Medical Device Development Process

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Abstract. Medical devices of increasing complexity are central to mankind’s continuously expanding ability to save lives and improve the quality of life. Within our business, we often reflect on how fortunate we are to have the opportunity to work on a variety of these remarkable devices. We believe that such rewarding experiences are made possible through the application of a rigorous system engineering process, ensuring that the resulting devices are safe, effective, and successful.

This paper describes a deployed System Engineering process tailored for Medical Device Development. This process (based on ISO 15288:2002, the INCOSE System Engineering Handbook and a Legacy Process), integrates compliance to international regulations, embeds a Safety Risk Management process as defined in ISO 14971:2007, and assures adherence to ISO 13485:2003 Quality management systems. Based on the classification and complexity of the device the process is scalable, may be tailored, and supports iterative design and development activities.

Introduction

There are over 38,000 registered medical device manufacturers in the United States alone. These 38,000 medical device manufacturers develop, manufacture and distribute over 90,000 unique medical devices a year. These medical devices touch upon the lives of countless people worldwide on a continuous basis; the societal impact is immense. Truly innovative and useful medical devices greatly benefit the public in terms of efficient spending of health care dollars, improved quality of life and improved survival rates. The application of systems engineering processes to the medical device domain enhances the likelihood that the medical device will meet these societal needs.

Medical devices range from low risk devices (tongue depressor) to moderate risk devices (drug delivery infusion pump) to high risk devices (implanted pacemaker). In a similar fashion, the complexity in terms of functionality of medical devices range from low complexity (tongue depressor) to moderate complexity (hand-held blood glucose meter) to high complexity (an in-vitro diagnostic clinical laboratory instrument). The development of medical devices requires the engagement of a wide diversity of stakeholders and disciplines as indicated in Table 1, Medical Device Development Stakeholders.
The consequences of not being inclusive of all of the stakeholders in the development of a medical device vary from developing a medical device that no one wants to purchase to placing a device in the market that can directly be attributable to the death of a patient. These consequences carry great risks for the medical device developer:

- From a company investment perspective, there is no device if the investors are not satisfied.
- From a marketing perspective, there is a financial impact if no one is willing to purchase the device.
- From a civil perspective, there is a financial impact from civil lawsuits over inadequate healthcare provided because of poor device performance.
- From a criminal perspective, company executives can be arrested, convicted, fined and imprisoned; companies’ devices can be barred from sale or import, and their CE Marking can be revoked.
- From a reputation perspective, the finished device manufacturer’s reputation is sullied and device acceptance and sales in the marketplace is reduced.
- From a regulatory perspective, there is increased post-market vigilance (inspections) by medical device regulators.
- From a societal perspective, patients and caregivers place faith and trust that the medical device is safe and effective. If this trust is violated, the general public and stockholders of a company can and will take action against the company and its executives.

The development and manufacture of medical devices under a controlled environment is essential to assure that the device will be safe and effective in accordance with its intended use.

Battelle Medical Device Solutions (MDS) is a contract medical device development service provider. As a contract service provider, Battelle MDS develops devices that are manufactured and sold by finished device manufacturers. Overall, this presented an additional level of

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**Table 1 – Medical Device Development Stakeholders**

<table>
<thead>
<tr>
<th>The Patient</th>
<th>The Patient’s Caregivers (Family)</th>
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<tbody>
<tr>
<td>Investors</td>
<td>Nurses</td>
</tr>
<tr>
<td>Physicians</td>
<td>Medical Technicians</td>
</tr>
<tr>
<td>Marketing</td>
<td>Sales</td>
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<tr>
<td>Customer Service</td>
<td>Senior/Executive Management</td>
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<tr>
<td>Distribution Management</td>
<td>Device Servicing Technicians</td>
</tr>
<tr>
<td>Regulatory Affairs</td>
<td>Hospital Administration</td>
</tr>
<tr>
<td>Project Management</td>
<td>Hospital Purchasing Agents</td>
</tr>
<tr>
<td>Systems Engineering</td>
<td>Mechanical Engineering</td>
</tr>
<tr>
<td>Electrical Engineering</td>
<td>Human Factors Engineering</td>
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<tr>
<td>Software Engineering</td>
<td>Manufacturing Engineering</td>
</tr>
<tr>
<td>Industrial Design</td>
<td>Life Scientists (Biologists)</td>
</tr>
<tr>
<td>Biomedical Engineering</td>
<td>Materials Engineering</td>
</tr>
<tr>
<td>Compliance Engineering</td>
<td>Packaging Engineering</td>
</tr>
<tr>
<td>Sustaining Engineering</td>
<td>Labeling Engineering</td>
</tr>
<tr>
<td>Verification Engineering</td>
<td>Reimbursement Code Committee</td>
</tr>
<tr>
<td>Quality Engineering</td>
<td>Health Insurance Companies</td>
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complexity in the development of the process by introducing wide variation in customer and product attributes. The customers range from virtual start-up companies with a few employees to well-established leaders in their field. Project scope ranges from technical problem solving through comprehensive device development. Device scope ranges from non-active devices (i.e. no active energy source) to electro-mechanical devices with software. The breadth of devices has ranged from point-of-care diagnostic, therapeutic, drug delivery, to large scale in-vitro diagnostic clinical laboratory instruments. Device classification has ranged from non-significant risk to life-sustaining devices. Devices have been developed for use in the home, doctor’s offices, clinical laboratories, and hospitals. Each combination of customer, the project scope, the device scope and classification, and the intended use results in a unique set of conditions under which the efficient development of a safe and effective medical device must occur.

This paper presents the foundations of a Medical Device Development Process (MDDP) which supports controlled device development under this diverse set of business conditions.

**Background.** Battelle MDS has deployed a structured development process since 1992. Throughout the years, as part of continuous improvement and the progressing regulatory environment for the development of medical devices, our structured development process evolved. Table 2, Development Process History, describes the major milestones chronologically.

<table>
<thead>
<tr>
<th>Year</th>
<th>Development Process History</th>
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</thead>
<tbody>
<tr>
<td>1992</td>
<td>Structured development process deployed based on an integrated product development approach using concurrent engineering concepts.</td>
</tr>
<tr>
<td>1995</td>
<td>Development process modified to be compliant with ISO 9001.</td>
</tr>
<tr>
<td>1996</td>
<td>ISO 9001 registration obtained.</td>
</tr>
<tr>
<td>1996</td>
<td>FDA publishes the Quality System Regulation in the Federal Register.</td>
</tr>
<tr>
<td>June 1997</td>
<td>One-year transition period starts for adherence to the Quality System Regulation.</td>
</tr>
<tr>
<td>1997/1998</td>
<td>Development process modified to be compliant with the Quality System Regulation.</td>
</tr>
<tr>
<td>2007</td>
<td>Development process modified to align with ISO 15288:2002; ISO 14971:2007; updated national and international statutes and regulations (e.g. FDA, EU Medical Device New Approach Directives); Medical Device Global Harmonization Task Force guidelines; and updated device standards (e.g. EN, IEC, ISO). In addition, incorporation of lessons learned and knowledge from bench marking of customer development processes.</td>
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The Medical Device Development Process (MDDP) presented in this paper is the latest embodiment of 15 years of continuous improvement. The MDDP was developed as an enabler for Battelle MDS to remain competitive in a fragmented, outsourced medical device development market. The current MDDP process initiative shown as the 2007 entry in Table 2, represents a major update to the legacy process. A systems engineering approach was applied to this most recent process improvement initiative. This began with requirements gathering as this
is “crucial to identify the practical goals of developing standard processes and determine what our colleagues really want.” (Hwang, 2006) The systems engineering approach key steps were as follows:

- The processes’ stakeholders were identified and interviewed.
- User and business requirements were identified.
- Development process requirements were derived.
- A common glossary was established (between Quality System and the MDDP.)
- Verification and Validation Plans were established during the development of the requirements.
- Design Reviews were conducted, verifying the outputs satisfied the inputs.
- Development process was validated by end users on medical device projects.

To ensure the MDDP remains in use and current, this process will be reviewed and updated according to a schedule by a team. As discussed in ISO 15288, this schedule and team (roles) will be predefined. Updates will be based on feedback and developments in the industry and applicable regulations and standards.

The MDDP is an integral component of the MDS Project Accountability Flow. The MDS Project Accountability Flow integrates the MDDP, the MDS Quality System, the MDS organizational infrastructure, and customer and project governance. Figure 1, Medical Device Solutions – Project Accountability Flow shows this integration graphically.

Figure 1 – Medical Device Solutions – Project Accountability Flow

Figure 2, Consideration Elements for the MDDP, graphically indicates the elements that
influenced the development of the MDDP.

The elements that were taken into consideration are as follows:

- **Principles of Systems Engineering.** System Engineering is an interdisciplinary approach and means to enable the realization of successful systems. (INCOSE, 2007) These principles found in ISO 15288:2002, INCOSE System Engineering Handbook and the legacy process are the foundation on which the MDDP is built.

- **Regulations.** The MDDP realizes the importance of early recognition of the regulations that govern medical devices. The regulations for medical device development in the United States are codified in Title 21 of the Code of Federal Regulations (CFR). Medical devices are governed in the European Union (EU) under New Approach Directives, which provide regulations to abide by to obtain a CE Marking for the medical device. In addition to medical device regulations, there are regulations if the device emits radiation; emits radio frequency energy or incorporates a telecommunication function (modem); environmental regulations (disposal); regulations for batteries; etc.

- **Legacy Process.** Legacy device development process, refer to Table 2.

- **Lessons Learned.** The consideration of lessons learned from execution of over 500 projects in a 15-year span.

- **Benchmarking Customers.** Invaluable insight as to how others in the same industry deploy development processes.

- **Quality System Management, ISO 13485:2003.** Canada and the EU require abidance to ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes for some classification of devices. Most other countries promote adherence to this standard.

- **Quality System Management, ISO 9001:2000.** Still an expectation of some customers of their outsourced vendors.

- **Safety Risk Management, ISO 14971:2007.** In many countries a safety risk
management process, as specified in ISO 14971:2007 Medical devices -- Application of risk management to medical devices, is required. Safety risk management is an integrated part in the development of safe medical devices.

- Existing ISO Registered Quality System. MDS Quality System, refer to Table 2.

**The Medical Device Development Process (MDDP)**

The MDDP was developed as an enabler for Battelle MDS to remain competitive in a fragmented outsourced medical device development market. The MDDP was structured to provide the following key subset of User Needs:

- Be a repeatable process that can be applied consistently across varying scopes of projects and devices
- Be inclusive of the entire life-cycle of a medical device
- Provide clear and concise direction
- Allow for Project Manager/Customer flexibility via tailoring versus a rigid process
- Be a vehicle for conveyance and reinforcement of lessons learned
- Identify well-defined milestones throughout the process
- Be a functional tool for Marketing such that they can convey the process to customers
- Provide a tiered and structured approach such that different views of the process are readily accessible, e.g. Marketing, Senior Management, Customers, Project Teams
- Provide documented direction for project teams in the form of templates, checklists, training materials, etc.
- Be harmonized with the MDS Quality System
- Be compliant with applicable regulations and standards
- Incorporate a common glossary of terms, abbreviations, and acronyms
- Support an iterative process for design and development
- Recognize all stakeholders and integrate them at appropriate points in the process
- Identify activities, tasks, and deliverables for each phase and the stages within a phase, clearly articulating gates with entry and exit criteria
- Clearly delineate where in the process Design Reviews need to occur
- Deploy a unified change control process with clearly articulated roles and responsibilities
- Recognize the need for defect tracking and integrate into the process
- Define a tool validation process (medical device regulatory requirement) that can be uniformly applied across projects

The design output of the MDDP resulted in a phase-gate approach as shown in Figure 3, MDDP Level I. It is possible that all activities will not be complete at the time of the Phase Gate Review. The MDDP will enable the project to move into the next phase based on a conditional acceptance. The items that have not been completed yet will be discussed as part of the Phase Gate Review. The risks of moving forward are documented and reviewed with the customer. Both the customer and the MDS management team need to accept the risks and align to move forward. This process will ensure that all major stakeholders are cognizant of where the project stands and are in alignment that the project should move forward or should stop until certain elements have come to closure.

The MDDP is viewed in three vertical levels as indicated in Table 3, MDDP Levels. This paper describes only Levels I and II. The Phases of Level I are described at a high level. The
Level II details of the Design and Development Phase are described in a moderate level of detail. Level III views are not included in the scope of this paper.

<table>
<thead>
<tr>
<th>Table 3 – MDDP Levels</th>
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<tr>
<td>Level I</td>
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<td>Level II</td>
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<td>Level III</td>
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**Level I – MDDP Life Cycle Phases**

The MDDP has six defined phases. These phases and their transitions are shown in Figure 3, MDDP Level I.

**Feasibility Phase.** Feasibility is the phase where the suitability of a technology as the basis for a solution to a clinical need is identified and valued, device concepts are generated and key technical risks are identified and reduced to acceptable levels. The outcomes of Feasibility include: a single feasibility concept; market needs assessment; identification of the technical risks going forward and their likely impact on the project; a management understanding and acceptance of the business case; and management understanding and acceptance of the safety and business risks for the device.

**Design and Development Phase.** The entry criteria is that the finished device manufacturer has declared that they are proceeding forth with developing a medical device. Design and Development is the phase where the device requirements are established and translated into a verified and validated device design. The outcomes of Design and Development include a verified design output that can be transitioned to a manufacturer; and a Design History File documenting the development of the design inputs and design outputs.

**Design Transfer Phase.** The entry criteria is that the device design outputs have fulfilled the design input requirements with documented objective evidence. “Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.” (FDA, 2007a) The outcome of Design Transfer is that all information necessary to manufacture the device has been properly specified, and manufacturing processes validated.
**Production Phase.** The entry criteria is that the design outputs have been correctly and completely translated into production specifications. Production is the phase where the decision has been made to proceed forward to manufacture the device for commercialization and sale. In the United States, a finished device manufacturer must receive clearance of the device if they utilize a 510(k) pre-market notification process with the FDA, or approval if the device required a pre-market approval (PMA) process. The finished device manufacturer must obtain/apply a CE Marking if they want to market the device in the EU. Most countries have a regulatory process the finished device manufacturer must traverse through prior to legally marketing the device in that country.

**Sustaining Engineering Phase.** The transition from Production to Sustaining Engineering is the Device Launch. Sustaining Engineering is the technical effort to support a marketed device in its operational environment. Sustaining Engineering is different than previous phases in that depending upon the scope, the activity can draw upon any or all of the previous phases. Some of these activities include: analyze field returns, technical support, cost reduction, changes or adding additional target market, Corrective and Preventative Action outputs, support of regulatory or compliance issues, improve the production process, improve or add a new feature to the device, the change in the Intended Use or the Claims of the device.

**Device Retirement Phase.** Finally, the last phase is Device Retirement. This is the when the medical device is no longer for sale and is no longer supported. The device has been removed, dismantled, destroyed, or recycled as per the manufacturer’s device retirement plan.

**MDDP Level II – Design and Development**

Figure 3, MDDP Level I, depicts the life cycle phases of the MDDP. This section will present the MDDP Level II for the Design and Development Phase. In the MDDP, Design and Development starts when the finished device manufacturer has a feasibility concept they would like to develop into a marketed medical device. Marketing requirements have been documented and the technical, safety, and business risks have been identified. Management has aligned, accepted these risks and collectively has determined to move forward and enter into the Design and Development Phase in MDDP.

The Design and Development Phase starts with the establishment of the User Needs and the translation of Business Needs into product requirements. Often these needs are described in qualitative terms. These qualitative terms need to be translated into meaningful quantitative requirements that the engineers can develop the device against, and verify and validate the design. This translation is accomplished in the Design Input stage. Next, Design and Development continues with the Design Process and the development of the Design Outputs. Throughout this progression there are informal and formal Design Reviews. Verification confirms that the Design Outputs meet the requirements established by the Design Inputs, and Validation confirms that the device meets the User Needs. A common way of showing this is through a waterfall diagram as shown in Figure 4, Design and Development Process, recognizing that in practice it is an iterative process.
Context diagrams were created for each Phase as defined in Level I, for each Stage within a phase and each Activity within a Stage. The context diagrams were used to provide the guidance for the development of the Level III material, e.g. detailed processes, templates, checklists. Context diagrams, when deployed on a project, provide the Systems Engineer and Task Leaders with the necessary direction and guidance such that the activity can be performed efficiently, consistently applied, and is repeatable across different projects. The context diagrams link to the detailed discipline processes (e.g. electrical, mechanical, and software engineering) and resources such as templates, checklists, and examples.

Figure 5, Design and Development Phase Context Diagram, illustrates a Phase context diagram. Figure 6, Design Inputs Stage Context Diagram, illustrates a Stage context diagram. Figure 7, Device Architecture Activity Context Diagram, illustrates a Stage Activity context diagram (Device Architecture is part of the Design Process).

The Design and Development Phase is classified into six main Activities:
- Design and Development Plan
- Design Inputs (inclusive of User Needs)
- Design Review
- Design Outputs (inclusive of Design Process)
- Design Verification
- Design Validation

**Design and Development Plan.** The Design and Development Plan (D&DP) is required as part of the Design Controls portion of the Quality System Regulations. “Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process. The plans shall be reviewed, updated, and approved as design and development evolves.” (FDA, 2007b)
Figure 5 – Design and Development Phase Context Diagram

- Controls
  - MDS Quality System
  - MDS MDOP
  - Customer’s SOPs
  - Applicable Regulatory Constraints
  - Applicable Voluntary Constraints

- Inputs
  - Market Needs Assessment
  - Technical Risk Signal Chart
  - Carry Forward Risk Assessment
  - Feasibility Concept
  - Initial Design and Development Plan
  - MDS Business Case
  - Customer Supplied Product Data

- Activities
  - Define User Inputs
  - Conduct User Input Design Review
  - Conduct Regulatory Activities
  - Perform Safety Risk Management Assessment, Control and Maintenance
  - Develop Design Inputs
  - Conduct Design Input Design Review
  - Create Device Architecture
  - Develop Design Outputs
  - System Integration and Test
  - Perform Design Verification
  - Perform Design Validation
  - Conduct Design Output Design Review
  - Complete Design Transition

- Outputs
  - Verified and Validated Device Design
  - Design Transition Elements
  - Device History File (DHF) Support
  - Device Master Record (DMR) Support
  - *Patent and Trademark Applications

- Enablers
  - Project Management
  - Systems Engineering
  - Project Support Delivery
  - Customer Project Management Team
  - Customer Manufacturing Team
  - Contract Manufacturer
  - Technical QC Leaders/Programmatic QC Leaders
  - Advisory Board Chair
  - Applicable Regulatory Bodies
  - Safety and Compliance Testing Organization

**Any non-specified party in this enabler block is considered to be MDS.

Figure 6 – Design Inputs Stage Context Diagram

- Controls
  - MDS Quality System
  - MDS MDOP
  - Customer’s SOPs
  - Applicable Regulatory Constraints
  - Applicable Voluntary Constraints

- Inputs
  - User Needs
  - Business Needs
  - Validation Criteria

- Activities
  - Develop Device Requirements
  - Develop Device Architecture Documentation
  - Develop Integration Plan
  - Create Top Down Risk Assessment
  - Develop SubSystem Requirements
  - Develop Design Documentation
  - Create Bottoms Up Risk Assessment
  - Determine Verification Criteria
  - Update Trace Matrix

- Outputs
  - Device Requirements
  - Device Architecture
  - Integration Plan
  - Top Down Risk Assessment
  - Sub-System Requirements
  - Design Documentation
  - Bottoms Up Risk Assessment
  - Device History File (DHF) Support
  - Verification Criteria
  - Updated Trace Matrix

- Enablers
  - Project Management
  - Systems Engineering
  - Project Support Delivery
  - Customer Project Management
  - Customer Team
  - Technical QC Leaders/Programmatic QC Leaders
  - Applicable Domain Experts

**Any non-specified party in this enabler block is considered to be MDS.
(Global Harmonization Task Force, 1999) states “design and development planning is needed to ensure that the design process is appropriately controlled and that device quality objectives are met.” The Design and Development Plan either contains or provides references to what is planned in this phase. This plan needs to be approved at the point where the formal Design Inputs review occurs, which is explained later in this paper. The D&D can contain or reference:

- High-level Organizational Chart including roles, and responsibilities
- Define external interfaces and how they are to be managed
- References (such as the project glossary)
- Schedule (e.g. Gantt, PERT, Critical Path)
- How the MDDP is tailored based on the scope of the project (customer procedures may be used in whole or part, either in place of or in addition to MDS procedures)
- Project Plans, e.g. Regulatory Plan, Master Test Plan, Quality Assurance Plans, Safety Risk Management Plan, Human Factors Plan (may be pointers)
- Documentation Plan (document and drawing trees, define reviewers and approvers)
- Quality System references (which QS standard operating procedures apply)
- How Design Transition will be completed

**Design Inputs.** The Design and Development phase of the MDDP begins by identifying user and business needs, and translating those needs into requirements, device architecture, and design documentation. These are called the Design Inputs. “Design Inputs are the physical and performance requirements of a device that are used as a basis for device design.” (FDA, 2007c)

The user needs, captured in the words of the user, can then be translated by the development team into quantifiable device requirements. Device requirements address the form, fit, and function from the standpoint of the users. (Robertson, 2006) states a “complete list of requirements will tell what the device should do and what qualities the device should have.” The device requirements should not provide design solutions rather the high-level requirements. This will allow more innovation during the design process.

There are several areas that are reviewed and taken into consideration prior to developing
**device requirements:**

- **User Needs** (inclusive of usability and human factors)
- **Business Needs** (e.g. target market implications; business model)
- **Regulatory Constraints**
- **Voluntary Constraints** (e.g. identified compliance standards; EN, IEC, ISO)

EU Competent Authorities, the FDA, and other regulatory bodies are communicating to the industry the significance of integrating human factors in device development. The analysis of how predicate devices are being used, including misuses, and the identification of elements that make the device usable are integrated into the requirements process.

As part of the Safety Risk Management activities, identified in the D&DP, the “decision to use a medical device in the context of a particular clinical procedure requires the residual risks to be balanced against the anticipated benefits of the procedure. Such judgments should take into account the intended use, performance, and risks associated with the medical device, as well as the risks and benefits associated with the clinical procedure or the circumstances of use.” (AAMI/ANSI/ISO, 2007) In the MDDP, the risk versus benefit assessment occurs in part by completing both a top-down risk assessment (Fault Tree Analysis, Hazard Analysis) as well as a bottoms-up risk assessment (Failure Modes and Effect Analysis). The top-down risk assessment occurs early in the Design Input Process, in conjunction with the device requirements development and the bottoms-up risk assessment occurs later after more design details have been elucidated. These methods reveal the level of risk that can be weighed against the benefit. Often, this analysis of determining if the overall benefits of the device outweigh the risk is decided by a pre-defined management committee.

After proper deliberation of the constraints, the device requirements can be outlined. The process of defining the device requirements is an iterative process. It is commonplace to develop the requirements and work on the device architecture in parallel. The architecture is the decomposition of the device into implementable or available components that together satisfy the device and project requirements. It includes the fully specified requirements of each component, including component-to-component interface requirements. The integration, verification, and risk management of the device has been taken into consideration.

If the device is complex, then it can be divided into sub-systems and requirements for the sub-systems can be developed. Therefore, this process can be scaled based on the complexity of the device. Once requirements have been approved the design documentation can be created. This is where design decisions and rationale are documented. The design documentation captures the “what” and the “why”.

This initial effort is essential in creating a device that is both safe and effective. (GHTF, 1999) states the “requirements which form the design input establish a basis for performing subsequent design tasks and validating the design. Therefore, development of a solid foundation of requirements is the single most important design control activity.” As these elements are developed, it is crucial to review that no new hazards were introduced in the process, the user needs are being addressed, and the requirements can be verified through testing, analysis, inspection, or demonstration.

**Design Review.** At the end of each stage within MDDP, a formal Design Review is held. A Design Review is a “documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.” (FDA, 2007d) Formal Design Reviews include the participation of the stakeholders for each part of the development process.
The MDDP has outlined a formal Design Review to occur once the User Inputs have been established, when Design Inputs have been established, and when the Design Outputs are complete. It is important to note that this section is addressing formal Design Reviews that review a major stage in Design and Development Phase. This does not address the technical design reviews that occur throughout Design and Development.

The Design Review will discuss all completed items and evaluate if the items successfully address the user needs, requirements, meet the intended use of the device, and ensure the device is both safe and effective.

**Design Output.** In the MDDP, once Design Inputs have been completed and approved (includes the formal Design Review) then the Design Process and the creation of Design Outputs transpires. Design Outputs are “results of a design effort at each design stage and at the end of the total design effort. The total finished design output consists of the device, its packaging and labeling, and the Device Master Record.” (FDA, 2007e) The Device Master Record (DMR) is a “compilation of records containing the procedures and specifications for a finished device.” (FDA, 2007f) Design outputs are the “work product, or deliverable item, of a design task listed in the Design and Development Plan, and the item defines, describes, or elaborates an element of the design implementation. Design Output includes production specifications as well as descriptive materials that define and characterize the design.” (FDA, 1997)

The development of design outputs begins with a preliminary design stage. At this stage challenging elements are identified, technical approaches are outlined, and design implementation to comply with regulations and standards is assessed. After the preliminary work is complete, the detailed design stage can begin. This work includes developing drawings, schematics, flow charts, software, specifications, labeling, and packaging. Once the design has been developed, the elements can be prototyped and engineering tests can occur on elements of the design.

If the device is complex and has sub-systems, then device integration and sub-system testing will also need to occur. This can be done in accordance with the architectural design and the integration strategy that occurred during the device architecture portion of the process. The integration “process combines system elements to form complete or partial system configurations in order to create a product specified in the system requirements.” (ISO/IEC, 2002)

The outputs of this stage will be part of the DMR and the Design History File (DHF) for the United States. In addition, Design Outputs will be part of the Technical File to obtain a CE Marking for the EU. The DHF is a “compilation of records which describes the design history of a finished device.” (FDA, 2007g) It is the history behind the device, while the DMR is the documentation that is needed to produce the device.

The design process and creation of the Design Outputs of the MDDP is also iterative. As outputs are created and tested, issues will be identified and changes will need to occur in the design to meet the requirements or specifications for the device.

During the Design Output development, it is important to remain cognizant of the following: the outputs meet the input requirements, the outputs contain product acceptance criteria, and the outputs are verifiable. It is also essential to identify the essential outputs. Essential outputs specify which characteristics of a device are critical for its safe and proper use. These items should be separately identified and tracked. These are often the elements that are tested as part of the production process. The device is also reviewed from a safety risk management perspective to ensure that the device’s required hazard mitigations are being implemented and there are no
additional hazards being created as part of the design process.

**Design Verification and Design Validation.** In the MDDP, Design Verification can begin as early as when the first Design Outputs are created. Design Verification is the “confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.” (FDA, 2007h) Verification confirms that the Design Outputs meet the Design Input requirements.

Design Verification and Design Validation are stages in the process that are frequently extensive and costly. To minimize cost and maximize efficiency, it is best to develop plans ahead of time. The Master Test Plan (MTP) is identified in the Design and Development Plan, and the Validation Plan and the Verification Plan are developed from the MTP. These plans identify items such as: any specific equipment, facilities or personnel, the statistical methods and guidelines, the statistical analysis and reporting guidelines, defines the discrepancy tracking method, the issue management and discrepancy escalation process, the process for re-test, and any tests that will take an extended period of time.

Design Validation occurs later in the MDDP. The finished production device (or the equivalent) is needed to conduct Design Validation. Design Validation is the “establishing by objective evidence that device specifications conform with user needs and the intended use.” (FDA, 2007i) Design Validation occurs with the end users in the operational environment or in a simulated operational environment to ensure the device meets their needs, its intended use.

Final packaging is examined during Design Validation. The environmental stresses that are encountered during the shipment and the acceptable range indicated for operational use of the device should be tested. In addition, the final labeling, which includes the instruction for use needs to be validated to ensure these are understandable and usable by the end users.

Design Verification should be completed prior to the start of Design Validation however; it must be completed prior to the completion of Design Validation. The Design Verification completion point will vary by the business risk profile of the MDS customer.

Design Verification confirms that the device was built right, while Design Validation confirms that the right device was built. These activities affirm that the device meets its intended use and the user needs and that the production level device is built safely and effectively.

**Conclusions.** The application of systems engineering processes to the medical device domain is essential to the successful development of medical devices that are safe and effective. The impact of not applying these processes unfortunately is seen all too often with device recalls and device removals from the market. The impact is measured both in terms of human life and financial losses to individuals and companies.

The future of medical device development is an extremely exciting place to dream about, but this world is becoming much more intricate and complicated. Devices, drugs, and biologics are beginning to be used in combination with each other. Medicine is becoming decentralized and more devices, sensors, and monitors are being designed for use at home. Miniaturized devices, and micro and nanotechnologies provide a new world of amazing design opportunities and a new world of unknowns as well. The integration of man and machine is not just the work of science fiction anymore it is a realization NOW with an endless realm of possibilities. The benefit these devices can have on the quality of a person’s life is hard to measure and can be quite great, but they must always outweigh the risk. As this sphere of science and engineering becomes more complex, the significance of the MDDP as the backbone to medical device development becomes more apparent. A medical device designed to an intelligent, thoughtful process will yield a device that has a higher likelihood of getting to the market and making a tangible,
positive difference in society.

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Biography

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