ISO 9001 Risk-Based Thinking and Process Approach Training Course

21 - 25 Dec 2026
LONDON
5900 € (Per Person)
Ref: #ISO7919_123720

Course Introduction / Overview:

This comprehensive training course is designed to demystify and master two of the most critical pillars of the ISO 9001:2015 standard: the process approach and risk-based thinking. In today's dynamic business environment, a reactive approach to quality management is no longer sufficient. This course provides a strategic roadmap for integrating proactive risk and opportunity management directly into your organization's processes, transforming your Quality Management System (QMS) from a documentation-heavy system into a powerful tool for achieving strategic objectives and enhancing customer satisfaction. We will explore the foundational principles laid out by quality management pioneers like W. Edwards Deming, whose Plan-Do-Check-Act (PDCA) cycle is the engine of the process approach. Participants will gain practical insights from established literature, such as "The ASQ ISO 9001:2015 Handbook," to build a resilient and agile QMS. BIG BEN Training Center has developed this program to empower professionals to not only meet compliance requirements but to leverage them for tangible business improvement, fostering a culture of continuous improvement and operational excellence. This course is your definitive guide to building a robust, efficient, and value-adding QMS.

Target Audience / This training course is suitable for:

- Quality Assurance Managers and Directors.
- Internal and External QMS Auditors.
- Process Owners and Department Heads.
- Management Representatives for Quality.
- Compliance and Regulatory Affairs Professionals.
- Operations Managers and Supervisors.
- Consultants specializing in ISO 9001 implementation.
- Anyone involved in the planning, implementation, or maintenance of a QMS.

Target Sectors and Industries:

- Manufacturing and Engineering sectors.

- Information Technology and Software Development.
- Healthcare and Pharmaceutical industries.
- Construction and Civil Engineering.
- Professional Services, including consulting and legal firms.
- Logistics and Supply Chain Management.
- Governmental agencies and public sector organizations.
- Aerospace and Automotive industries.

Target Organizations Departments:

- Quality Assurance and Quality Control.
- Operations and Production.
- Engineering and Product Development.
- Compliance and Risk Management.
- Internal Audit and Corporate Governance.
- Strategic Planning and Business Development.
- Procurement and Supply Chain.
- Customer Service and Support.

Course Offerings:

By the end of this course, the participants will have able to:

- Interpret the requirements of ISO 9001:2015 related to the process approach and risk-based thinking.
- Develop and document business processes using systematic mapping techniques.
- Identify, analyze, and evaluate risks and opportunities within the QMS.
- Integrate risk-based thinking into strategic planning and operational controls.
- Apply the Plan-Do-Check-Act (PDCA) cycle to manage and improve processes.
- Establish effective key performance indicators (KPIs) to monitor process performance.
- Enhance decision-making by using risk analysis as a predictive tool.
- Lead the transition towards a proactive quality culture within their organization.
- Prepare for and effectively manage internal and external QMS audits.
- Drive continuous improvement initiatives based on risk and process performance data.

Course Methodology:

The training methodology at BIG BEN Training Center is centered on creating an immersive and practical learning experience. This course moves beyond theoretical lectures to engage participants through a dynamic blend of interactive workshops, real-world case study analysis, and collaborative group exercises. We believe in learning by doing, which is why a significant portion of the course is dedicated to hands-on activities such as process mapping, conducting SWOT analysis, and performing failure mode and effects analysis (FMEA). Participants will work in teams to solve complex problems, simulating the challenges they face in their own organizations. This collaborative environment encourages the sharing of diverse perspectives and experiences. Our expert instructors facilitate discussions, provide personalized feedback, and guide participants in applying the learned concepts to their specific contexts. The program is designed to be highly participatory, ensuring that every individual can build the confidence and competence needed to implement risk-based thinking and the process approach effectively upon returning to the workplace. The focus is on practical application and skill mastery, not just knowledge acquisition.

Course Agenda (Course Units):

Unit One: Foundations of ISO 9001:2015 and Core Principles

- Introduction to the ISO 9000 family of standards.
- Understanding the High-Level Structure (Annex SL) and its benefits.
- The seven Quality Management Principles underpinning ISO 9001:2015.
- Clause-by-clause overview of the ISO 9001:2015 standard.
- Defining the concept of the Process Approach.
- Introducing the core tenets of Risk-Based Thinking.
- The synergistic relationship between the process approach and risk-based thinking.

Unit Two: Mastering the Process Approach

- Identifying and defining key organizational processes.
- Techniques for process mapping and flowcharting.
- Determining process inputs, outputs, resources, and controls.
- Understanding the interaction and sequence of processes.
- Establishing process performance indicators (KPIs) and objectives.
- Applying the Plan-Do-Check-Act (PDCA) cycle for process management.
- Documenting processes in line with ISO 9001 requirements.

Unit Three: Implementing Risk-Based Thinking

- Understanding risk and opportunity in the context of ISO 9001 (Clause 6.1).
- Systematic methods for identifying risks and opportunities.
- Qualitative and quantitative risk assessment techniques (e.g., Risk Matrix, FMEA).
- Developing and implementing risk treatment and mitigation plans.
- Integrating opportunity management into strategic planning.
- The role of leadership in promoting risk-based thinking.
- Documenting the approach to addressing risks and opportunities.

Unit Four: Integrating Concepts into QMS Operations

- Applying risk-based thinking to the context of the organization (Clause 4).
- The role of leadership and commitment in driving the QMS (Clause 5).
- Integrating risk and process management into operational planning and control (Clause 8).
- Managing risks in the supply chain and procurement processes.
- Using the process approach to manage nonconforming outputs.
- Risk-based thinking in design and development activities.
- Ensuring competence and awareness through a process-oriented approach (Clause 7).

Unit Five: Monitoring, Improvement, and QMS Auditing

- Monitoring and measuring process performance against objectives (Clause 9.1).
- Conducting effective internal audits with a risk and process focus.
- Preparing for and participating in management reviews (Clause 9.3).
- Managing nonconformities and implementing effective corrective actions (Clause 10.2).
- Leveraging risk and process data for continual improvement (Clause 10.3).
- Fostering a culture of proactive improvement across the organization.
- Preparing for a successful third-party certification audit.

FAQ:

Qualifications required for registering to this course?

There are no requirements.

How long is each daily session, and what is the total number of training hours for the course?

This training course spans five days, with daily sessions ranging between 4 to 5 hours, including breaks and interactive activities, bringing the total duration to 20 - 25 training hours.

Something to think about:

How can an organization effectively measure the return on investment (ROI) of implementing a robust risk-based thinking culture, beyond simply achieving ISO 9001 certification?

What unique qualities does this course offer compared to other courses?

This course distinguishes itself by moving beyond a purely clause-based interpretation of the ISO 9001:2015 standard. While many courses focus on what the standard requires, our program emphasizes the "how" and "why." We concentrate on the practical integration of the process approach and risk-based thinking into the very fabric of an organization's operational and strategic decision-making. The curriculum is uniquely designed to bridge the gap between theoretical knowledge and real-world application, using a series of hands-on workshops where participants actively map their own processes and conduct risk assessments on relevant case studies. This applied learning methodology ensures that participants leave not with a checklist, but with a strategic mindset. We delve into the behavioral and cultural shifts necessary to sustain a proactive quality system, exploring how to champion these concepts and gain buy-in from leadership and staff. The course provides a holistic view, connecting QMS activities directly to business objectives like resilience, agility, and customer value, transforming the QMS from a compliance obligation into a strategic asset for sustainable growth.