Quality Management and Regulatory Compliance in R&D Training Course



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Berlin

5800 € (Per Person)

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Course Introduction / Overview:

For industries like pharmaceuticals, medical devices, and aerospace, quality management and regulatory compliance are not just legal requirements, they are critical to the success of every R&D project. This training course is designed to provide R&D managers, quality assurance professionals, and engineers with the tools and knowledge to integrate quality into every stage of the research and development lifecycle. It goes beyond a simple checklist of regulations to focus on building a proactive culture of quality that minimizes risk and accelerates product approval. We will explore how to implement quality systems, manage documentation, and prepare for regulatory audits from agencies like the FDA or EMA. The curriculum is informed by the foundational work of global academics like W. Edwards Deming, whose principles of total quality management have shaped industries worldwide. This program provides a clear blueprint for ensuring that your R&D efforts not only produce innovative products but also meet the highest standards of safety and compliance. BIG BEN Training Center is committed to empowering professionals to navigate the complex regulatory landscape and build quality into their DNA.

Target Audience / This training course is suitable for:

- R&D directors and managers.
- Quality assurance and control professionals.
- Regulatory affairs specialists.
- Engineers and scientists.
- Clinical research associates.
- Compliance officers.
- Project managers in regulated industries.

Target Sectors and Industries:

- Pharmaceutical and biotechnology.
- Medical device manufacturing.
- Aerospace and defense.
- Food and beverage.
- Automotive.
- Clinical research organizations.
- Government regulatory bodies.

Target Organizations Departments:

- Research and Development (R&D).
- Quality Assurance (QA).
- Regulatory Affairs.
- Engineering.
- Compliance.
- Manufacturing.
- Clinical Operations.

Course Offerings:

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

- Implement quality management systems (QMS) in an R&D setting.
- Ensure regulatory compliance throughout the R&D lifecycle.
- Prepare for and manage regulatory audits and inspections.
- Develop and maintain a robust documentation system.
- Understand and apply Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP).
- Conduct root cause analysis for quality deviations.
- Create a risk-based quality strategy.
- Build a proactive culture of quality and compliance.

Course Methodology:

This training course uses a highly interactive and case-based methodology to ensure participants gain practical, real-world skills in quality management and regulatory compliance. The program incorporates detailed case studies of companies that have faced significant compliance challenges and of those that have successfully navigated complex regulatory approval processes. We will use interactive workshops and mock audit simulations to practice critical skills like preparing for an inspection, responding to a quality deviation, and documenting a corrective action plan. The course includes a hands-on group project where participants will work together to create a full quality management plan for a fictional R&D project. BIG BEN Training Center believes that hands-on training is essential for mastering this complex field. Our expert facilitators will guide discussions and provide personalized feedback, ensuring that participants leave with the confidence and practical experience needed to lead their teams in a regulated environment.

Course Agenda (Course Units):

Unit One: Foundations of Quality in R&D

- The strategic importance of quality and compliance.
- Key regulatory bodies (e.g., FDA, EMA).
- Quality management systems (QMS).
- Risk-based quality management.
- Building a culture of quality.

Unit Two: Regulatory Compliance in the R&D Lifecycle

- Compliance in the discovery phase.
- Good Laboratory Practice (GLP).
- Compliance in the clinical and development phases.
- Good Manufacturing Practice (GMP).
- Documentation and data integrity.

Unit Three: Audits and Inspections

- Preparing for an internal and external audit.
- Common audit findings and how to avoid them.
- Responding to an audit observation.
- The role of the audit team.
- Best practices for a successful inspection.

Unit Four: Quality Tools and Techniques

- Root cause analysis.
- Change control management.
- Corrective and preventive actions (CAPA).
- Process validation.
- Quality metrics and performance measurement.

Unit Five: The Future of Quality and Compliance

- The impact of technology on quality management.
- Data analytics for quality control.
- Global harmonization of regulations.
- Ethical considerations in compliance.
- Developing a personal quality leadership roadmap.

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 R&D leaders balance the speed and creativity required for innovation with the methodical, often slow, processes required to ensure quality and regulatory compliance?

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

This training course is a highly specialized program that focuses on the unique and critical intersection of R&D and quality management, which sets it apart from generic compliance or quality control courses. We go beyond theoretical frameworks to provide a practical, hands-on learning experience through realistic case studies and interactive exercises. Our curriculum is tailored to address the specific needs of R&D professionals, providing them with the tools to embed quality into their work from the very beginning. The course distinguishes itself by emphasizing not only the technical skills needed to manage quality but also the leadership and cultural acumen required to foster a proactive mindset. By focusing on both the strategic and the practical aspects of quality and compliance, this program provides an invaluable skill set that is essential for any professional committed to a successful and responsible R&D career.