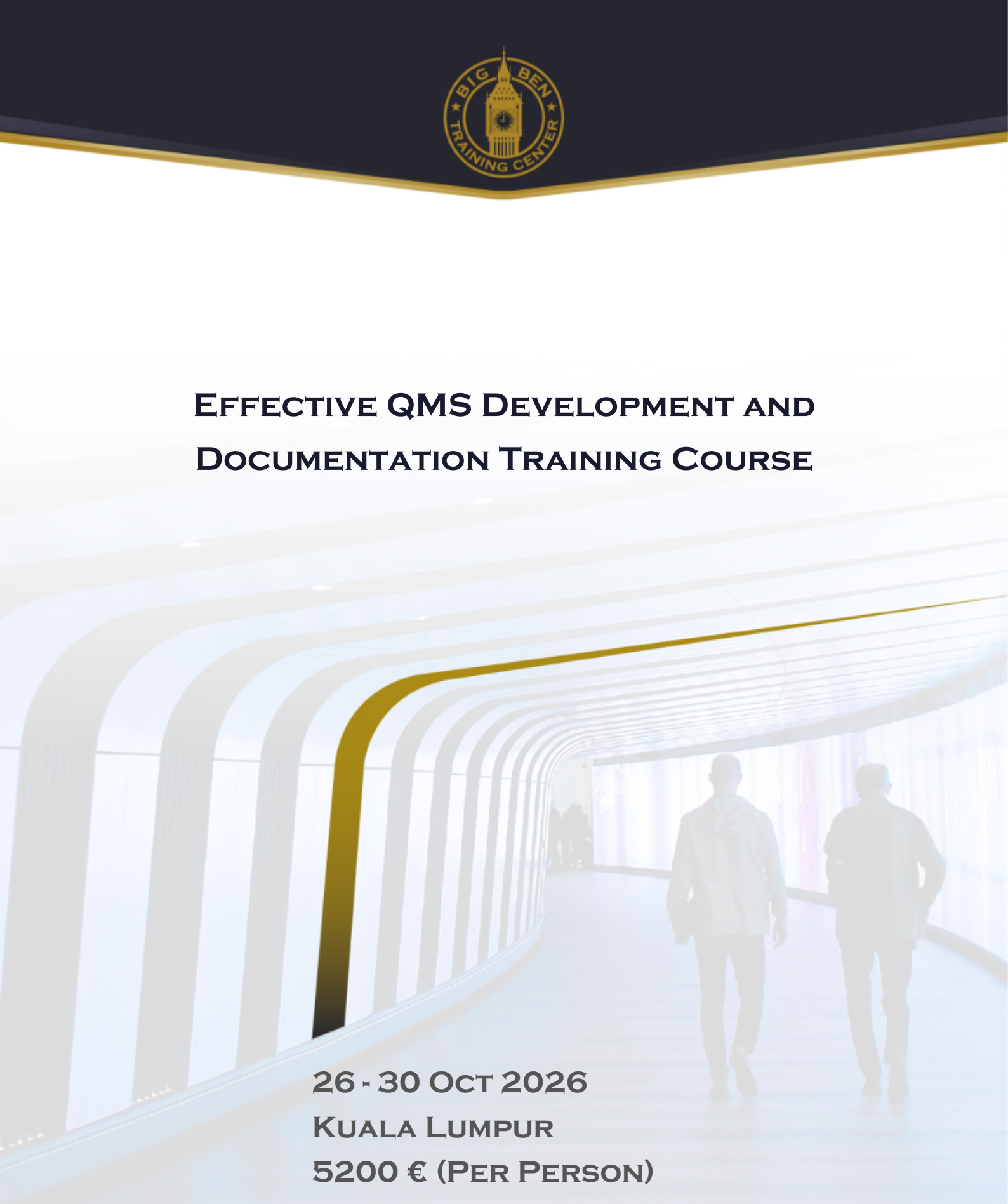
Effective QMS Development and Documentation Training Course



26 - 30 Oct 2026

Kuala Lumpur

5200 € (Per Person)

Ref: #ISO6494_116059

Course Introduction / Overview:

This course provides a comprehensive A-to-Z guide on developing and documenting a robust Quality Management System (QMS) that drives organizational excellence and ensures consistent customer satisfaction. Moving beyond mere compliance, the curriculum delves into the practical application of quality principles to create a system that adds tangible value to business operations. Participants will explore the core tenets of quality management, heavily referencing the globally recognized ISO 9001 standard as a framework for success. The program emphasizes a process-based approach, risk-based thinking, and the importance of leadership commitment in fostering a culture of continuous improvement. Drawing upon the foundational philosophies of quality pioneers like W. Edwards Deming, particularly his insights in "Out of the Crisis," the course connects theory with actionable strategy. BIG BEN Training Center has meticulously designed this training to empower professionals to not only build a QMS from the ground up but also to refine and enhance existing systems, ensuring they are efficient, effective, and aligned with strategic business objectives. This is an essential program for any organization aiming to streamline processes, reduce waste, and build a reputation for quality and reliability in the marketplace.

Target Audience / This training course is suitable for:

- Quality Assurance Managers and Specialists.
- Internal and External Auditors.
- Process Owners and Department Heads.
- QMS Implementation Team Members.
- Operations and Production Managers.
- Compliance and Regulatory Affairs Professionals.
- Consultants in quality management.
- Anyone responsible for process improvement and documentation.

Target Sectors and Industries:

- Manufacturing and Engineering.
- Healthcare and Pharmaceutical sectors.
- Information Technology and Software Development.
- Construction and Civil Engineering.
- Aerospace and Automotive industries.
- Food and Beverage production.
- Government agencies and public sector organizations.
- Logistics and Supply Chain Management.

Target Organizations Departments:

- Quality Assurance and Quality Control.
- Operations and Production.
- Engineering and Design.
- Compliance and Legal.
- Procurement and Supply Chain.
- Customer Service and Support.
- Research and Development.
- Human Resources and Training.

Course Offerings:

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

- Interpret the requirements of the ISO 9001 standard for practical application.
- Develop a clear and concise quality policy and measurable quality objectives.
- Design and document a hierarchical QMS structure, including a quality manual and procedures.
- Apply risk-based thinking to identify and mitigate risks within key processes.
- Map organizational processes to improve efficiency and control.
- Establish effective document control and records management systems.
- Plan and prepare for an effective internal audit program.
- Implement robust corrective and preventive action (CAPA) processes.
- Facilitate a productive management review meeting to drive strategic improvements.

Course Methodology:

The training methodology at BIG BEN Training Center is designed to be highly interactive, engaging, and practical, ensuring that participants can immediately apply their learning in a real-world context. We move beyond traditional lectures by incorporating a dynamic blend of training techniques. The course is built upon a foundation of expert-led presentations that simplify complex QMS concepts, followed by intensive group discussions and collaborative workshops where participants can share experiences and solve common challenges. A significant portion of the training is dedicated to hands-on exercises, such as process mapping, drafting quality procedures, and conducting risk assessments. Case studies from various industries will be analyzed to provide insights into successful QMS implementation and common pitfalls to avoid. Role-playing scenarios, particularly for internal audit situations, will help build confidence and practical skills. Continuous feedback is provided by the instructor throughout the course, creating a supportive learning environment that encourages active participation and deep understanding. This blended approach ensures a comprehensive learning experience that bridges the gap between theoretical knowledge and professional competence.

Course Agenda (Course Units):

Unit One: Foundations of Quality Management Systems

- Introduction to Quality Management Principles.
- The Evolution of Quality and Key Thinkers.
- Understanding the ISO 9000 Family of Standards.
- Detailed Overview of ISO 9001:2015 Clauses.
- The Process Approach and the PDCA Cycle.
- Benefits of Implementing a Formal QMS.
- Defining the Scope and Boundaries of the QMS.

Unit Two: Strategic QMS Planning and Leadership

- Understanding the Context of the Organization (Clause 4).
- Demonstrating Leadership and Commitment (Clause 5).
- Establishing and Communicating the Quality Policy.
- Planning for the QMS (Clause 6).
- Applying Risk-Based Thinking to Processes and Objectives.
- Setting SMART Quality Objectives and Planning to Achieve Them.
- Managing and Communicating QMS Changes.

Unit Three: QMS Documentation and Resource Management

- The Hierarchy of QMS Documentation.
- Developing a Practical Quality Manual.
- Writing Effective Standard Operating Procedures (SOPs).
- Creating Work Instructions, Forms, and Records.
- Implementing a Document Control System (Clause 7.5).
- Managing Resources for the QMS (Clause 7).
- Ensuring Competence, Awareness, and Communication.

Unit Four: Operational Control and Performance Monitoring

- Planning and Controlling Operations (Clause 8).
- Managing Requirements for Products and Services.
- Control of Externally Provided Processes, Products, and Services.
- Production and Service Provision Control.
- Monitoring, Measurement, Analysis, and Evaluation (Clause 9).
- Conducting Effective Internal Audits.
- Techniques for Data Collection and Analysis.

Unit Five: Improvement and Management Review

- The Concept of Continual Improvement (Clause 10).
- Managing Nonconformity and Corrective Actions.
- Root Cause Analysis Tools and Techniques.
- Implementing Preventive Actions and Improvement Projects.
- Preparing for and Conducting Management Review Meetings.
- Outputs of Management Review and Action Planning.
- Preparing for Third-Party Certification Audits.

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:

Beyond compliance with standards like ISO 9001, how can an organization truly embed a culture of quality that drives innovation rather than just procedural adherence?

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

This course distinguishes itself by focusing on the strategic integration of a Quality Management System into the very fabric of an organization, rather than treating it as a standalone function for achieving certification. While other courses may focus heavily on the clauses of the ISO 9001 standard, this program emphasizes the "why" behind the "what," enabling participants to build a QMS that is both compliant and a powerful driver of business performance. We prioritize practical application through extensive hands-on workshops where participants draft actual documentation, map real-world processes, and conduct simulated risk assessments. The curriculum is designed to foster critical thinking, moving beyond templates and checklists to cultivate a deep understanding of how to tailor a QMS to an organization's unique context, challenges, and strategic goals. The emphasis is on creating a lean, efficient, and value-adding system that reduces bureaucracy and empowers employees. It is this focus on building a sustainable culture of quality and continuous improvement, rather than simply passing an audit, that provides a unique and lasting benefit to both the participant and their organization.