Looking to the future

Learning about the changes to **ISO 13485**

ISO 13485 is the medical device Quality Management System (QMS) standard. The latest version, ISO 13485:2016, was published in February 2016.

Understanding the changes to the new version of the standard is essential to not only meet the requirements, but to do so before the end of the transition period, in 28 February 2019.

Trauson understood that ISO 13485:2016 would bring significant changes to their business and so proactively attended training to understand the full implications. The training then allowed them to go back and thoroughly assess their business.

The manufacturer

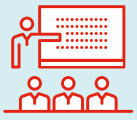
TRAUSON

- Orthopaedic device manufacturer
- Based in China
- Key products include plates, screws and spinal systems
- Specialize in trauma devices
- Focus is on providing affordable, innovative devices to improve the patient's quality of life.

The challenge of change

Trauson recognized the need to **modify** its QMS to meet the new requirements.

Trauson acted quickly to **learn** about the changes.



Trauson chose to **educate** its staff through training.

Why BSI?

Trauson prefer to use its Notified Body for training as it recognizes the **expertise** and **knowledge** of the BSI specialists, who help to develop and lead its courses. Learning from a team with real world **experience** provides **confidence** in the course content and the tutor delivering it.

"We needed training on QMS requirements, so our first consideration was our Notified Body. We think BSI is professional and has expertise with ISO 13485."

Chunfeng Li, Quality System Manager at Trauson

Course attended:

ISO 13485:2016 Internal Auditor

This course explores the **principles** and **practices** of effective QMS process audits to **develop** your understanding of the standard, and allow you to **evaluate** the **effectiveness** of the QMS in your organization.

What was the value of training with BSI?

BSI's in-house training allowed Trauson to train colleagues from across the business who have QMS responsibilities.

After training with BSI experts, Trauson is able to perform internal audits against the new version of the standard.

Now Trauson understands the new requirements, its staff are able to effectively plan its transition to the new standard.

"We improved our overall quality awareness by training colleagues about the changes to ISO 13485." *Chunfeng Li, Quality System Manager at Trauson*

Trauson's aim in attending this course was to learn about the changes to the standard and modify their quality system to meet the new requirements. The internal auditor course discusses both the requirements of the standard and explores the practice of performing audits. This allowed Trauson not only to educate their staff about how the requirements of the standard have changed in the new version, but to interpret these for implementation in their own business.

Learn more from BSI experts

BSI ISO 13485 training courses

BSI has a full suite of ISO 13485 training courses suitable for any level of understanding, from those completely new to the standard, to those looking for a deeper explanation of the requirements:

Introduction to ISO 13485:2016

ISO 13485:2016 Clause by Clause

Implementing ISO 13485:2016

Internal Auditor ISO 13485:2016

Lead Auditor ISO 13485:2016

Transition training courses

Explore the requirements of the new version of the Standard ISO 13485:2016 and refresh your auditing techniques.

ISO 13485:2016 Senior Management Briefing

ISO 13485:2016 Transition

ISO 13485:2016 Auditor Refresher

BSI has developed a range of resources to support manufacturers through the transition to the new standard. You can find the latest resources, guidance and developments on our transition webpage.

To learn more about BSI training courses, talk to us today:
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