

Dreading Certification - Becoming ISO 13485 Certified



[1]Achieving ISO certification is a tedious, time consuming, often difficult and complex process BUT there are a multitude of reasons why you're doing it.

Farm has been going through the lengthy process and although we are not "required" to be ISO certified since we are a medical product development consultancy, we know that our business can benefit dramatically by obtaining ISO certification and so can our clients.

If you're in the process of becoming ISO 13485 certified and you're starting to rip your hair out - keep the following in mind...

- You are doing this because you want to offer your clients a high level of customer satisfaction. A certified quality system establishes your company's credibility and commitment to quality, helping you earn your client's trust and confidence.
- You want to comply with statutory and regulatory requirements to assure clients that you are committed to developing products that are safe and effective.
- You want to unlock doors that were previously closed since many medical device companies won't even speak to a development company that is not certified.
- You want to experience financial growth by gaining access to a larger market share that operates in a highly regulated medical sector.
- You want to motivate your staff and increase productivity. This is achieved through proper training, a documented, straightforward communication of the quality management system and evaluation process in order to create a work environment that embraces accountability.

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- You realize the importance of mitigating risks in all stages of the product development process in order to detect and prevent errors in all stages of a product's lifecycle.
- You want the ability to identify when processes are obsolete or inefficient so you can reassess and correct them.

The process of achieving ISO 13485 certification shouldn't be feared, it should be embraced. It's a chance for a company to create a quality management system that works for them, not against them. It's an opportunity to develop a system that will offer a competitive advantage and help your business be the best that it can be.

If you reach your goal in obtaining ISO certification and are thanking your lucky stars that it's finally over - you're missing the point! Certification and the process in and of itself NEVER ends. Your quality system must continue to be audited and improved, tracked and reviewed, trained and understood by everyone in your business. It's not a course you've completed and will soon forget but instead a promise you've made to your business, employees, clients, suppliers and industry liaisons. If you want to be successful as a business, you must realize there is always room for performance improvement and by changing your perception you will not just raise the bar but go above it.

[Source](#)

[2]

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<http://www.mdtmag.com/blogs/2010/05/dreading-certification-%E2%80%93-becoming-iso-13485-certified>

Links:

[1] <http://www.farmpd.com/Farm-Blog/>

[2] <http://www.farmpd.com/Farm-Blog/bid/36735/Dreading-Certification-Becoming-ISO-13485-Certified>