



Product Regulatory Compliance for Product Managers Training Course



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Overview

Product Regulatory Compliance for Product Managers Training Course is a one-week course for product managers, product owners, portfolio leaders, and compliance partners who need a Product Compliance Decision File. The course connects product regulatory compliance, compliance risk management, roadmap governance, launch readiness, lifecycle monitoring, and retirement decisions across medical technology and industrial products. Participants convert obligations into requirements, evidence, gates, and accountable decisions. Agile Leaders Training Center frames product compliance governance as a product-management operating discipline.

Who Should Attend

- Functions responsible for product discovery, requirements, and roadmap decisions
- Teams responsible for portfolio governance and investment priorities
- Functions responsible for regulatory obligations and market access evidence
- Teams responsible for quality, legal, and compliance assurance
- Functions responsible for product launch, change, monitoring, and retirement

The course assumes participants already make or support product lifecycle decisions and leaves out introductory product management and basic compliance terminology.

Departments and Industries

The course supports departments and industries that must connect product decisions with applicable obligations and evidence.

- Product management, portfolio, and innovation functions
- Regulatory affairs, quality, legal, and compliance teams
- Engineering, operations, supply chain, and market-support functions
- Medical technology, diagnostics, and healthcare product organizations
- Industrial equipment, electronics, and consumer product companies

Learning Objectives

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



- Analyze product obligations and discovery constraints
- Apply ISO 37301:2021 to product governance interfaces
- Use ISO 31000:2018 to prioritize compliance risks
- Build traceable requirements and evidence ownership
- Evaluate launch, change, and corrective-action decisions
- Diagnose monitoring signals and retirement requirements

Course Agenda

Day 1: Obligations and Discovery

- Product Compliance Context and Obligation Map
- ISO 37301:2021 Product Governance Interface
- Market and Product Requirement Applicability Matrix
- Discovery Constraint and Assumption Log
- Product Compliance Stakeholder RACI

Day 2: Risk and Requirements

- ISO 31000:2018 Product Risk Assessment
- Compliance-Risk Backlog Prioritization Method
- Regulatory Requirement Acceptance Criteria
- Product Evidence Ownership Matrix
- Roadmap Compliance Dependency Map

Day 3: Roadmap and Launch Governance

- Product Compliance Stage-Gate Model
- Technical Documentation Evidence Index
- Labeling, Claims, and User Information Review
- Launch Compliance Readiness Checklist
- Product Release Decision Record

Day 4: Change and Market Monitoring

- Product Change Compliance Impact Assessment
- Traceability and Market Monitoring Plan
- Complaint and Safety Signal Triage Workflow
- Corrective Action and Recall Decision Method
- Product Retirement and Records Plan



Day 5: Product Compliance Practice

- Exercise: Obligation and Discovery Constraint Review
- Exercise: Compliance-Risk Backlog Prioritization
- Exercise: Launch Evidence and Decision Gate Test
- Exercise: Product Change and Safety Signal Assessment
- Capstone Exercise: Product Compliance Decision File

Practical Exercises

The course uses suggested activities that connect product choices with obligations, evidence, ownership, and escalation.

- Suggested activity: map discovery constraints for a connected healthcare product.
- Suggested activity: prioritize compliance risks for an industrial equipment roadmap.
- Suggested activity: test launch evidence for a consumer electronics release.
- Suggested activity: assess a product change, safety signal, and corrective-action decision.

FAQs

Who should attend product regulatory compliance training for product managers?

Product regulatory compliance training suits professionals responsible for discovery, requirements, roadmaps, launches, changes, monitoring, or retirement. It assumes experience making or supporting product lifecycle decisions.

How does product regulatory compliance training differ from general compliance management training?

Product regulatory compliance training centers on product decisions, requirements, evidence, launch gates, changes, monitoring, and retirement, while general compliance management training addresses the wider organizational compliance system.

How should product managers incorporate regulatory requirements into a roadmap?

Product managers should translate applicable obligations into acceptance criteria, evidence needs, accountable owners, dependencies, decision gates, and monitored assumptions linked to roadmap items.

What evidence supports product launch readiness?

Product launch readiness requires traceable requirements, technical evidence, reviewed labeling and claims, assigned obligations, resolved risks, approved exceptions, and a documented release decision.



How should product compliance risks be monitored after launch?

Product compliance risks should be monitored through complaints, safety signals, performance evidence, market feedback, changes, corrective actions, and documented decisions about continued availability or retirement.

Conclusion

The course integrates obligations, risk, requirements, evidence, roadmap gates, launch decisions, change assessment, monitoring, and retirement. Participants take back a Product Compliance Decision File linking each lifecycle choice to its basis, owner, evidence, and escalation path. The file gives product teams a traceable method for governing regulated decisions.



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