

Welcome to ISO 13485

Our Company is working on becoming ISO 13485 Registered. ISO 13485 is a Quality Management System that outlines some basic good business practices that we need to have in place.

By implementing a Quality Management System that complies with ISO 13485 we will be able to make our company run more efficiently, increase our customers' satisfaction and communicate to potential customers that we have good quality processes in place.

Surveyed ISO 13485 Registered Companies state that they have:

- Higher customer satisfaction
- Increased profitability because of efficiencies
- Market advantages
- Improved communications
- Higher job satisfaction

What will employees need to do for the ISO 13485 Quality Management System?

First Management will be identifying our "Key Processes". Those are the processes that affect the quality of our product and our services. Then they will identify how we will control these processes to make sure that we are all doing them the same way, and the best way our organization has identified.

Controlling the process means documenting the work instructions, training employees or finding other ways to make sure that the process is done consistently no matter who is doing it. This means that employees may be required to have certain training, or to follow specific work instructions.

Employees will also need to be aware of how their job affects the quality of our product and customer satisfaction.

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

Our Quality Policy

We will identify our Quality Policy, and will be communicating it to all employees. It is important that all of us are aware of what this statement says about our company's vision is for meeting customers' expectations and for quality.

Registration Audit

To become ISO 13485 registered, we will be audited by a Registrar. This Registration Audit will be done after we have set up processes to meet all the requirements of the standard. The Registrar will send an auditor or audit team to come in to our facilities and evaluate the processes we have set up. They will check to see if the processes meet the requirements of the standard, and to see if we are following the processes. If everything looks good, we will be recommended for Registration!

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