People frequently ask me where to locate information about ISO 13485, so this whitepaper was written specifically to address their needs, as well as review in detail the six steps to preparing for ISO 13485 certification:

1. Planning the Quality System
2. Meeting Regulatory Requirements
3. Implementing Design Controls
4. Documents, Records & Training
5. Management Processes
6. The Certification Audit

*Please note that if you need to be licensed in Canada, you should refer to an even shorter list of possible certification bodies: http://bit.ly/RecognizedRegistrars. The selection of your registrar is also an opportunity to create a record of supplier qualification.

Why You Need ISO 13485 Certification

International Organization for Standardization (ISO) 13485 is a quality management system standard based upon ISO 9001. Initially, there were two versions of the Standard: ISO 13485 for manufacturers (i.e., Original Equipment Manufacturers (OEM) and ISO 13488 for contract manufacturers (i.e., suppliers). The two standards were merged in 2003—along with some major revisions. In other industries, ISO certification is a "nice to have," but in the medical device industry it is rare to be ISO 13485 "compliant," rather than "certified." The reason for the prevalence of certification is that Health Canada made ISO 13485 certification mandatory for any company that wants an Establishment License for distribution of Class I devices (http://bit.ly/CanadianMDEL) or a Medical Device License (http://bit.ly/CanadianMDALL) for Class II-IV devices.

In Europe, the ISO 13485 standard is harmonized with the Medical Device Directive (http://bit.ly/M5MDD), and therefore OEMs become ISO 13485 certified as the first step to Conformite Europeenne (CE) marking. In addition, both Canada and the European Union (EU) maintain that significant subcontractors (e.g., contract sterilizers and suppliers of finished devices) must be ISO 13485 certified, or the supplier must be audited.

In the United States (U.S.), the Food and Drug Administration (FDA) requires that medical device design and manufacturing is conducted in accordance with 21 CFR Part 820 (http://bit.ly/21CFR820). This regulation is also referred to as the Quality System Regulation (QSR). The FDA participated in the development of ISO 13485 while the QSR was being developed. As a result, the two documents are very similar. In fact, sections like Design Controls (i.e. – 21 CFR Part 820.30) are nearly identical to ISO 13485 (i.e., Section 7.3).

Due to the importance of ISO 13485 for the United States, Europe and Canada, OEMs frequently use ISO 13485 as justification for supplier qualification, for reducing the frequency of supplier audits, or possibly to justify re-evaluating the supplier remotely. If you are a U.S. supplier to OEMs, it is extremely likely that you will be audited by each OEM on a one, two or three-year cycle. If you have twenty OEM customers, this could result in the need to support twenty customer audits each year. If you are located in Minneapolis, it's possible that your customers will want to conduct 100% of those audits during the summer months—when you would like to go on vacation. If the desire to take a family vacation the first week of August doesn't apply to you, then maybe the cost of supporting 20 different customer audits would justify the investment in ISO 13485 certification.

Step 1: Planning Your Quality Management System (QMS)

Once you have made the decision to pursue ISO 13485 certification, the next step is to create a quality plan for achieving certification. Many companies create this plan retroactively to address the requirement for evidence of Quality Planning in Clause 5.4.2 of the Standard. One of my favorite auditors, Debbie Iampietro, has a spreadsheet she uses to help her consulting clients plan the activities for building the QMS and preparing for certification. There is no required format for quality plans. Spreadsheets and Gantt charts are the most common tools for quality planning, but you might also try using an A3 report. A3 reports are best practices for making decisions by consensus within your organization, and the A3 report includes an implementation plan with documented metrics for tracking the progress of the plan once project execution begins.

Dan Matthews is a professional public speaker who focuses on teaching companies the principles of Lean Manufacturing. (http://leankeys.com/). He wrote a book called *"The A3 Workbook"* which includes the following:

- Case studies that readers can use to complete A3s
- Tips on how to improve the readability of A3s
- Examples of problem solving A3s, and a proposal A3
- Exercises to reinforce what's learned
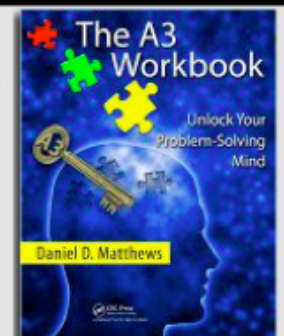
CMDR/CMDCAS Training

April 16/17 Billerica, MA

Debbie Iampietro is a third-party auditor for SGS, a regulatory consultant and fantastic training instructor. I highly recommend her CMDCAS training course (http://www.cmdrtraining.com/). I have also had the pleasure of auditing several quality systems that Debbie personally helped to create from scratch. Each quality system included a unique feature that surprised and impressed me.

A quality plan for QMS implementation typically requires six months to execute, but it can be executed in three months with sufficient resources and planning. The quality plan should identify all of the required procedures for the QMS. ISO 13485 requires 19 procedures and a Quality Manual, but there are additional regulatory requirements for each country. The quality plan should also identify the proper sequence of writing and implementing each document in the QMS. Typically, this plan will begin with the Quality Manual and the first two procedures will be for Control of Documents and Control of Records.

I recommend identifying a process owner for each of the 19 procedures and the Quality Manual. Some managers, such as the QA Manager, may have responsibility for more than one procedure. However, the practice of assigning responsibilities for all procedures to the Quality Department often results in procedures that don't match the actual practice of each department. The Quality Department can help streamline the process by writing a work instruction for writing procedures that define the preferred format and content in outline format. There are additional ideas for writing procedures in Step 4 of this whitepaper.

During the planning stage, another recommendation is to obtain a quotation and select your Certification Body for the Stage 1 and Stage 2 audits that are required for certification. Most third party auditors have scheduled their audits at least 90 days in advance. Therefore, you will have the greatest selection and most convenient timing for the Stage 1 and Stage 2 audits if you schedule the audits at the beginning of the process—approximately six months prior to the Stage 2 audit. There are additional details explaining the auditing stages in Step 6 of this whitepaper.

The last step of the planning process, and one of the most critical parts of this planning stage, is to ensure that you have sufficient resources available to implement your quality plan. Resources include people, money, equipment and time. In addition to writing procedures, you must have sufficient resources to complete the following prior to certification:

1. You need to train everyone on the new procedures
2. You need everyone to implement the new procedures, and begin generating records in accordance with the procedures
3. You need qualified auditors to perform internal audits after processes are implemented
4. You need process owners that have adequate time to support internal audits
5. You need process owners, trained on the CAPA process, to write corrective actions to internal audit findings
6. You need to conduct a management review to evaluate the effectiveness of the QMS
7. You need to take action(s) to address aspects of the QMS that are not yet effective

Step 2: Implementation of Additional Regulatory Requirements

While you are developing your quality plan for certification, you will need to define which global markets your company is going to seek regulatory approval in. The most common markets for U.S. companies are: 1) USA, 2) Europe, and 3) Canada. Each of these markets has additional requirements that will need to be addressed. If your company is a supplier, however, there are very few country-specific requirements that you need to address.

For most products, I recommend starting with Canadian Medical Device Licensing because it's the easiest of the three markets. Most consultants and Certification Bodies disagree with me. They recommend that you extend the scope of certification at a later date for Canada. I think this is a reflection of how poorly most companies prepare for this extension to scope—rather than a reflection of the difficulty. If you read the following critical documents, you will have the information you need to properly prepare:

1. Canadian Medical Device Regulations (CMDR)
2. GD210: ISO 13485 QMS Audits Performed by Health Canada

The first document is updated every few months, and therefore I search for the most current version instead of relying on an obsolete link. Instructions for searching for the CMDR can be found at: http://bit.ly/FindCMDR. The CMDR has 89 sections and 62 pages. The content you read is actually only half this long, because the entire document is bilingual (i.e., French & English, side-by-side). Don't worry though, during the QMS certification process, you need very little of the CMDR. The most critical sections of CMDR during the certification process are those sections specific to distribution records, Medical Device Licensing, Mandatory Problem Reporting and recalls. These sections are important, because each requirement must be addressed in your procedures.

Please note that if you need to be licensed in Canada, you should refer to an even shorter list of possible certification bodies: http://bit.ly/RecognizedRegistrars. The selection of your registrar is also an opportunity to create a record of supplier qualification.

To help you prepare for ISO 13485 certification to the CMDR, referred to as the Canadian Medical Device Conformity Assessment System (CMDCAS), you should read GD210 first (http://bit.ly/GD210Guidance). This is the guidance document that your auditor will use to identify if you meet all the requirements of the CMDR. There is a cross-reference table in the back of GD210 that is organized according to the standard. The table also includes audit checklist questions that your internal audit team should use to verify conformity to the CMDR during internal audits.

The next easiest regulatory pathway, of the three, is the European CE Marking process. This process is defined in the Medical Device Directive (MDD). There is also a similar directive for Active Implantable Medical Devices (AIMD), and *In Vitro* Diagnostics Directive (IVDD). If you are not already ISO certified, these three directives may be obsolete before you complete the process. The European Commission issued a draft proposal to replace the three directives with two new regulations. The proposed medical device regulations combine the MDD and the AIMD, while the proposed *in vitro* diagnostic regulations replace the IVDD.

Certification bodies are generally much easier to work with than the United States Food and Drug Administration (USFDA). This has a lot to do with the fact that you can choose from many certification bodies and they are all competing against one another to be your partner. The FDA is the only choice for U.S. regulatory approval, and they do not treat you like a partner. Once the new EU regulations are approved (best guess is June 2014), the FDA might look better and the certification bodies might not resemble partners.

If you did not select a certification body during Step 1, now is the point in time at which you **really** need to select a certification body to work with. You are allowed to have a different certification body for each location, but I don't recommend it. Instead, save yourself time and money by selecting one partner for all your locations.

In order to select a certification body, first you need to contact a certification body in order to obtain an application form. Most quality managers either contact a certification body they worked with in the past, or friend and ask for a referral. I recommend **neither** approach.

There is an official Europa page that helps you identify the complete list of "possible" candidates based upon the product category: http://bit.ly/NBDatabase. My personal short-list is as follows (in alpha order):

1. BSI
2. Dekra
3. LNE/GMED
4. TUV SUD
5. SGS

If you have the time, I recommend requesting a quote for a new Certificate from all five. The quoting process will tell you a lot, but you should consider the following before you make your final decision:

1. Larger certification bodies add creditability to your company, while smaller organizations may be able to offer faster service at lower prices.
2. Not every certification body can audit to the Japanese and Canadian regulations. If you are considering either of these markets, you should verify that the certification bodies can provide the certification you need.
3. Some auditors charge extra for travel and each certificate copy, while others include these charges. Therefore, you should compare the total cost, including all applicable fees, rather than the cost of certification audits alone.
4. Responsiveness to requests for information and availability of auditors are frequent complaints. If new customer quotations are processed slowly, customer service is unlikely to improve once you are a customer.
5. Many certification bodies have only one or two auditors qualified to review certain types of high-risk devices, and certain types of certificates (e.g. – CMDCAS) require additional auditor qualification. Ask for the names and profiles of each auditor that is qualified to review your device, or recommend the type of certification you need.
6. In 2011, a Notified Body Code of Conduct was drafted for European Certification Bodies. NB's that have endorsed the Code of Conduct v3.0 as your short-list. The last time I checked, there were only 12, but the expectation is that this will be mandatory: http://bit.ly/CoCNBV3.

Step 3: Design Controls

Design controls are one of the more difficult subject matters for any company to master, and often this subject is not applicable for contract manufacturers. For OEM manufacturers that design their own products, the key to mastering design controls is use a simple process and develop forms that are intuitive for design team members to complete.

There are seven sections to the design control requirements in ISO 13485: Clause 7.3.1, 7.3.2…and 7.3.7. They are:

7.3.1. Design Planning
7.3.2. Design Input
7.3.3. Design Output
7.3.4. Design Reviews
7.3.5. Design Verification
7.3.6. Design Validation
7.3.7. Design Changes

Waterfall Diagram

These sections are nearly identical to the USFDA QSR requirements for design controls in 21 CFR 820.30. The seven sections also are written in the order your design team should be following. This process is often described using a diagram called the "Waterfall Diagram."
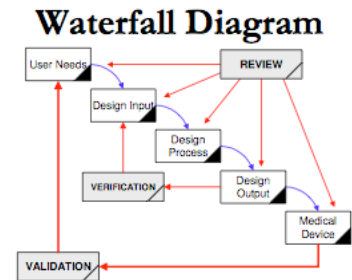
Design Planning

The first step of the process is design planning. There is no particular format required for design plans, but using Gantt charts is a best practice, and it is helpful to combine the risk management plan (refer to ISO 14971, section 3.4 for the requirements of a risk management plan) with your design plan when developing a new product. If you use a Gantt chart, you may want to include an executive summary that describes the design project, defines user needs as described by marketing or the customer, and identifies each of the design team members—including their roles and responsibilities for the project. This plan can, and should evolve, as the product design changes over time.

Defining and Approving Design Inputs

The next step of the design process is defining and approving the design inputs. This is not a list of features that your design team thinks this product should have in order to meet user needs. This is a list of standardized tests that your product will need to pass. These tests should include any safety testing identified during hazard identification and preliminary risk analysis. This is why risk analysis is required as a design input. You can test the components of the device. or test the device as a whole, but this is typically bench top testing that will be performed before the product is considered for human use. Examples of these types of tests are biocompatibility testing. The best practice for defining design inputs is to use an ISO standard or some other harmonized standard. If none exists, then you should develop a test, and document it in an approved test method before you proceed too far with your design project.

Development

The next step of the design process is development. This is all the reiterative engineering work that results in a prototype product. The final result of this step of the process should be an approved drawing(s) or product specification(s). This is referred to as the design output. Some companies also refer to approval of design outputs as "design freeze." If you have a specification or tolerance in your drawing that does not correspond to a design input, then you have one of two problems: 1) you over-designed your product, or 2) you forgot to list a design input. Both of these scenarios happen frequently, and sometimes in the same project. Using an Excel spreadsheet can help ensure

that this traceability from user needs, to inputs, to outputs is complete. Often, companies will refer to this spreadsheet as an "Input/Output/Verification/Validation Matrix" (IOVV) or "Design Requirements Matrix" (DRM).

As your project progresses, you are required to have at least one design review at the very end of the project, but most companies have a design review at each step (i.e., planning, inputs, outputs, etc.). Often companies will call this a phase/gate review. This means that the end of each phase of the design plan is considered to be a gate. All tasks listed in the design plan must be completed prior to proceeding to the next phase. The USFDA has specific requirements for design reviews that should be documented in a design review form.

Verifying Outputs Meet Inputs

After you have approved design outputs, the next step in the design process is to verify that the outputs meet the inputs. This is why it is critical to re-read the paragraph next to warning sign above. If your design inputs are not based upon an objective test that can be verified, the verification step in the design process is difficult to complete. However, if your design inputs reference standardized testing, such as ISO 10993-1 for biocompatibility, then your design verification activities are straightforward. In addition, limiting verification tests to standardized test methods also increases the predictability of the design verification process with regard to costs and duration.

Design validation

The next to last step in the design process is validation. Many people confuse design validation and process validation. Design validation is verification that the device actually meets user needs in an actual or simulated use environment, while process validation verifies that the process will consistently produce a device that meets design specifications or outputs. Design validation may be performed on a computer in some cases (i.e., finite element analysis), but typically it is performed on animals, cadavers or patient volunteers participating in clinical studies. In some cases, it is possible to simulate procedures with models (i.e., a "saw bones" model or orthopedic procedures), but this is typically limited to training practitioners, and to evaluate various surgical techniques prior to conducting cadaver testing.

Due to the precious value of test subjects, it is critical that all design validation is well planned, and protocols are approved in advance with appropriate reviewers. For these reasons, design validation should require minimal modifications between products, or the same indication. Therefore, design validation protocols should be quite predictable with regard to costs and duration. Design validation protocols should also begin development immediately after the design outputs are approved

Design Transfer

The final step of the design process is design transfer. Design transfer is not a discrete point in time. Design transfer begins when the first design output is released as a controlled drawing and the component may be ordered or manufactured. Transfer ends when the product is finally released for commercial distribution. This process step may involve years in the case of high-risk devices that require clinical studies.

The ISO 13485 standard indicates that design change control is the last clause in the design controls, but design change control is a task that can happen at any time during a product lifecycle. If design changes are made prior to design transfer, then the design team must consider changes required to: 1) design plan, 2) risk management plan, and 3) IOVV Matrix. When these changes are made later in the design process, these changes will cause extensive delays and costs increases; this is the reason why the concept of "design freeze" was developed.

If your company is an OEM manufacturer that intends to design medical devices, you need a design control procedure that explains each of the seven steps described above and illustrated by the "Waterfall Diagram." You do not need a design controls book. You need to write a procedure, and need to train your team on the basics of design controls and risk management. You need to develop intuitive forms that remind the team of what they are required to document at each phase of the design process. Finally, you also need to define verification and validation testing that will be required prior to designing the device—not after.

For achieving ISO 13485 certification, you will need records of following the design control requirements. Therefore, you need to develop and implement the design control procedures well in advance of certification, so that there are records from at least some of the design steps. There do not need to be records of all steps in the process, but your certification auditor will indicate in their audit report that records were not available for all stages of the design process due to the early stage of product development. Therefore, the design control process will be re-sampled during the subsequent audits until all aspects of the design process have been sampled.

Step 4: Document Control & Training

Many people seem to think document control is the core of a quality system, but it's really just a support system that helps you keep track of changes. You should think of document control as the left hand supporting all other processes, and training as the right hand supporting all other processes. Every time you make a change to a document, you need to do all seven of the following tasks (no exceptions) below:

1. Review changes (requires defining the approval roles for each document)
2. Approve changes (requires each of the functions that originally approved the document)
3. Communicate the changes made
4. Control distribution of documents (old and new)
5. Train everyone responsible for using the document
6. Create records of document changes and training
7. Retain the records of document changes and training

Since all seven tasks must be performed for each document change, you will notice that the best procedures include the following information:

1. What changes were made from previous versions to help anyone comparing the changes
2. Names, titles and dates of approval for each person that approved the procedure change
3. Affectivity date for the document change (ideally after training is completed)
4. Whether the document is a controlled copy, an uncontrolled copy or an obsolete copy
5. Who is responsible or being trained or **re-trained** on the document
6. Change order number (i.e., "ECO" number)
7. What quality records are associated with the document, which records shall be retained, where the records shall be retained, who is responsible for record retention, and how long records shall be retained

There are a few basic numbering systems that different companies use for documents, but the two most common are: 1) sequential numbers assigned chronologically (i.e., "dumb" document numbers), and 2) numbers with a "smart" number that matches the applicable clause in the ISO standard, or the FDA QSR (e.g., SOP-423-01 is the procedure for document control). My personal preference is the "smart" numbers based upon the ISO 13485 standard, because it is intuitive to **me**. This system will also be intuitive to any certification auditor, but that's really the only benefit. It doesn't matter which system you pick, but don't you dare change it!

The more important decision is how to document training. It is not sufficient to have your employees sign a piece of paper acknowledging that they "read and understood" a procedure. That's like saying "yes dear" when your wife asks you whether you would like your mother-in-law to visit for the next two months. Pay attention. You need an exam to prove you understood. That's called training effectiveness. A multiple choice is exam is ok, but don't make it too easy.

You also need to verify that trained employees are competent. The only way to verify competency is to observe the person performing a procedure. One of the best systems I have seen for doing this is by including the training document on the back of the procedure or work instruction. Each trainee signs and dates the training form when they read and understand. Then the trainee's supervisor

initials and dates each time the trainee is observed doing the procedure correctly. If the procedure is done incorrectly they must be retrained. If the trainee performs the procedure three times correctly then the trainee is competent. This is especially helpful when auditing production employees performing a work instruction.

Step 5: Internal Auditing, CAPA, and Management Review

Internal auditing, CAPA and management review are considered the most important processes in a quality system by most certification auditors—not document control and training. Document control and training are support processes that provide a foundation for your product realization processes (i.e., clauses in Section 7 of ISO 13485 standard). Internal Auditing, CAPA, and Management Review are the management processes that provide a roof for your quality system. The purpose of internal auditing is to identify problems in the quality system. The CAPA process identifies the root cause of those problems and eliminates them. The purpose of the management review process is to ensure that adequate resources are made available to maintain the effectiveness of the quality system. Top management may initiate actions to address negative trends that are observed, prepare for anticipated changes, or accelerate actions being taken when adequate improvements are not occurring.

In order to achieve ISO 13485 certification, you must document a full quality system audit or several audits that collectively address all clauses of the ISO 13485 standard. If your quality system is new, there can be no exceptions or clauses that were skipped. The certification auditor is supposed to sample your quality system—not do your internal audits for you. Once you have a mature quality system, then you can develop data to support why you don't need to cover certain clauses in the standard each year. Without previous audit results to show a certification auditor, you are not ready for certification.

Internal auditors do not need to work for the company. You may use consultants to fill this need—especially in small companies where an employee auditor may have a conflict of interest (i.e., they may not audit their own work). Once you have completed a few internal audits, then you are ready to audit the internal auditing process. This can be done remotely if the following records are made available:

1. Procedure
2. Internal audit schedule
3. Internal audit reports and auditor notes

The most common problem with these records is a lack of detail identifying the objective evidence sampled during an internal audit. Most companies use audit checklists, and auditors are required to

pass a formal lead auditor class. The class does not need to be accredited, but ensure the course covers the content within ISO 19011. You should consider purchasing the 2011 version, which is a guidance document for auditors.Regardless of your requirements, ensure you document the requirements for being an internal auditor, lead auditor, and managing the internal auditing program. This is important, because some day you might not be wearing all three hats.

Once you conduct internal audits, you will have findings that require correction(s) and corrective action(s). If you don't have these findings in a new quality system, your internal audits were not thorough enough. For a certification audit, you will need to provide samples of completed Corrective And Preventive Action (CAPA). These samples will need to include both corrective and preventive actions. Unlike the FDA QSR, the ISO 13485 and 9001 standards consider corrective action (Clause 8.5.2) and preventive action (Clause 8.5.3) to be two distinct requirements. ISO certification auditors are purists. They believe that actions cannot be "preventive" if a problem already occurred. Therefore, you will need to identity potential issues that have not become a problem yet. The best tool for this is monitoring and measuring data.

Once you have initiated several CAPAs, and closed a least a few, then this process is ready to be audited internally. This can be done remotely if the following records are made available:

1. Procedure
2. CAPA form(s)
3. CAPA log (no requirement for this, but every auditor and FDA inspector will ask for it)
4. Records of completed CAPAs—including at least one preventive action

The most common problem with these records is a lack of depth in the investigation of root cause. If the investigation does not identify the true reason why there are problems, then the problems will continue. In this case, actions taken would only be corrections rather than corrective actions. This is why there is a requirement to perform and document an effectiveness check. If your company does not have prior experience with CAPAs, then formal training on the CAPA process is recommended. These are the most valuable training dollars your company will ever spend.

The last thing you need to do before your certification process begins is to conduct a management review. The requirements for a management review are simple and take up less than a page in the standard. Therefore, help yourself by creating a management review template that includes each requirement on a separate slide. Put this template under document control. Don't delete any of the slides when you are preparing a management review. If you did not identify any new or revised regulatory requirements during your preparation for the management review, then you need help from a regulatory consultant. This person can provide you, remotely if needed, with a slide to

address requirement 5.6.2h—new and revised regulatory requirements, and can also audit your management review process remotely by reviewing the following documents and records:

1. Procedure or Quality Manual if you don't have a management review procedure
2. Management review slide template
3. Slides you prepared as an input
4. Meeting minutes from the meeting, which includes
   a. time/place
   b. attendance
   c. agenda
   d. discussion of inputs
   e. outputs
   f. action items

The regulatory consultant that you hire should also be able to audit your internal auditing process and your CAPA process. This is important, because the person that performs the bulk of your internal auditing may have a conflict of interests (i.e., they may not audit their own work).

Step 6: Stage 1, Stage 2 and Responding to Findings

ISO 17021:2011 is a standard that defines requirements for bodies providing audit and certification of management systems. These requirements include performing the initial certification in two stages. Stage one is typically a one-day audit intended to review the QMS documentation and to verify the company's readiness for stage two of the certification process. Historically, the certification process would begin with a desktop audit of the QMS documentation. The problem with the desktop audit is that companies that have all the required documentation may not have records to verify the systems have been fully implemented. The new two-stage process now includes a review of records from the internal auditing, CAPA, and management review processes during Stage one. This is why Step five must be completed before the Stage one certification audit.

Another purpose for the two-stage process is to verify that the quoted duration for the combined Stage one and Stage two audits meets the requirements of the International Accreditation Forum (IAF) (http://bit.ly/IAFMD9-2011). The guidance documents published by the IAF include a table that defines the relationship between the minimum number of days for the combined duration and number of employees in the company. The auditor is expected to assess the appropriateness of this minimum value during the Stage one audit. Deductions may be taken for mature quality systems (unlikely for an initial certification audit), simple products/processes, and for exclusion of design controls (e.g., – a contract manufacturer). The duration may also be increased for companies with

multiple buildings that may require extra transit time, complex products/processes, and addition of multiple certification schemes (e.g., – ISO 13485 and CMDCAS).

In order to ensure that the Stage one audit proceeds smoothly, the following documents and records should be prepared in advance:

1. Quality Manual
2. Company organization chart
3. Controlled list of procedures—if they are not all identified in the Quality Manual
4. Internal auditing procedure
5. CAPA procedure
6. Management review procedure (if applicable)
7. Internal Audit schedule
8. CAPA log
9. Most recent management review meeting minutes

For most auditors, review of the above items will require most of the Stage one audit. However, the goal is to have the auditor cover this material as quickly as possible so that there is time to review other processes, and sample internal audit reports and CAPAs. If the auditor is able to sample these other areas during the Stage one audit, the auditor can let your company know if corrective actions are required in order to achieve certification. However, if the QMS is not well organized, or the auditor has to wait for documentation, then the auditor may not sample the audit reports and CAPAs until Stage two. If the auditor finds serious gaps in these processes during Stage two, the company must repeat the Stage two audit.

During the Stage two audit, the auditor is supposed to verify that 100% of the clauses are addressed and fully implemented. If the internal auditing, CAPA, or management review processes are not fully implemented, the auditor will not be able to recommend certification. If there are other processes that are not fully implemented by Stage two, then the auditor may still be able to recommend certification.

Once your certification auditor has recommended your company for ISO 13485 certification, then the auditor will arrange for surveillance audits semi-annually or annually. I highly recommend annual surveillance audits, because the short duration of surveillance audits becomes unrealistically short when the auditor is asked to split their time between two semi-annual visits.

A few clients have indicated that the semi-annual audits help them by maintaining pressure on the organization to be ready for audits all year-round and prevents them from procrastinating to implement corrective actions. This is really an issue of management commitment that needs to be

addressed by the company. Scheduling semi-annual surveillance audits does not address the lack of management commitment. The only good argument I have for semi-annual cycles is if you have a very large facility that would have an audit duration of at least two days on a semi-annual basis.

The most important thing to remember about scheduling surveillance audits is to ensure that you schedule the audits well before the anniversary. I recommend 11 months between audits. By doing this, you end up scheduling the re-certification audits three months before the certificate expires. No matter what, schedule early.

QA/RA Expert
Robert Packard

Robert Packard is a regulatory consultant with 20 years experience in the medical device, pharmaceutical and biotechnology industries. He is a graduate of UConn in Chemical Engineering. Robert was a senior manager at several medical device companies—including President/CEO of a laparoscopic imaging company. His Quality Management System expertise covers all aspects of developing, training, implementing, and maintaining ISO 13485 and ISO 14971 certification. From 2009-2012, he was a lead auditor and instructor for one of the largest Notified Bodies. Robert's specialty is regulatory submissions for high-risk medical devices, such as implants and drug/device combination products for CE marking applications, Canadian medical device applications and 510(k) submissions. The most favorite part of his job is training others. He can be contacted at rob@13485cert.com or visit his website http://www.medicaldeviceacademy.com if you have specific questions about ISO 13485 certification, or to request help with training or implementation of your Quality Management System.