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# ISO 13485 Software

ISO 13485 & CFR 820 Compliant Quality Management Software System

## Complete change of the ISO 9001 Quality Management System



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Thread post #1 by aypsila: "Complete change of the ISO 9001 Quality Management System". Content: "Dear all I have recently complete the course for ISO 9000:2008 Auditor under the IRCA. My problem arises as a friend of mine has asked me to help him with his ISO status as Lloyds did not renew it due to many major non confs. The person that create the QMS, has made a rather complicated and difficult system to follow. Even in the course I took, the instructors were negative to the point of changing systems I believe that in case of my friend would be a relief if I will restructure the system all over the beginning. Please advise me what to do."

Sponsored Links section featuring "ISO 9001:2015 In-Depth" with a description: "A Major Revision is Coming. Get Inside Info in Our Webinars."

Thread post #2 by arios: "Re: Complete change of the ISO 9001 Quality Manual". Content: "I would change the manual if helps to improve its clarity and better align the system."

Thanks to arios for your informative Post and/or Attachment!

Sponsored Links section with links for ISO 9000 ISO 9001, Quality Audit, Quality Assurance, and Quality Training.

Thread post #3 by Ted Schmitt. Includes a logo and the word "EXHIBIT" with a large letter "G".

Sunday Business Systems advertisement: "Affordable software solutions for Quality Management Systems" with a list of services like Document Control, Employee Training Management, etc.

AS9102 Get DISCUS advertisement: "Join 100s of other aerospace manufacturers that are saving 50-70% on First Article Inspection preparation time."

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**Re: Complete change of the ISO 9001 Quality Manual**

**Quote:**

In Reply to Parent Post by [aypsila](#)

Dear all

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Welcome to the Cove !!

It's difficult for us to determine if it would be better to start a new system from zero or fix the one that is in place. It also depends on what the Management of this company is willing to do (if the management is your friend, that will help out alot).

I suggest you perform a thorough internal audit (chance to practice what you learned in your course! ) and determine if there is a complete system breakdown or is it a bunch of smaller problems. The outcome of this audit, will answer your question...

Good luck and feel free to come back if you have more doubts !!

Thanks to **Ted Schmitt** for your informative Post and/or Attachment!

[aypsila](#)

16th June 2009, 02:10 PM

Post Number #4



**Wes Bucey**

Total Posts: 11,014

**Re: Complete change of the ISO 9001 Quality Mangement System**

Normally, a consultant works WITH the client to perform a gap analysis of a system to compare its present state with some "ideal" state. As they discover the discrepancies together, each one becomes a teaching moment to understand why it doesn't meet a Standard and a possible course of action to remedy the discrepancy.

The curse of many of the "trash and dash" folks touting their service to achieve registration in 40 days (or 90 days) is they frequently counsel trashing everything and starting from scratch with the so-called expert's generic templates. The underlying failure is no one in the target organization has a clue whether the new generic system has any relevance to the actual business being operated.

As a consultant myself, I long ago adopted the mantra of medical doctors: "First, do no harm!"

You might gather some interesting clues based on the Lloyds report.



Don't take this in the wrong way.

An auditor, no matter how competent as an auditor, still needs special skills and abilities beyond auditing to be an effective consultant in creating and implementing a QMS from scratch. What looks easy for a consultant when looking at his work from the outside is deceptive because the onlooker has little concept of the hours and years a consultant has worked to achieve that apparent smoothness of operation. Few folks watching the US Open golf tournament this weekend will have any real understanding of the thousands of hours of training and practice a pro golfer puts in to make it look so easy to shoot par and sub par rounds. Even then, the pressure gets to some and, no matter how skilled on the practice tees, they will still slice one into a lake or into the crowd.

Same thing with consultants. Sometimes, no matter how many successful assignments have been completed, a consultant will have one blow up in his face. The consultants who have the first assignment blow up in their face rarely get a chance for a second assignment.

Last edited by Wes Bucey; 17th June 2009 at 12:11 PM. Reason: typo fix

Thanks to **Wes Bucey** for your informative Post and/or Attachment!

[aypsila](#)

16th June 2009, 02:32 PM

Post Number #5

[ingabramrobles](#)

Total Posts: 11

**Re: Complete change of the ISO 9001 Quality Mangement System**

I guess that you need to do a GAP Assessment , into your current system , and consider your mayor finding and do corrective actions  
THX

Thanks to **ingabramrobes** for your informative Post and/or Attachment!

[aypsila](#)

17th June 2009, 04:03 AM

Post Number #6

Total Posts: 3,518



**JaneB**

**Re: Complete change of the ISO 9001 Quality Mangement System**

**Quote:**

*In Reply to Parent Post by [aypsila](#)*

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It's very hard to advise with such very limited information about whether to start again from the beginning, or to restructure. But you've said it was complicated and difficult to follow, so my inclination would be that it may be a good idea to discard it and start again - there could be benefits from doing that, including the feeling of 'starting anew' and leaving aside the old. As a consultant, I've sometimes been asked to restructure or simplify systems - when they're really really bad, I've usually advised leaving them behind and almost starting again. Bad news for the owner, but ultimately better result.

But I also have to add that the skills and competencies required to audit are not really the same as those for designing and implementing a good system. They may be helpful to some extent.

Thank You to **JaneB** for your informative Post and/or Attachment!

[AndyN](#), [aypsila](#)

17th June 2009, 06:04 AM

Post Number #7

Total Posts: 490

***Polly Pure Bread***

**Re: Complete change of the ISO 9001 Quality Mangement System**

If the QMS documentation at hand is complicated and it's a good idea to start again, be it. However, I suggest don't start from scratch. There are great stuffs (pre-written QMS documentations) available in the cove that you can use (analyze) for you to see the ISO 9001 requirements in action.  
.....just ask Marc's permission. 😊

However, keep in mind that it is your organization's unique processes that will drive on your documentation.

Thanks to **Polly Pure Bread** for your informative Post and/or Attachment!

[aypsila](#)

17th June 2009, 08:22 AM

Post Number #8

Total Posts: 212



**Peter West**

**Re: Complete change of the ISO 9001 Quality Management System**

Following on from dqapprentice, it is important that when you approach this you keep in mind it is a system that needs to work for this company. I came off of a course with a lot of good ideas in theory, but where the resources were not available for them to be put in to practice. If I had tried to change things then all systems would have crashed. I have made my case and now do what I can to ensure that the existing systems run optimally.

I also came away from the course with the strong tendency to think if something conforms to the Standard, then it is good. Of course it needs to conform but it needs to bring benefit to the company which will help in keeping top level management committed to driving on with ISO 9001.

Good luck

PS: I agree that you need to do a GAP analysis and see whether it is the procedures or the system itself that is failing.

Thanks to **Peter West** for your informative Post and/or Attachment!

[avpsila](#)


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 **Complete change of the ISO 9001 Quality Management System**

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