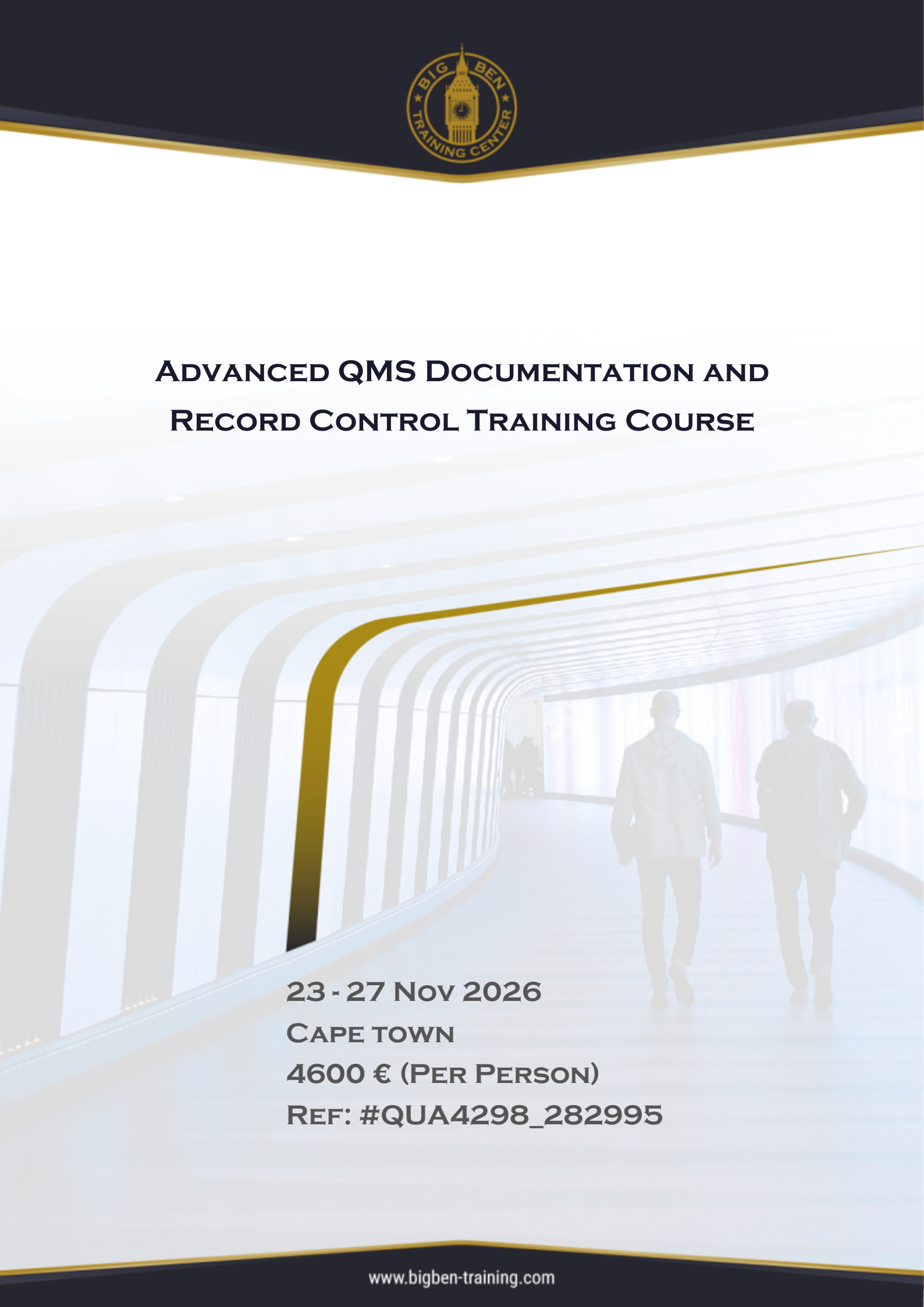
Advanced QMS Documentation and Record Control Training Course



23 - 27 Nov 2026

Cape town

4600 € (Per Person)

Ref: #QUA4298_282995

Course Introduction / Overview:

Effective documentation and record control are the backbone of any successful Quality Management System (QMS), providing the essential framework for consistency, compliance, and continuous improvement. This course offers a comprehensive exploration of the principles and practices required to manage QMS documentation and records in line with international standards like ISO 9001. It moves beyond mere compliance, teaching participants how to create a streamlined, efficient, and value-added documentation system. As the renowned quality guru W. Edwards Deming emphasized, a system cannot be understood or improved without proper documentation. This training program, offered by BIG BEN Training Center, delves into the complete document lifecycle, from creation and control to retention and disposition. Participants will gain practical skills in developing quality manuals, procedures, and work instructions, and learn to manage records as vital evidence of operational conformity. The course draws on established methodologies, similar to those discussed in works like "The Quality Toolbox," to equip professionals with the tools to build and maintain a robust documentation system that supports organizational goals, facilitates audits, and drives quality culture.

Target Audience / This training course is suitable for:

- Quality Assurance Managers and Professionals.
- Document Control Specialists and Coordinators.
- QMS Implementation Team Members.
- Internal and External Auditors.
- Compliance Officers and Managers.
- Operations and Production Managers.
- Process Owners and Department Heads.
- Anyone responsible for creating or managing QMS documentation.

Target Sectors and Industries:

- Manufacturing and Engineering.
- Healthcare and Pharmaceutical.
- Aerospace and Automotive.
- Information Technology and Software Development.
- Construction and Infrastructure.
- Energy and Utilities.
- Governmental agencies and public sector organizations.
- Consulting and professional services.

Target Organizations Departments:

- Quality Assurance and Quality Control.
- Operations and Production.
- Regulatory Affairs and Compliance.
- Research and Development.
- Engineering and Technical Services.
- Human Resources (for training records).
- Procurement and Supply Chain Management.
- Information Technology (for EDMS support).

Course Offerings:

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

- Develop and implement a compliant document control procedure.
- Establish a structured hierarchy for QMS documentation.
- Master document identification, distribution, and version control techniques.
- Differentiate between documents and records and manage each effectively.
- Create and manage a robust record control system.
- Define and apply appropriate document and record retention policies.
- Prepare documentation systems for successful internal and external audits.

- Identify and address common documentation-related non-conformities.
- Utilize risk-based thinking in documentation processes.
- Streamline documentation to improve efficiency and reduce waste.
- Evaluate and contribute to the selection of an Electronic Document Management System (EDMS).
- Drive continuous improvement within the documentation and record control system.

Course Methodology:

The training methodology at BIG BEN Training Center is designed to be highly interactive, practical, and engaging, ensuring that participants can immediately apply their learning in the workplace. This course moves beyond traditional lectures by incorporating a blended learning approach. We utilize a mix of expert-led presentations, real-world case studies, and interactive group workshops where participants can analyze and solve documentation challenges. Practical exercises, such as drafting procedures and creating record matrices, provide hands-on experience. Open discussions and Q&A sessions are encouraged to facilitate knowledge sharing and address specific participant queries. The course emphasizes collaborative learning through team-based activities, allowing professionals to benchmark their practices against others. Feedback is a continuous process, with instructors providing guidance and assessment throughout the sessions. Our approach ensures that participants not only understand the theoretical requirements of standards like ISO 9001 but also gain the practical skills and confidence to implement and manage an effective documentation and record control system within their own organizations.

Course Agenda (Course Units):

Unit One: Foundations of QMS Documentation

- Introduction to Quality Management Systems and the role of documentation.
- Understanding the requirements of ISO 9001 for documented information.
- The hierarchy of QMS documentation: quality manual, procedures, and work instructions.
- Differentiating between documents and records.
- Principles of Good Documentation Practices (GDP).
- The strategic importance of a well-maintained documentation system.
- Defining the scope and applicability of the QMS documentation.

Unit Two: Mastering Document Control

- Developing a robust document control procedure.
- Best practices for document creation, review, and approval.
- Techniques for effective document identification and numbering.
- Managing document distribution, access, and communication.
- Implementing a foolproof version control system.
- The process for managing document changes and revisions.
- Handling external documents and controlling their use.

Unit Three: Effective Record Management

- Establishing a comprehensive record control procedure.
- Methods for record identification, collection, and indexing.
- Ensuring record legibility, storage, and protection from damage.
- Best practices for record retrieval and access control.
- Developing and implementing a record retention and disposition schedule.
- Managing electronic records and ensuring data integrity.
- The role of records as evidence of conformity and for audits.

Unit Four: Auditing and Compliance for Documentation Systems

- Preparing the documentation system for an internal or external audit.
- Common non-conformities related to document and record control.
- How to conduct an effective audit of the documentation process.
- Developing corrective actions for documentation-related findings.
- Ensuring ongoing compliance with regulatory and standard requirements.
- The role of management review in overseeing the documentation system.
- Creating and maintaining an effective audit trail.

Unit Five: Advanced Strategies and Continuous Improvement

- Introduction to Electronic Document Management Systems (EDMS).
- Principles of lean documentation: reducing waste and improving efficiency.
- Applying risk-based thinking to documentation processes.
- Integrating documentation with other management systems.
- Using documentation as a tool for knowledge management and training.
- Metrics for measuring the effectiveness of the documentation system.
- Strategies for the continuous improvement of document and record control processes.

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, how can an organization leverage its QMS documentation system as a strategic asset for knowledge management and continuous improvement?

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

This course distinguishes itself by moving beyond a purely theoretical or compliance-driven approach to documentation and record control. While it thoroughly covers the requirements of international standards like ISO 9001, its core focus is on transforming the documentation system into a dynamic, value-adding business asset. Unlike other programs that may focus solely on procedural steps, this training emphasizes the strategic "why" behind the "what," empowering participants with critical thinking skills. We explore advanced concepts such as lean documentation to eliminate bureaucratic waste and risk-based thinking to focus efforts where they matter most. The curriculum is built on practical application, featuring hands-on workshops for drafting procedures and developing retention schedules, ensuring participants leave with tangible skills. Furthermore, the course content is designed to foster a mindset of continuous improvement, teaching attendees how to use their documentation system as a foundation for knowledge management, process optimization, and building a resilient quality culture, rather than viewing it as a static administrative burden.