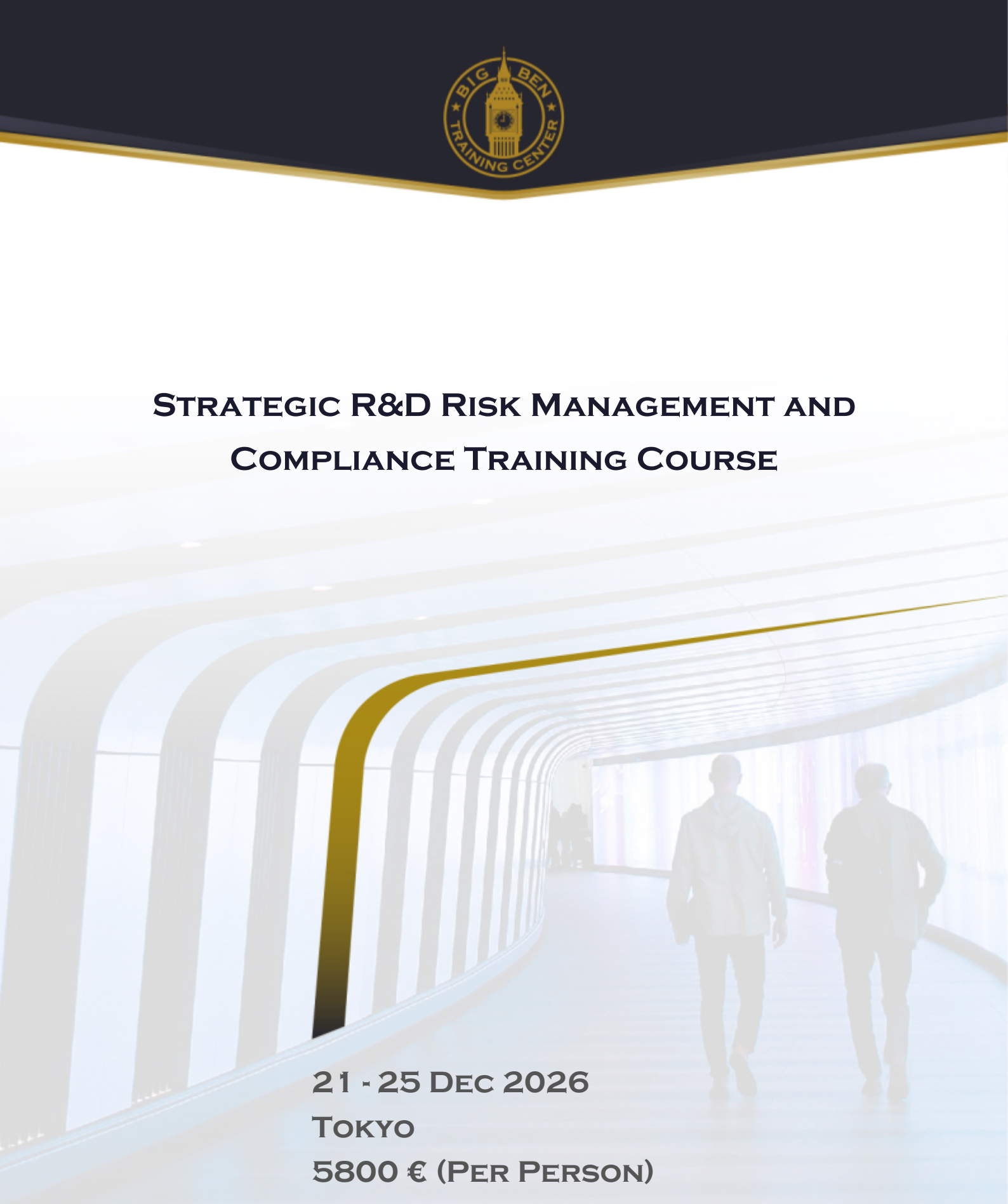
Strategic R&D Risk Management and Compliance Training Course



21 - 25 Dec 2026

Tokyo

5800 € (Per Person)

Ref: #RD4116_140271

Course Introduction / Overview:

In the dynamic and high-stakes world of research and development, the ability to innovate is directly linked to the ability to manage risk and navigate a complex web of compliance standards. This course provides a comprehensive framework for mastering the critical balance between fostering creativity and ensuring rigorous adherence to regulatory requirements. It moves beyond theoretical concepts to offer practical, actionable strategies for identifying, assessing, and mitigating risks throughout the entire R&D lifecycle. As highlighted by the renowned academic Dr. Robert G. Cooper in his seminal work, "Winning at New Products", a structured process is essential for success, and this principle extends deeply into risk and compliance management. This program, offered by BIG BEN Training Center, is meticulously designed to equip professionals with the tools to build robust R&D governance, protect intellectual property, and maintain impeccable data integrity. Participants will learn to transform compliance from a perceived obstacle into a strategic advantage, ensuring that innovation is not only groundbreaking but also safe, ethical, and commercially viable in a global marketplace. This training empowers organizations to de-risk their innovation pipeline and accelerate the journey from concept to market with confidence.

Target Audience / This training course is suitable for:

- Research and Development (R&D) Managers and Directors.
- Scientists, Engineers, and Researchers.
- Quality Assurance and Quality Control Professionals.
- Compliance Officers and Managers.
- Regulatory Affairs Specialists.
- Product Development and Project Managers.
- Internal Auditors involved in R&D processes.
- Legal Counsel and Intellectual Property (IP) Managers.
- Clinical Research Coordinators and Managers.
- Laboratory Managers and Supervisors.

Target Sectors and Industries:

- Pharmaceuticals and Biotechnology.
- Medical Device Manufacturing.
- Chemical and Materials Science Industries.
- Aerospace and Defense.
- Automotive and Engineering.
- Consumer Goods and Electronics.
- Information Technology and Software Development.
- Food and Beverage.
- Governmental research agencies and public-sector laboratories.
- Energy and Utilities.

Target Organizations Departments:

- Research and Development (R&D).
- Quality Assurance (QA) and Quality Control (QC).
- Regulatory Affairs.
- Legal and Intellectual Property (IP).
- Project Management Office (PMO).
- Clinical Operations and Development.
- Manufacturing and Operations.
- Internal Audit and Corporate Compliance.
- Product Management and Strategy.
- Information Technology (IT), particularly data governance teams.

Course Offerings:

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

- Develop a systematic process for identifying and categorizing risks across the R&D lifecycle.
- Apply qualitative and quantitative risk assessment techniques, such as FMEA and risk matrices.
- Navigate the complexities of key regulatory frameworks, including GxP, ISO standards, and FDA regulations.
- Design and implement effective risk mitigation and control strategies for R&D projects.
- Establish robust protocols for ensuring data integrity and protecting intellectual property.
- Create a strong R&D governance structure to oversee risk and compliance activities.
- Plan and conduct effective internal audits of R&D processes and systems.
- Integrate Quality by Design (QbD) principles into the product development process.
- Manage compliance during technology transfer and scale-up activities.
- Anticipate and prepare for emerging trends and future challenges in R&D compliance.

Course Methodology:

The training methodology at BIG BEN Training Center is designed to be highly interactive, engaging, and focused on practical application. We believe that adult learning is most effective when participants can directly relate new concepts to their professional challenges. This course moves beyond traditional lectures to incorporate a blended learning approach. Sessions will feature in-depth presentations grounded in current industry best practices, followed by dynamic group discussions and collaborative workshops. A significant portion of the training will be dedicated to analyzing real-world case studies, examining both successful R&D projects and instances of compliance failures to draw critical lessons. Participants will work in teams on practical exercises, such as developing a risk register for a hypothetical product or designing a compliance checklist for a clinical trial. These hands-on activities provide a safe environment to apply new skills and receive constructive feedback from the instructor and peers. The course fosters a participatory atmosphere where sharing experiences is encouraged, ensuring that the learning is not only comprehensive but also relevant and immediately applicable to the participants' work environments.

Course Agenda (Course Units):

Unit One: Foundations of R&D Risk and Compliance

- The Dual Imperative of Innovation and Control.
- Defining the Landscape of R&D Risk: Technical, Market, Financial, and Operational.
- Introduction to Global Compliance Frameworks and Regulatory Bodies.
- The Strategic Role of Risk Management in the R&D Value Chain.
- Understanding the Cost of Non-Compliance.
- Key Terminology and Concepts in Risk and Compliance.
- The Intersection of Corporate Governance and R&D Oversight.

Unit Two: Risk Identification and Assessment Methodologies

- Systematic Techniques for Proactive Risk Identification.
- Conducting Stakeholder Brainstorming and Expert Interviews.
- Introduction to Failure Mode and Effects Analysis (FMEA) for R&D.
- Developing and Utilizing Risk Assessment Matrices.
- Qualitative vs. Quantitative Risk Analysis Approaches.
- Creating and Maintaining a Comprehensive R&D Risk Register.
- Tools and Software for Supporting Risk Assessment.

Unit Three: Navigating the Regulatory and Compliance Maze

- Deep Dive into Good Laboratory, Clinical, and Manufacturing Practices (GxP).
- Understanding Key ISO Standards for R&D (e.g., ISO 9001, ISO 13485).
- Navigating FDA Regulations (e.g., 21 CFR Part 11 on Electronic Records).
- Intellectual Property (IP) Law and Protection Strategies.
- Ensuring Data Integrity and Cybersecurity in a Research Environment.
- Environmental, Health, and Safety (EHS) Compliance in Laboratories.
- International Harmonization and its Impact on R&D.

Unit Four: Risk Mitigation, Control, and Quality by Design

- Developing Effective Risk Mitigation and Contingency Plans.
- Implementing Robust Change Control Management Systems.
- Principles of Quality by Design (QbD) in Product and Process Development.
- Supplier and Vendor Risk Management in the R&D Supply Chain.
- Documentation Best Practices and Record-Keeping Requirements.
- Strategies for Protecting Trade Secrets and Proprietary Information.
- Crisis Management and Response Planning for R&D Incidents.

Unit Five: Governance, Auditing, and Future-Forward Compliance

- Establishing an Effective R&D Governance and Oversight Committee.
- Planning and Executing Internal R&D Compliance Audits.
- Techniques for Reporting and Communicating Risk to Senior Management.
- Fostering a Culture of Quality and Compliance within R&D Teams.
- Managing Risk During Technology Transfer and Commercialization.
- Emerging Trends: AI in R&D, Personalized Medicine, and New Regulations.
- Continuous Improvement and a Lifecycle Approach to Risk Management.

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:

As automation and AI increasingly influence R&D processes, how might traditional risk and compliance frameworks need to evolve to address novel ethical and data integrity challenges?

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

This course distinguishes itself by offering a holistic and strategic perspective that bridges the often-separate worlds of creative R&D and stringent compliance. While many programs focus on either innovation management or regulatory adherence, this training integrates them, treating compliance not as a barrier but as a critical enabler of sustainable innovation. Its core strength lies in its practical, application-focused methodology. Rather than merely reciting regulations, the curriculum is built around real-world case studies and hands-on workshops where participants actively develop risk registers, critique compliance strategies, and design mitigation plans. This emphasis on "learning by doing" ensures that skills are not just understood but mastered. Furthermore, the course is uniquely forward-looking, dedicating significant time to emerging trends like the impact of artificial intelligence on data integrity and the evolving global regulatory landscape. This prepares participants not only for current challenges but also for the future of R&D, equipping them to build resilient, adaptable, and ethically sound innovation ecosystems within their organizations. The focus is on developing strategic thinkers who can balance opportunity with oversight effectively.