Welcome to ISO 13485:2016

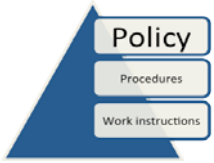
Coming Soon: Gap Analysis

The next step in our ISO 13485:2016 Project is to conduct a "Gap Analysis". This is an evaluation of our current processes to see what we have in place that already meets the requirements of ISO 13485:2016, and what we will need to do to meet the rest of the requirements.

People from our company will be coming to all departments and asking how you do things. They will want to see procedures and records so they can evaluate the current method of doing things against the requirements of the standard. This information will help us plan our ISO 13485:2016 Project.

Introducing our Quality Policy

Top Management has developed a Quality Policy to demonstrate their commitment and leadership in providing quality products and services to our customers. How does your work contribute to meeting our quality policy? Each and every individual has an impact on quality of the product and service we deliver.



"Insert your quality policy here"

After the Gap Analysis …

When we have completed the Gap Analysis we will put together a plan to address the ISO 13485:2016 requirements.
This plan will include outlining new ways of doing things, and developing documented information for the quality system processes.

Many employees will be involved in this effort. We have established a Quality Team to lead the effort and create Point Teams to identify how to meet requirements in different areas, and documenting and updating the way of doing things in Procedures and Work Instructions.

ISO 13485 Highlights: Things that you will be hearing about as we proceed with this project….

Documented Information
Documented information will support the operation of the processes and will provide confidence that they are carried out as planned.
Procedures will be written to describe how a process is done. For example, a procedure for the Document control is written to describe the overall document control process.
When detailed instructions are needed, a **Work instruction** will be written to describe how to do a task or process.
In the example above, a procedure is written describing the overall control process. A work instruction is written to describe how to assign control numbers for the documents.

Watch for our next newsletter for more introduction to ISO 13485:2016, what it will mean to you and your coworkers.

ISO 13485:2016: Introduction to the Requirements

Introduction to ISO 13485:2016 Requirements

Section 4: Quality Management System
Section 5: Management Responsibility
Section 6: Resource Management
Section 7: Product Realization
Section 8: Measurement Analysis and Improvement

Section 5: Management Responsibility

Throughout our ISO 13485:2016 implementation project, management will have specific responsibilities. Top management needs to demonstrate the commitment to the QMS and to customer focus. Management will be working to ensure that customer requirements are determined and met to enhance customer satisfaction.

In addition to establishing the Quality Policy, management will be setting Quality Goals and Objectives.
These will help us measure and improve the performance of our QMS. Goals and objectives will be established at many different levels of the company. As we progress, you will hear more about goals specific to your area or department.

Management Representative

Top management has also designated a "Management Representative". Every ISO 13485:2016 registered company has such a function that is responsible for leading the implementation project, reporting to management on the performance of the QMS, and promoting awareness of customer requirements throughout the organization.

This means that the 'ISO-Rep' will make sure that internal communication is established and takes place.
Our ISO Management Representative is:

Fill in your Management Rep name here

Management Review

Management will also be holding regular meetings to evaluate how the QMS is working. When the QMS is complete, processes will be monitored, progress towards quality goals will be measured, and management will hold Management Review meetings to see how the QMS is working and how it can be improved.

During these meetings, management will look at:

- Data on how processes are working throughout our company
- Action items for improvement of processes and the QMS
- Follow-up on action items from previous management review meetings
- Planned changes that could affect the Quality Management System
- The Quality Policy

Our procedure **P-500, Management responsibility** outlines our plans to address clause 5.

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Announcing our Internal Audit Program

Internal Auditors

As a requirement of ISO 13485:2016, we have trained a team of employees to become "Internal Auditors". They have learned how to plan, conduct and document an Internal Audit. They will be scheduling an audit of each area of the company.

During these audits, they will look at the documented information, such as procedures and work instructions, and observe / watch how processes are being performed.

On behalf of our top management, the internal auditors want to find out if the quality system / procedures and work instructions are being followed, and if they lead to quality products and services.

Auditors will prepare checklists to identify the process details they will audit in the different departments and areas of the company, and will include management functions as well as production activities.

The auditors will be looking for things such as:

- Commitment and leadership from top management.
- Appropriate training records
- Verified and calibrated equipment
- Employee training and qualifications
- Nonconforming product is correctly controlled
- Product is properly labeled and identified
- Materials are purchased from external providers / suppliers that have been evaluated and approved
- Corrective actions are completed and effective
- Any other requirements of our QMS.

An Internal Audit is an Audit of the Process and not the Person

It is important to remember that the purpose of the audit is to evaluate if the QMS processes are being followed, and if they are effective. It is not about an evaluation of employees. Although it is part of the job of each employee to follow the requirements of the QMS, it is up to an employee's supervisor/manager to evaluate performance, and not up to an internal auditor.
An audit is a welcomed opportunity to identify where we can improve our processes. Internal auditing is best described as the "Key to Improvement" because effective audits lead to continual improvement and success for our company!

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ISO 13485:2016

Congratulations!

Thank You -- Our Company has received our ISO 13485:2016 Registration!

A big thank you for your hard work in building and following the Documented Information for our Quality Management System. Our company can look forward to new customers, improved operations and improved profitability!

Let's Celebrate!

Announce your company's celebration here. A gathering for all employees, whether an informal gathering at break with some special food, or a more formal lunch or dinner gathering goes a long way in emphasizing the importance of what you have achieved.

What comes next?

Now that we have achieved registration we will continue to use and improve our Quality Management System.

We will continue with internal audits, management review, corrective and preventive actions and measuring monitoring and improving.

Our registrar will be back every six months to audit different parts of the management system to make sure we stay on track.

Your role in the future of our QMS is to:

- Continue to follow documented information in procedures and work instructions.
- Start Corrective and Preventive Actions when you see a problem or potential problem.
- Continue to help Internal Auditors evaluate and improve the system.
- Always be aware of your role in meeting customer requirements.

ISO 13485:2016
Registered