ONE STOP FOR ALL YOUR QUALITY MANAGEMENT SYSTEM NEEDS

Total Solutions Provider
BSI Healthcare ISO 13485 Quality Bundle

BSI Healthcare understands the challenges that medical device manufacturers face when trying to meet customer and regulatory requirements. You continue to be tasked with broadening employees’ knowledge and understanding of medical device regulations, conducting internal audits, raising, monitoring and closing non-conformities, and tracking preventive and corrective actions. Juggling these responsibilities and manually performing tasks creates more complexity than needed to effectively reach goals.

One Stop Shop Delivers...
- Assessment, Auditing, and Certification Services
- Management System Software
- Training
- Access to Standards

BSI offers a comprehensive package to jumpstart your quality assurance efforts while allowing you to optimize control, maximize ROI, and drive operational performance to the next level. The BSI Healthcare ISO 13485 Bundle brings together assessment services, training, and a software tool that can provide your organization with the means for improved:
- Quality Management Systems
- Knowledge and Competency Through Training
- Access to Key Medical Quality and Risk Standards
- Internal Control, Transparency, Improved Performance, and Productivity

BSI, a global leader in business services, brings together its portfolio of products and services to deliver a comprehensive tool kit to organizations like yours.
Assessment, Auditing and Certification Services

The BSI Healthcare ISO 13485 Quality Bundle for medical device manufacturers covers assessment and certification for ISO 13485. The bundle is comprehensive and includes all the elements of certification including an appropriate number of assessment days, continuing assessment over the life of the certificate, and the maintenance fees associated with your certification.

BSI is recognized and accepted around the globe for conducting robust, comprehensive assessments, auditing, and certification. Our leadership role allows clients to have direct access to top industry resources and information.

Training

BSI offers specific courses for the medical device community that will give your employees the practical knowledge and tools to apply in their everyday business practices. The bundle contains generous credits toward e-learning web-based training and classroom training. Our accelerated learning processes and dynamic group exercises have made BSI's training solutions the choice of over 70% of the top medical device manufacturers worldwide.*

As a cutting-edge training provider, BSI is the first in the marketplace to offer ISO 13485 Lead Auditor courses which are certified by RABQSA through its Training Provider and Examiner Certification Scheme (TPECS). TPECS is a module-based training focused on competency. It is designed to reflect innovative learning and assessment practices. Students will achieve the level of knowledge needed for RABQSA personnel certification. Each bundle contains Lead Auditor Training, e-learning, and specially designed e-learning on Entropy software.

Entropy® Software Solution

Entropy Software is a market-leading quality management software solution assisting organizations in delivering products to market on-time with transparency, real-time reporting, and improved quality at over 14,000 sites worldwide. In the introductory configuration, BSI Entropy delivers the powerful Audit workflow, which will provide your organization a robust on-line tool to conduct internal audits; raise, monitor, and close non-conformities; and track preventive and corrective actions. Designed and developed to meet recognized international standards, Entropy Software provides the technology framework to assist companies in effectively managing ISO 13485 and U.S. FDA requirements.

For organizations looking to go beyond the introductory configuration, BSI can deliver additional modules of our Entropy Software into your bundled purchase. These modules are designed to address the functionality needs of a complete management system including document management, eSignatures, training, equipment inventory, calibration, products and services, and performance, incidents and risk management.

Access to Standards

The BSI Healthcare Quality Bundle offers client access to the key standards of ISO 13485, ISO 14971 and ISO 14969 (Guidance on the application of ISO 13485). By providing these key standards in our bundle, BSI provides a reference point for your quality management systems to meet requirements for regulations as well as to manage risk and guidance for ongoing continuous improvement.

*Based on 2011 BSI Customer Satisfaction Surveys
Why Choose The BSI Healthcare ISO 13485 Quality Bundle?

**BENEFITS**

- **One Company, One Solution.** Benefit from maintaining an all-encompassing relationship. BSI is your trusted partner and is committed to building a relationship to better serve your needs.

- **Convenience and Predictability.** One low monthly payment enabling you to manage multiple services to achieve cross functional goals, saving time and resources.

- **Enhanced Productivity.** Benefit from greater control over performance, productivity and consistent quality standards. The centralized coordination and execution of these bundled services is the key to successfully meeting compliance goals and corporate objectives.

- **Best of the Best.** For more than a century, BSI has led the way in developing standards and services for a variety of business operations. We are a leading global provider of risk-based solutions, assessments and training programs that improve a company's efficiencies and serve to protect your corporate brand and reputation. Our solutions experts, global presence, and long history in this business allow us to provide our clients around the world, with an unsurpassed level of service with a unique product portfolio.

By packaging assessment, certification, standards, training and Entropy Software, BSI delivers a simple solution that:

- **Drives Quality, Performance and Speed-To-Market**
- **Assists Customers in Driving Down Costs**
- **Fosters Continuous Improvement**
- **Manages Risk**
- **Enhances Organizational Competency**
- **Protects Your Brand by Proving Internal Control & Processes**
Why BSI?

Our legacy in raising standards worldwide™ has guided us to become a leading global provider of risk-related services designed to protect your corporate brand and reputation. Our technical experts, global presence, and long history in the industry allows us to provide clients, within the Americas and around the world, an unsurpassed level of service with a unique product portfolio.

BSI offers a results-focused portfolio of products and services for each stage of your certification journey. We are committed to establishing synergistic, long-term, and proactive relationships with our clients. We understand that Management Systems Registration is the culmination of much effort, but it is not the end of the journey. We have designed our service and pricing to reflect a value proposition which enables us to work with our client from the decision to improve existing systems, through registration and on-going continuing improvement. Our portfolio includes both training and software tools to support your organization’s certification efforts. Our goal is to add value at every step along the way.

BSI strives to understand our customers’ unique goals to best assist them in their management journey. Our holistic, flexible, and on-going account management approach ensures that we deliver the strongest service and satisfaction. BSI’s consistent ranking in the 90th percentile for global customer satisfaction is a testament to our commitment to our clients.

BSI provides comprehensive service offerings for a variety of industry sectors based on industry-specific standards. This approach allows us to provide our clients with integrated approach tailored to their specific needs.

BSI offers:

• Product Expertise
• Global Access
• Speed-To-Market
• Management System Software
• Valued Partnership
• Training
• On-line Access to Standards