 2.1 Tool Setup Heiaht Machine Setup 3 Visually Inspect Cover 6.0 Pressure Control Protrusions 2.1 Tool Setup Filled Out 2.2 Machine Setup Cover - Flash Free Tool Setup 2.2 Machine Setup Cover Filled Out Tool Setup Machine Setup 8.0 2.1 2.2 Free Of Foreign Material Machine Setup



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PFMEA Example Process Failure Mode And Effects Analysis Outside Suppliers Affected: Primary Process Responsibility: Model Year/Vehicle(s): Part Number: Other Div. Or People Involved Scheduled Production Released: PFMEA Date: Rev. Approvals: Quality Assurance Manager Quality Assurance Engineer Mode Potential Effects Of Failure Potential Cause Of Failure Current Controls Material Certification Required With Each SIR Take TPPE Wrong Material Fragmented Container Insufficient Supplier Control Material Held In Container Unpredictable Deploymen Improper Handling Storage Area Misidentified Material Shipment Release Verification Fragmented Container Unpredictable Deploymen Periodic Audit Of Supplier Material Out Of Spec Supplier Process Control Material Contaminated Fragmented Container Open Boxes Visual Inspection Material Unpredictable Deployment Fragmented Container Unpredictable Deployment Engineering Change Release Verification Supplier Change Composition Change Customer Notification Move To Fragmentation Untrained LTO 2 Unreleased Check For Green "OK" Tag At Press Untrained Personnel Approved Trace Card Check List Training Hold In Approved Contamination Fragmentation Open Containers Boxes Kept In Sealed Storage Area Until Storage Until Process Problems Housekeeping Needed Area Maintenance Needed Plastic Liner On Pallets Inside Storage P. M. Facility Marc T Smith Version: May 1, 2013 Slide 143 **Advanced Product Quality Planning** The Cove! -- Elsmar.com



Control Plan Methodology

- Aids in the manufacturing of products according to customer requirements
- Provide structured approaches
- Contain a written summary of the system used in minimizing process and product variation
- Forms provided in the AIAG handbook are examples of how to document
- Alternate formats can be used if they contain necessary information
- Must be maintained and used throughout the product life cycle

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Control Plan Use

- Initial: To document and communicate initial process control
- Next: Guidance in controlling processes and to ensure product quality
- Last: A living document reflecting current methods of control and measurement systems used

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Control Plan

- Ensure Control Plan is aligned to, and correlates with, DFMEA, Process Flow, PFMEA
- Control Methods appropriate to variation type(s)
- Incorporates Lessons Learned, Statistical Data
- Use A-8 Control Plan checklist in APQP manual to evaluate

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Prototype Build Control Plan

- A description of the dimensional measurements
- Material tests

Functional tests that will occur during prototype build

Depending upon product complexity, several prototype builds may be necessary and may require updates to the control plan

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Standard Control Plan Example

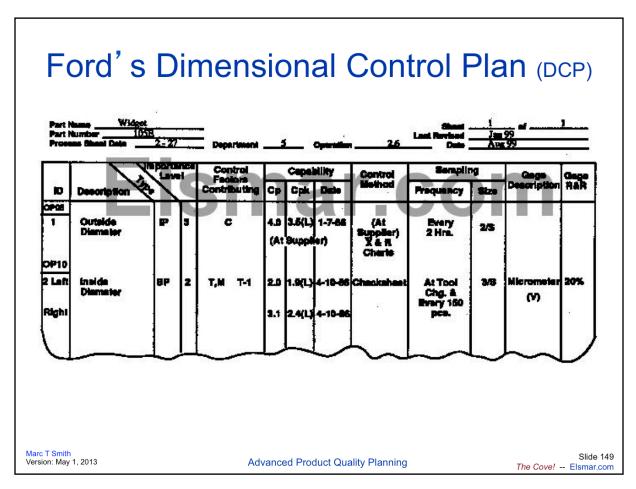
Control Plan Number Part No./ Latest Change No.				Key Conta	ct / Phone	е		Date (Orig.)		Date (Rev.)					
				Core Team				Customer Engineering Approval/Date							
Part Nan	ne/Description			Supplier/P	lant Apop	roval/Date	val/Date Customer Quality Approval/Date								
Supplier/	Supplier/Plant Supplier Code				Other Approval/date (If Req'd)				Other Approval/date (If Req'd)						
Part/ Process Number	Process Name/ Operation Description	Machine, Device, Jig, Tools for Mfg.	No.	Product	Process	Special Char. Class	Product/ Process Spec/ Tolerance	Evaluation Measurement Technique	Size	Frequency	Control Method	Reaction Plan			

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Notes & Commentary

The full form is in the APQP Manual on page 100 in appendix G.

Control Plan Example (GM)

							Proce	ess Contro	Plan								
	Supplier Name:				er Code:					Part Number:							
	Supplier Rep.:			Te	lephone:					art Description:							
	Title:					4/5/93				Change Letter:				Plan Effec		4/5/93	
Key P	roduct Control	Characteristics			Gage St	udy			Process Capat hort Term Capa			ss Perforr Term Cap			Controls		
[1] Item	[2] Key Product Characteristic/ Spec		[4] Operation Description	[5] Gage Operation	[6] Attr./ Variable	[7] Last R&R Date		[9] Process Capability Date	[10] % Process Capability		Perform.	Perform	[14] Cpk or Dev From Target/Nom.	Control	[16] Freq. Of Inspect.	[17] Operator Set-Up Gage Instruction (Proced. #)	[18] Proces Audit Metho and Frequer
1.0	Vinyl Material Spec													Check Vendor Cert(s).	Every Box		Green "C Releas Each B
2.0	Tear Strip (Cover) 1 = 0.41mm .+/- 0.11mm 2-7 = 0.685mm .+/- 0.135mm [7]		Auto Injection Mold Cover In TL#						[2] [3] [4] [5] [6]	[1] [2] [3] [4] [5] [6] [7]				SQC Database	Start Of Each Run And Each Shift	3.607	
2.1		Tool Setup Machine Setup												Verify To Spec Sheet			
3.0	Hole Diameter (Cover) 4.60mm .+/- 0.25mm		Auto Injection Mold Cover TL#						[2] [3] [4] [5]	[1] [2] [3] [4] [5]				X bar and R Charts SQC Database	5 Pieces Every 6 Months	3.609	

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Prototype Build

- · Make -buy decisions
- · Part inspections
- Assemble prototypes
- Perform layout inspection
- Validation testing (Who will do testing?)
- · Redesign as required
- Update DFMEA and SFMEA if required

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Customer or Supplier Engineering Drawings (including math data)

- Review for special and/or critical characteristics
- Review controlling drawings when engineering drawings are nonexistent
- Review drawings for:

Dimensions for form, fit, function, durability, government S&R Control or datum surfaces/locators for function gages and equipment

Feasibility/compatibility with industry standards

 Compatibility of math data with two-way communications (Written waivers acceptable)

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Customer or Supplier Engineering Specifications

- Review and understand controlling specifications
- Identify functional, durability and appearance requirements
- Should define:
 Sample size

Frequency

Acceptance criteria

Otherwise, determined by supplier and included in control plan

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Material Specifications

 Review Material Specifications for **Special Characteristics**

> Physical properties ar.com

Performance

Environmental

Handling

Storage

Include in Control Plan

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Drawing and Specifications Changes

- Change control requirement applies
- Ensure proper communication
- QS 9000 Element 4.5 'Document and Data Control' applies (requires a Change Control system)

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APQP Team Outputs

- New equipment, tooling and facilities requirements
- Special product and process characteristics
- Gage and testing equipment requirements
- Team feasibility commitment and management support
- · Subcontractor build
- · Supplier build

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New Equipment, Tooling and Facilities Requirements

- Preliminary identification of new equipment, tooling and facilities
- · Address these items on the timing chart
- Address capability requirements
- · Establish delivery times
- Complete check list in AIAG APQP & Control Plan reference manual Appendix A-3

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Special Product and Process Characteristics List

 Upgrade preliminary list started in Phase 1 from information gathered through review and development of design features

Additional sources

- DFMEA
- SFMEA if applicable
- These may overlap

- PFMEA
- · Previous history
- Must be on control plans for prototype, pre-launch and production
- Listing should be a team consensus

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Gage and Testing Equipment Requirements

- Preliminary identification of inspection, test and measurement equipment
- Requirements on timing chart

Complete in time to conduct measurement systems analysis

Equipment builder

Pilot build

Production trial run

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Team Feasibility, Commitment and Management Support

- · Team feasibility commitment
- Complete program review check list, including:

Design feasibility

Can be manufactured, assembled, tested and packaged

Can be delivered in the right quantities on schedule at acceptable cost

Review design information check list in AIAG APQP Reference manual Appendix A-2 as part of feasibility inputs

- Open issues that require resolution with assigned responsibility and timing.
- Management Support

Report project status to management

Recommend continue or drop project depending on feasibility

Cover open issues and concerns

Management support as required

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Subcontractor Pilot Build

- Supplier participated, if appropriate
- · Sample quantity required
- Check that it is according to:
 Work instructions
 Control plan
- · Where to be produced

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Supplier Pilot Sample Build

- Parts availability
- Tooling and equipment availability
- Measurement equipment availability

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Phase 2 Responsibility Matrix

Engineering Phase 2: Product Design and Development Quality Output DFMEA DFM / DFA Design Verification Design Reviews Prototype Build Engineering Drawings (inc. math data) Engineering Specifications Material Specifications Drawing / Specification Changes New Equipment, Tooling, Facilities Requirements Special Product & Process Characteristics Prototype Control Plan Gages / Testing Equipment Requirements Team Feasibility Committment Management Support Subcontractor Built Supplier Build

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Phase 2 Project Review Title Part # Customer Date Our advanced quality planning team has considered the following questions in Phase 2 of our APQP process. The documents provided have been used as a basis for analyzing the ability to meet all specified requirements. All 'NO' answers are supported with attached comments identifying our concerns and/or proposed changes to enable us to meet specified requirements. Is the product adequately defined (application requiremetns, etc.) to enable feasibility evaluation? 2. Can engineering performance specifications be met as written? Can product be manufactured to tolerances specified on the drawing? Can product be manufactured with Cpks which meet requirements? Is there adequate capacity to produce product? 6. an the product be manufactured without incurring any unusual: 6a Costs for tooling? 6b Costs for capital equipment? 6c Alturnate manufacturing methods? Is Statistical Process Control required on the product? 8. Where Statistical Process Control is used on similar product? 8a Are the processes in control and stable? Are Cpks greater than 1.33? Product can be produced as specified with no revisions. Feasible Changes recommended (See attached) Design revision required to produce product within specified requirements Feasible Not Feasible Team Member/Title/Date Team Member/Title/Date Team Member/Title/Date Team Member/Title/Date

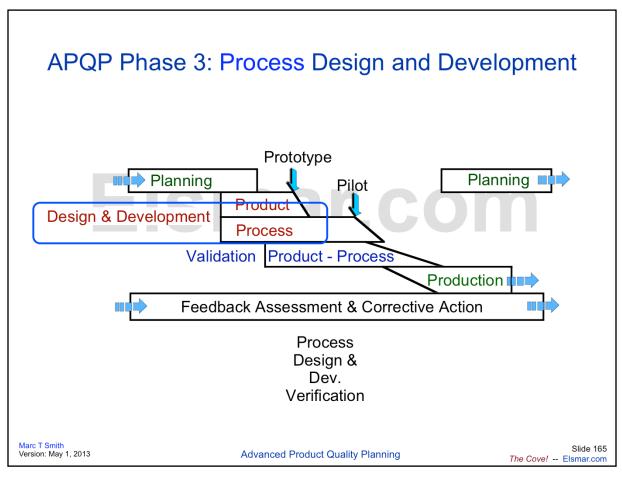


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Notes & Commentary

Phase 3 Outputs

- Packaging Standards
- Product / Process Quality System Review
- Process Flow Chart
- Floor Plan Layout
- Floor Plan LayoutCharacteristics Matrix
- Process Failure Mode and Effects Analysis
- Pre-Launch Control Plan
- Process Instructions
- Measurement Systems Analysis Plan
- Preliminary Process Capability Study Plan
- **Packaging Specifications**

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Typical Design Responsibility Outputs

- DFMCA
- DFM/DFA
- DV
- Design Reviews
- Prototype Build
- Engineering Drawings
- Engineering Specifications
- Material Specifications
- Drawing and Specification Changes

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Typical APQP Team Outputs

- New Equipment
- Facilities
- · Etc. Ismar.com

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Process Design and Development Outputs

- Packaging standards
- Product and process quality system review
- · Process flow chart
- Floor plan layout
- Characteristics matrix
- PFMEA
- · Pre-launch control plan
- Process instructions
- Measurement systems analysis plan
- Preliminary process capability study plan (Typically 100 Parts)
- Management support

Additional Outputs

Update tooling, equipment and facilities list

Update process flow chart

Update PFMEA

Quote in-house gages, tooling and equipment

Order gages, tooling and equipment

Delivery of gages in time for MSA plan

Delivery of equipment

Must consider approval at equipment subcontractor, inhouse installation, debugging and process potential studies (runoff)

Subcontractor pilot build

Supplier pilot build

Salable units?

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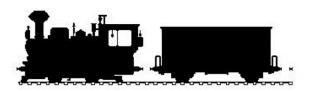
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Notes	8	Commentary
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Packaging Standards

- From customer
- Developed during prototype or prelaunch runs







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Notes & Commentary

Product and Process Quality System Review

- Team must review existing quality systems manual to ensure that changes resulting from APQP (if any) are reflected
- Must comply with QS 9000
- Changes must be reflected in control plan
- Reference AIAG APQP Reference manual Appendix A-4 check list

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Process Flow Chart

- Update process flow chart (Example in AIAG APQP Reference manual Appendix A-6)
- Describes current or proposed process flow
- Used to analyze sources of variation
- Helps analyze total process
- Needed for process FMEA, characteristics matrix and control plan
- Reference AIAG APQP Reference manual Appendix A-6 check list

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Process Flow Diagram Example Process Flow Diagram Approved By: Date: 4/5/93 Part Number: Part Description: Rev. : C Operations Manager Prepared By: Senior Advisor QA Enginee Key Product Characteristic Key Control Characteristic Move "OK" Vinyl Material Material Specs Material Certification Tag From Storage Area and Load Into Press. Tearstrip In Cover 2 Auto Injection Mold Cover 2.0 2.1 Tool Setup In Tool # 2.2 Machine Setup Hole Diameter In Cover Tool Setup 2.2 Machine Setup Flange Thickness In Cover Tool Setup 5.0 Pressure Control Protrusions 2.1 Tool Setup Heiaht Machine Setup 3 Visually Inspect Cover 6.0 Pressure Control Protrusions 2.1 Tool Setup Filled Out 2.2 Machine Setup Cover - Flash Free Tool Setup 2.2 Machine Setup Cover Filled Out Tool Setup Machine Setup 8.0 2.1 2.2 Free Of Foreign Material Machine Setup



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Floor Plan Layout

- · Determine acceptability of inspection and test points
- Control chart location(s)
- Visual aides
- Interim repair stations (rework)
- · Nonconforming material storage
- · Keyed to material flow and control plan
- Reference AIAG APQP Reference manual Appendix A-5



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Notes & Commentary

Characteristics Matrix

• Displays relationship between:

Process parameter

Manufacturing stations

Reference AIAG APQP Reference manual Appendix B, page 82

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Process FMEA

- To the extent possible, potential failure modes have been considered and addressed
- May be started after design FMEA in Phase 2
- Needs to be updated regularly
- Must be done prior to committing new tools and equipment
- Living document
- Typically started too late!
- Reference AIAG APQP Reference manual Appendix A-7

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Automotive Process FMEA

Process:				Cess Failure Mode And Effects Ar Outside Suppliers Affected										Low - Hig 1 - 10
Primary Process Responsibility: Model Year/Vehicle(s): Part Number: Other Div. Or People Involved: Scheduled Production Released: PFMEA Date:												Rev.		
Approvals:	Quality /	Assurance Manager Operations Manager			Scheduled Production Released: PFMEA Date: Rev. Quality Assurance Engineer Senior Advisor									
Part Name Operation Number	Process Function	Potential Failure Mode	Potential Effects Of Failure	Potential Cause Of Failure	Current Controls	Occured	Severity	Detection	RPN	Recommended Actions And Status	Actions Taken	Occured	Detection	Responsib
SIR Container 1	Take TPPE Material Held In Storage Area	Wrong Material	Fragmented Container Unpredictable Deployment	Insufficient Supplier Control Improper Handling Misidentified Material	Material Certification Required With Each Shipment Release Verification	1	9	2						
		Out Of Spec Material	Fragmented Container Unpredictable Deployment	Supplier Process Control	Periodic Audit Of Supplier Material	3	10	3	90			П		
		Contaminated Material	Fragmented Container Unpredictable Deployment	Open Boxes	Visual Inspection	1	9	7	63					
		Material Composition Change	Fragmented Container Unpredictable Deployment	Engineering Change Supplier Change	Release Verification Green "OK" Tag Customer Notification	1	10	7	70					
2	Move To Approved Storage	Unreleased	Fragmentation	Untrained LTO Untrained Personnel	Check For Green "OK" Tag At Press Trace Card Check List Training	5	10	1	50					
3	Hold In Approved Storage Until Needed	Contamination	Fragmentation Process Problems	Open Containers Housekeeping Area Maintenance	Boxes Kept In Sealed Storage Area Until Needed Boxes Lined With Plastic Liner On Pallets Inside Storage P. M. Facility	1	10	3	30					

Notes & Commentary

Pre-launch Control Plan

- Description of dimensional measurements, materials and functional tests
- Adds additional product and/or process controls
- Purpose is to contain potential nonconformities utilizing:

More frequent inspections and/or tests

More in-process and final inspection and/or check points

Statistical evaluations

Increased audits

Reference AIAG APQP Reference manual Appendix A-8 check list

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Automotive Control Plan

Control Plan Number Part No./ Latest Change No.				Key Conta	ct / Phone	Э		Date (Orig.)		Date (Rev.)			
				Core Team				Customer Engineering Approval/Date					
Part Nam	ne/Description			Supplier/P	lant Apop	roval/Date		Customer Qua	lity App	Approval/Date			
Supplier/	r/Plant Supplier Code Other Approval/date (If Req'd) Other Approval/date (If Req'd)												
Part/ Process Number	Process Name/ Operation Description	Machine, Device, Jig, Tools for Mfg.	C No.	haracteristic	Process	Special Char. Class	Product/ Process Spec/ Tolerance	Evaluation Measurement Technique	Metho Size	Frequ- ency	Control Method	Reaction Plan	

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Additional Phase 3 Outputs

- · Updated equipment, tools and facility lists
- Updated process flow chart, PFMEA and control plan
- Quotes for in-house tooling, equipment and gages
- · Selection of potential new subcontractors
- Quote and delivery of gages in time for MSA plan
- · Equipment build and runoffs
- · Generation of a subcontractor pilot build
- · Generation of a supplier pilot build

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Updated Tool, Equipment and Facilities Lists

- Information from PFMEA and other sources
- Address on timing chart
- Address capability requirements
- Reference AIAG APQP Reference manual Appendix A-3 check list

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Quoting In-House Tooling, Equipment and Gages

- Delivery timing for pilot build or production trial run
- · Include capability requirements
- Include trial run/runoff/prove-out requirements
- Gage delivery for MSA plan and runoff
- Reference AIAG APQP Reference manual Appendix A-3

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Selecting Potential New Subcontractors

- Responsible for planning, tracking and follow-up for subcontracted work
- Provide technical resources for tool and gage design, fabrication and full dimensional inspection

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Subcontractor Pilot Sample Build

- · Supplier participation, if appropriate
- · Build sample quantity required

Machine trial runs
Pilot run(s)

- In accordance with appropriate work instructions
- · In accordance with control plan
- · Production tooling and equipment, if possible

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Supplier Pilot Build

- Provide for customer participation, if specified
- have process instructions in place
- · Have control plan in place
- Provide required quantity
- Complete MSA
- Generate required documentation as planned

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Project Review III

- Include in control plan
- Manufacturing location's quality system manual should be reviewed
- Procedures and control plans to be updated to reflect changes
- Last chance to eliminate problems before ramp-up

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Phase 3 Responsibility Matrix





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Phase 3 Project Review Project # Customer Model/Year Our advanced quality planning team has considered the following questions in Phase 3 of our APQP process. The documents provided have been used as a basis for analyzing the ability to meet all specified requirements. All 'NO' answers are supported with attached comments identifying our concerns and/or proposed changes to enable us to meet specified requirements. Checklist Item Does packaging design ensure product integrity at point of use and meet customer specs? s the product process quality checklist completed for the system review? 3 Does the process flow chart indicate any problems with the process? 4. Does the floor plan checklist indicate any problems with the aceptability of inspection points, control chart locations, applicability of visual aids, interim repair stations, and storage area to contain defective materials? Is a characteristics matrix appropriate and has one been constructed? 6 Does the process FMEA check list indicate any problems and is there a system for periodic review of the PFMEA? 7 Does the control plan check list indicate that all dimensional requirements, material, and functional tests that will occur after the prototype, and before full production, are included? Are clear process instructions in appropriate detail and are they cross-referenced to all 8. appropriate sources? Does the measurement systems analysis plan include responsibility to ensure gage linearity, accuracy, repeatrability, reproducability, and correlation for duplicate gages? 10 Has the preliminary process capability study plan been completed? Do the packaging specifications resulting from the packaging design assure that product performance and characteristics will remain unchanged during packing, transit, unpacking, and will it have compatability with all material handling equipment, including robots? Feasible Product can be produced as specified with no revisions. Feasible Changes recommended (See attached) Design revision required to produce product within specified requirements Not Feasible Team Member/Title/Date Team Member/Title/Date Team Member/Title/Date Team Member/Title/Date



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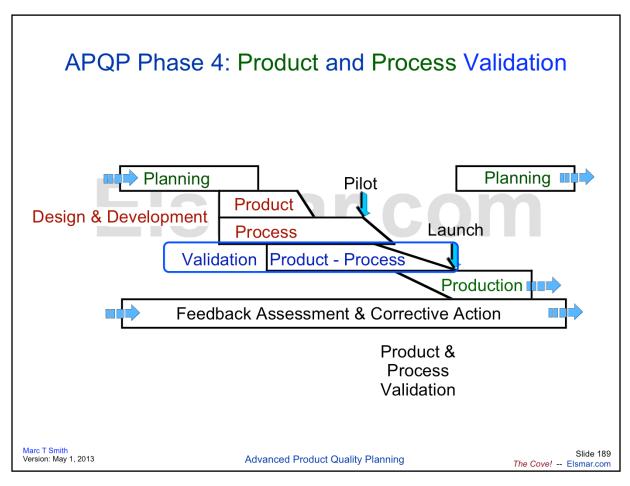
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Phase 4 Outputs

- Production trial run
- Measurement system evaluation (complete)
- Preliminary process capability study
- Production part approval
- · Production validation testing
- · Packaging evaluation
- Production control plan
- Quality planning sign-off and management support

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Process Instructions

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- · Work instructions for operating personnel
- · Sources:
 - + FMEAs
 - t Control plans
 - † Engineering drawings and specifications
 - + Material specifications
 - Visual standards
 - f Industry standards
 - Process flow chart
 - + Floor plan layout
 - † Characteristic matrix
 - † Packaging standards
 - Process parameters
 - † Producer expertise
 - † Handling requirements
 - † Operators of process
 - † Accessible operators
 - t Include set-up parameters
 - Reference QS 9000 Element 4.9 'Process Control'

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Measurement Systems Analysis (MSA)

- Complete studies as defined in the MSA plan
- Minimum are those identified in the control plan
- Subjected to evaluation prior to or during production trial

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MSA Studies

Measurement uncertainty determined
 Gage R&R, Bias, Stability, and Linearity

Gage R & R acceptance guidelines

< 10% acceptable

10-30% may be acceptable, evaluate total variation

>30% unacceptable, measuring system needs improvement

Verify study performed correctly

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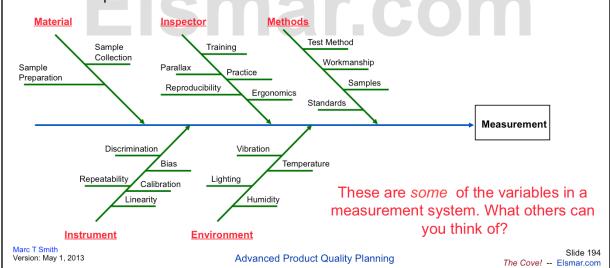
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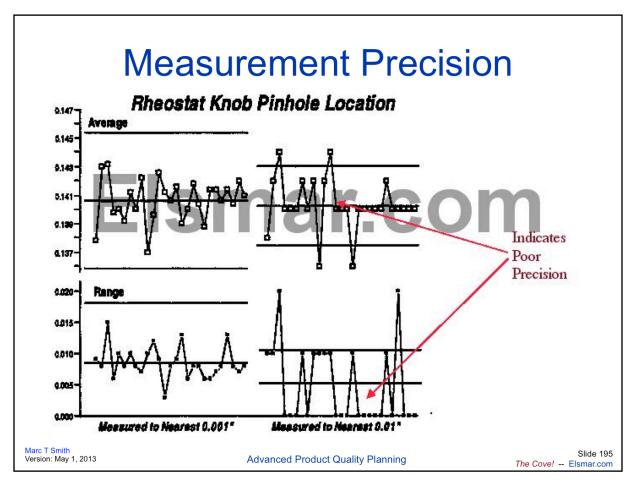
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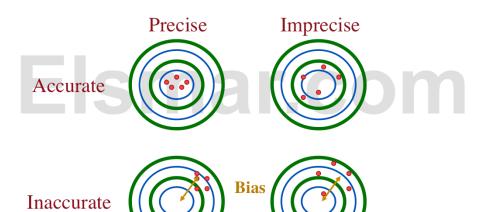
Measurement Systems Analysis Plan Ensures Gage:

- Linearity
- Accuracy
- Repeatability
- · Reproducibility
- · Correlation for duplicate gages
- Gages may be needed prior to gage sign-off at subcontractor plant or any inhouse pilot runs





Measurement Bias & Repeatability



You can correct for Bias
You can NOT correct for Imprecision

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Preliminary Process Capability Study Plan

- Must include characteristics identified in control plan
- Few characteristics for simple component
- Many characteristics for complex product with many parts
- Reference AIAG Fundamental SPC Reference Manual

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Packaging Evaluation

- Packaging must conform to specifications developed by customer or supplier
- Assess protection of product
- Customer specified packaging must be evaluated by team
- Pilot or production trial run parts usually used in evaluation

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Packaging Specifications

- For individual products
- Customer packaging
- Generic standards where appropriate
- Must ensure delivery quality
- Compatible with all material handling equipment used

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Production Part Approval Process

PPAP

- Production parts are manufactured at the production site using production tooling, gaging, equipment, operators, etc
- Parts from production run are analyzed.
- Test results and records from APQP are submitted with Part Submission Warrant.

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Notes & Commentary

When PPAP is required is defined in Section I.3 of the PPAP Manual (starting on page 11) - customer notification required.

Purpose of PPAP

For the supplier to demonstrate:

- All design records and specification.
- Requirements are properly understood.
- The process has the capability to produce product that meets requirements.

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Production Part Approval Process (PPAP)

- Production Part Approval Process
- · Parts produced at production site using:

Production tooling

Production gages

Process

Operators

Environment

Process settings

- Feeds
- Speeds
- · Cycle times
- Pressures
- Temperatures
- Intent is to validate (prove) that products made using production equipment meet engineering requirements
- If submission level is not known, contact customer
- Default level is 3
- Customer approval is required prior to quantity production
- Reference AIAG Production Part Approval Process reference manual

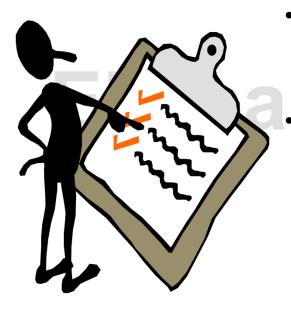
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PPAP Review Checklist



- Checklist to assist with evaluation of PPAP package
- Action plan created with use of checklist

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Notes & Commentary

Ford: PPAP Manual page 30 - Check list for managing change.

PPAP Scope

- Production parts generally 300 'pieces'
- Service subcontractors fulfill requirements
- Bulk material
- Includes internal and external sources for information
- Submission required prior to first production shipment
- PPAP Manual Section I.3 "Customer Notification and Submission Requirements" (starting on page 11) for guidance

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Notes & Commentary

Section I.3.3 of the PPAP Manual (page 13) describes situations where PPAP submission is not required (customer notification not required).

Application



AIAG PPAP Manual Defines When PPAP Submission is Required

- New part
- Correction to discrepancy in previous submission
- Design or process change
- Change in source of subcontracted materials or services
- Transfer or rearrangement of tooling & equipment

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Methodology

- Buyer enters PPAP submission date on purchase order.
- Approver determines submission level.

Default level 3
Default level 4 for raw material

Supplier submits PPAP
 PPAPALL.xls electronic submission (Delphi)

 Approver evaluates PPAP package.

Level 5 at supplier site

- Approver determine part submission status.
- Notify supplier and manufacturing of status.

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Notes & Commentary

Default level for raw material is 4

PPAP package forms, checklists, charts, capability analysis, measurement analysis included in PPAPall in an Electronic Format

Supplier Data Received

- Warrant
- Appearance
 Approval Report
 (AAR), as required
- Sample Parts
- Print/Design Record
- Engineering Change Documents
- Check fixtures/aids
- Process Flow Diagram
- PFMEA

- DFMEA
- Control Plan
- Early Production Containment Plan (Pre-Launch Control Plan)
- Process capability studies
- Gage Measurement System Analysis
- · Lab Accreditation & scope
- Restricted & Reportable Materials form
- · Interim Worksheet, if required

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Flow Chart

- Linkage of Product Characteristics from DFMEA to Operational Steps.
- Operation numbers consistent with PFMEA, Control Plan, Operator Instructions.
- Ensure identification of inspection and rework.
- Use A-6 Process Flow Chart checklist in APQP manual to evaluate.

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DFMEA

- Assess Feasibility, Risk, Design Intent Issues
- Confirm Manufacturing Process
 Capability Considered
- Focus on Critical Characteristics
- Lessons Learned Incorporated
- Use A-1 Design FMEA Checklist in APQP Manual to Evaluate

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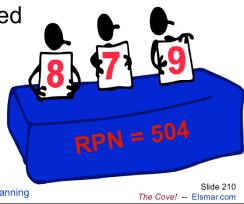
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PFMEA

- Linkage with DFMEA, Process Flow, Control Plan, Operator Instructions, etc
- Degree to which high RPN's are addressed with preventive strategies
- Action Plans assigned, implemented, effectiveness assessed and RPN recalculated
- Use A-7 Process FMEA checklist in APQP manual



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Pre-Launch Control Plan

Early Production Containment Requirements

- 1. Additional controls included for proper duration or quantity.
- 2. PFMEA and statistical data used to determine what additional controls necessary.
 - Short Term Capability
 - Long Term Capability on similar process

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Production Control Plan

- Update pre-launch control plan (living document)
- Add:

Sampling plans

Control method

SPC, inspection, attribute data and mistake-proofing

Reaction plan

- Nonconformances clearly identified, quarantined and disposition made
- Requires customer approval unless otherwise specified
- Reference AIAG APQP Reference manual Appendix A-8, B and G

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Production Validation Testing

Engineering tests validate products manufactured with:

Production tools

Production processes

Production operators

- Performed under end-use operating conditions
- Multiple validations for multiple intended uses
- Reference QS 9000 Element 4.4.8

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Production Trial Run

- Production tooling, equipment, environment, facilities and cycle time
- Process instructions and control plans
- Minimum quantity set by customer (Can be increased by team)
- Generally 300 parts

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Production Trial Run Product Used For:

- · Preliminary process capability studies
- MSA (if not completed earlier)
- Final feasibility
- Process review
- Production validation testing
- PPAP
- Packaging evaluation
- · First time capability
- Quality planning sign-off
- Design changes (if required)

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Ppk vs. Cpk

In 1991, the ASQC/AIAG Task Force published the "Fundamental Statistical Process Control" reference manual, which shows the calculations for Cpk as well as Ppk. These should be used to eliminate confusion about calculating Cpk. So which value is best to report, Cpk or Ppk? Although they show similar information, they have slightly different uses.

Estimated sigma and the related capability indices (Cp, Cpk, and Cr) are used to measure the potential capability of a system to meet customer needs. Use it when you want to analyze a system's aptitude to perform.

Actual or calculated sigma (sigma of the individuals) and the related indices (Pp, Ppk, and Pr) are used to measure the performance of a system to meet customer needs. Use it when you want to measure a system's actual process performance.

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Notes & Commentary

For a detailed discussion of Cp, Cpk, Cr, Cpm, Pp, Ppk, and a number of other p's and pk's, see:

http://16949.com/ubb/Forum10/HTML/000001.html

Preliminary Process Capability Studies

- · Characteristics identified in the control plan
- Usually 100 pieces minimum
- May be 30 if run is less
- Ppk ≥ 1.67 is acceptable unless otherwise specified
- Ppk ≤ 1.67 requires action plan unless otherwise specified
- Reference AIAG Fundamental SPC Reference Manual

1.0 at spec limit

+-3 sigma = 1.67

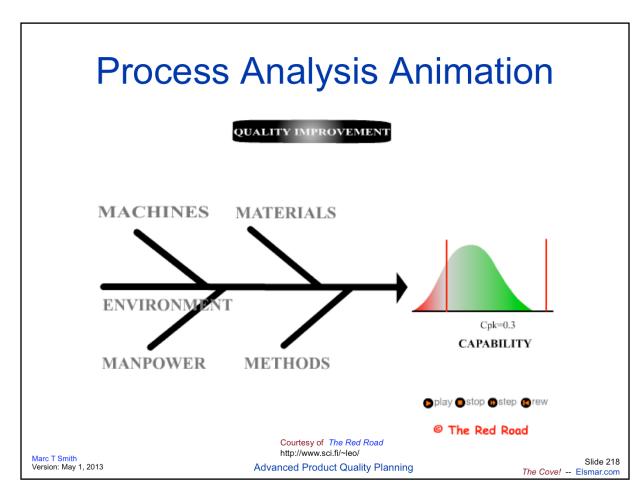
Allows 'flop' within spec limit

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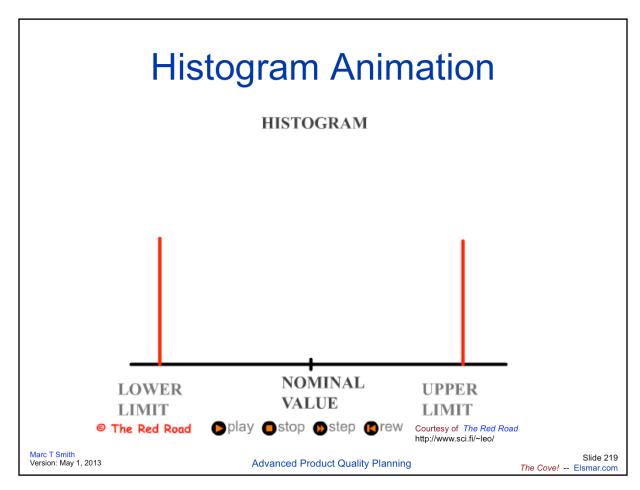
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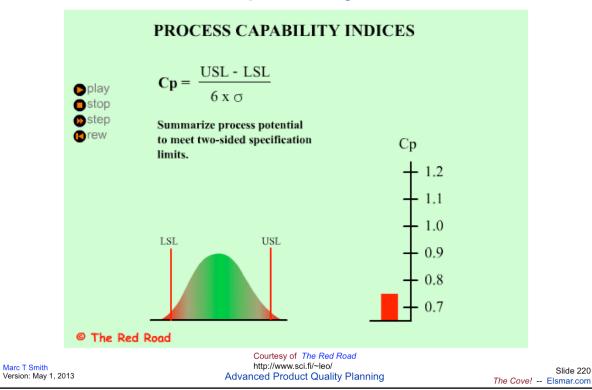


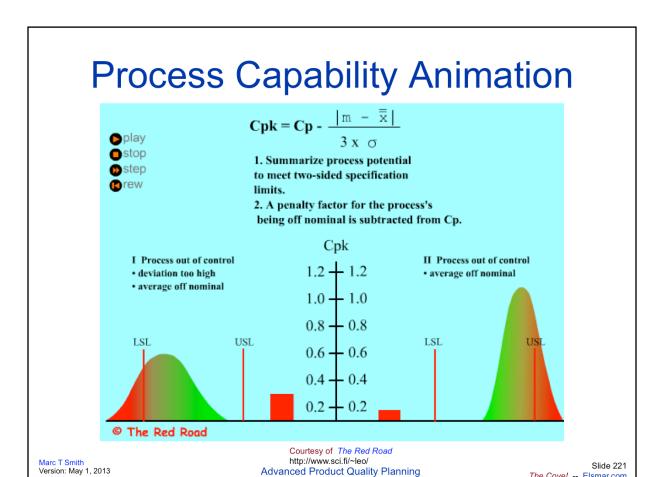
Notes & Commentary

Figure 1 on page 46 of the APQP Manual has an excellent process analysis diagram.



Process Capability Animation





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Process Capability Studies

Capability	Interpretation	Conclusion
Ppk > 1.67	Process probably meets customer requirements	Current control plan sufficient
1.33 <ppk<1.67< td=""><td>Process may not meet customer requirements</td><td>Additional controls needed until Cpk>1.33 achieved</td></ppk<1.67<>	Process may not meet customer requirements	Additional controls needed until Cpk>1.33 achieved
Ppk<1.33	Process will not meet customer requirements	100% inpection is needed until Cpk>1.33 achieved

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Part Submission Status Possibilities

- Full Production Approval
- Interim Approval
 - Authorize shipment to Delphi without Full Production Approval
 - Corrective Action Plan is required.
- Rejected

Corrected submission required before production quantities may be shipped.

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Interim Part Classes

- A Parts from production tooling and meet specs, not all PPAP requirements have been met.
- C Parts not from production tooling, parts meet specs.
- D Parts do not meet specs.
- B Parts from production tooling and require rework to meet specs.
- E Parts do not meet specs and vehicles with class E parts require retrofit to make them saleable.

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Notes & Commentary

Documents accompanying Interim approvals - Warrant, control plan, PFMEA, etc. as completed

Review and Sign-Off

- Process instructions in place and followed
- · Flow charts in place and followed
- · GR&R plans exist and are followed
- · Publish final feasibility report
- · Obtain formal sigh-off
- Schedule and conduct management review
- Obtain management commitment to assist in open issues

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Phase 4 Project Review

Model/Year Date Our advanced quality planning team has considered the following questions in Phase 4 of our APQP process. The documents provided have been used as a basis for analyzing the ability to meet all specified requirements. All 'NO' answers are supported with attached comments identifying our concerns and/or proposed changes to enable us to meet Yes No Checklist Item Has the production trial run been conducted and does it indicate the need for any change? 2. Does the evaluation of the measurement systems indicate any need to modify the control plan characteristics? Does the preliminary process capability study indicate any potential problems? 3. 4. Has the production part been approved? Has the production validation testing indicated any problems? 5 Has the evaluation of the packaging of test shipments, where feasible, and test methods indicated any difficulty? 7 Has the control plan methodology check list indicated any problems with that document? Product can be produced as specified with no revisions. Feasible Feasible Changes recommended (See attached) Not Feasible Design revision required to produce product within specified requirements Team Member/Title/Date Team Member/Title/Date Team Member/Title/Date Team Member/Title/Date

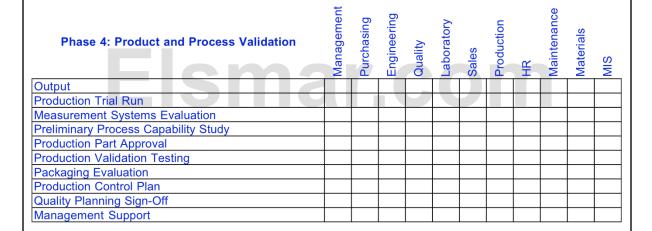
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Phase 4 Responsibility Matrix



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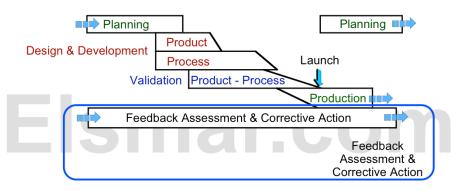
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APQP Phase 5: Feedback, Assessment and Corrective Action



- The results of continuing production are evaluated for common or special causes of variation during this phase to ensure that the products satisfy customer satisfaction requirements
- The effectiveness of the quality process should be evaluated during this process step

Includes continual improvement efforts
Includes delivery and service performance

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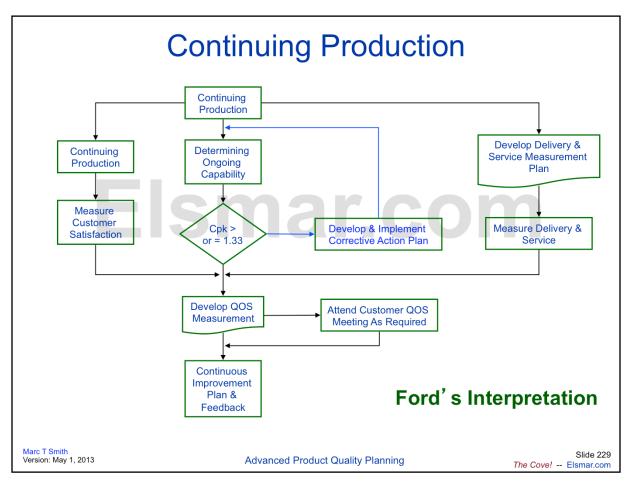
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Notes & Commentary

Discussion:

Analysis and use of data.

Corrective Action ---> Continuous Improvement



Phase 5 Outputs

- Reduced variation
- Customer satisfaction
- Delivery and service

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Reducing Variation

- Identify process variation
- take corrective action to reduce variation
- Develop proposal for customer review
- Gain customer decision to implement, negotiate or change design

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Customer Satisfaction

- Product or service must perform in customer's environment
- Supplier must participate
- Supplier and customer must be partners
- Reference QS 9000 Element 4.1.6

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Customer Satisfaction Metrics

- Warranty
- · Labour claims
- Concerns reports
- Nonconforming material reports
- Corrective actions
- On time delivery
- Tech calls

- Customer rating
- Returns
- PPM
- Response time
- On-site representative
- Market share
- Cost control (total cost)

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Delivery and Service

- Continues the supplier customer partnership in problem solving and continuous improvement
- Replacement parts and services are important
- Leads to possible price reduction from:

Inventory cost reduction

Process cost reduction

Cost of quality reduction

Reference QS 9000 Element 4.15

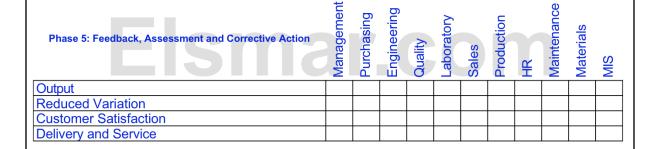
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Phase 5 Responsibility Matrix



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Phase 5 Project Review

Model/Year	Part #		CustomerDate	-
1. 2. 3.	of our APQP process. The documents provided have been used as a basis for analyzing the ability to meet all specified requirements. All 'NO' answers are supported with attached comments identifying our concerns and/or proposed changes to enable us to meet specified requirements. Yes No Checklist Item Has a system for reducing future variation been developed and is it in place? Is there a system for ensuring continuing customer satisfaction? Is there a process in place for monitoring delivery and service so that it continues to met customer needs? Feasible Product can be produced as specified with no revisions. Feasible Changes recommended (See attached) Not Feasible Design revision required to produce product within specified requirements			
	Team Member/Title/Date	_	Team Member/Title/Date	-
	Team Member/Title/Date		Team Member/Title/Date	



Summary

- AIAG PPAP Manual Defines Requirements
- APQP Product and Process Validation
- Supplier submits PPAP to proper level
- PPAP package evaluated and status determined
- Supplier and customer manufacturing site notified of PPAP approval status

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