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## [Quality Manual - Process Interactions - Two part process overview map](http://Elsmar.com/Forums/showthread.php?t=8776)

(<http://Elsmar.com/Forums/showthread.php?t=8776>)

peterd

20th June 2004 06:45 AM

### **Quality Manual - Process Interactions - Two part process overview map**

1 Attachment(s)

Hi All,

I have been doing work on our I2K manual and have put together a two part process overview map for the business. The idea was for an easy way to reflect and communicate the processes used to run the business, both internally and to auditors.

Part one covers management processes and part two is the product realisation map.

I would welcome comments and views, positive and negative on whether they work and whether there are any gaping holes.

Always open to suggestions

Peter :)

Greg B

20th June 2004 08:17 PM

Peter, :applause:

I love it. The simple use of colours and schematics is a very simple and effective way to sell flow charts and process charts. My company is adopting Process charts across the board with all of our standard procedures now adopting this method. Combined with increased awareness training and competency checks we are developing a people and user-friendly system.

I assume that your BIG SIX quality clauses are detailed in your QM  
Control of Docs and Records,  
Internal Auditing,  
Corrective & Preventative Action, and  
Control of NC product (I see that BP-16-1 would probably cover this).

Again, well done.

Greg B

**WALLACE**

21st June 2004 12:21 AM

peterd,  
Great stuff. I've been slabbering all over your excellent work, Its just great.  
:applause:  
Wallace.

**Howard Atkins**

21st June 2004 07:35 AM

Ialso agree that it it is very clear and conscise.  
Great work!! :agree1:

**MEANMC**

26th April 2013 06:01 AM

**Re: For Review: Quality Manual - Process Interactions - Two part process overview map**

Excellent job, one of the best I have seen.

What I found helps (with support from our notified body) is to split the charts out into 3 tiers of detail. This helps show the QMS main processes, supporting processes and interactions between them. Ensure methods on how to monitor, measure and analyse these processes are part of the integrated approach.

1. Develop a single systemic flowchart for the QMS as a whole. This is to show how the processes are interrelated and integrated. You have done an excellent job on that. Be clear to identify which processes are main processes and which are secondary\support processes. This chart must be contained in the Quality Manual.

The great thing with ISO is that is allows you to pick which processes are your 'main' processes. Therefore you could have 3 main processes and downgrade the other processes as 'support'. For example CAPA proces could be a main process or a support.

Note: Don't forget that some 'systemic' processes (which I would recommend making into secondary processes) may need to be referenced in more than one place in your chart e.g. risk management is throughout the product realisation process (so may need to link to a number of your main processes).

2. Develop one flowchart for each main process and use it to describe how it interacts with other processes using input-output arrows. This set of flow charts will describe how the processes interact. This chart could be either in the Quality Manual or governing SOP, as it is systemic e.g. may show how Internal Auditing (if you pick IQA as a main process) interacts with CAPA and management review. It is only a minor tweak to the single systemic chart above.

3. Develop one flowchart for each main process (e.g. purchasing) and use it to describe how the process should be performed. This set of flowcharts will make up the procedures that control how the process should be performed. I would normally have this chart in the main\corporate guiding SOP.

I find doing tier 2 and tier 3 charts adds most value to our organisation. It helps identify gaps and makes your processes more robust. For example when I did a tchart for CAPA I had risk management

as an output of CAPA as well as an input to CAPA. But my procedure did not have risk management as an input to CAPA.

We have been asked to do tier charts only for our 'main' processes. But have found tier 3 charts so useful, that we are applying them to secondard processes as well.

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