Non-Conforming Product and Hold-Release Procedures Training Course

Professional Development Training Course Outline

Category	Food processing and Technology	**Duration**	10 Days
Base Fee	$3,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

In today?ÇÖs competitive business environment, organizations must prioritize quality management and compliance standards to maintain customer trust and regulatory approval. Non-Conforming Product and Hold-Release Procedures Training Course provides an in-depth understanding of handling non-conforming products, implementing corrective actions, and managing release decisions in alignment with ISO standards and global best practices. This training enhances quality assurance, reduces risks of recalls, and strengthens operational efficiency while reinforcing compliance with industry requirements.

This course is designed to equip participants with the tools and strategies needed to identify, document, and resolve non-conformities effectively. With a strong emphasis on trending quality management practices, digital traceability, and risk-based thinking, the program empowers professionals to implement robust hold-release systems. Participants will gain hands-on experience through case studies and simulations that reflect real industry challenges, ensuring practical application in manufacturing, supply chain, and service industries.

Programme Curriculum

Non-Conforming Product and Hold-Release Procedures Training Course

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Course Objectives

1. Understand the fundamentals of non-conforming product management.
2. Apply ISO 9001 and ISO 13485 requirements to hold-release processes.
3. Develop effective documentation practices for non-conformities.
4. Implement risk-based decision-making in product release procedures.
5. Enhance traceability using digital quality management systems.
6. Identify root causes of non-conformities using trending problem-solving tools.
7. Apply lean quality practices to reduce process inefficiencies.
8. Establish communication protocols for handling non-conforming products.
9. Design preventive and corrective action plans.
10. Integrate regulatory compliance requirements in product hold-release.
11. Conduct internal audits on non-conformance management systems.
12. Apply data-driven decision-making in quality assurance.
13. Strengthen organizational culture around continuous improvement.

Organizational Benefits

- Improved compliance with international quality standards.
- Enhanced risk management strategies.
- Reduced product recalls and customer complaints.
- Strengthened market reputation through consistent product quality.
- Streamlined documentation and traceability systems.
- Increased operational efficiency across production and supply chains.
- Empowered workforce with modern quality management skills.
- Cost savings through effective non-conformance handling.
- Stronger stakeholder and customer confidence.
- Alignment with sustainable quality practices.

Target Audiences

- Quality Assurance Managers
- Regulatory Compliance Officers
- Production Supervisors
- Manufacturing Engineers
- Supply Chain Managers
- Internal Auditors
- Operations Managers
- Quality Control Technicians

Course Duration: 10 days

Course Modules

Module 1: Fundamentals of Non-Conforming Products

- Definition and classification of non-conforming products
- ISO 9001 requirements for non-conformance
- Common industry scenarios of product non-compliance
- Key challenges in quality management systems
- Documentation and record-keeping basics
- Case study: Mislabeling incident in pharmaceutical manufacturing

Module 2: Regulatory and ISO Standards

- ISO 9001 and ISO 13485 frameworks
- FDA and EU compliance guidelines
- Industry-specific quality regulations
- Risk-based approaches to compliance
- Legal implications of releasing non-conforming products
- Case study: Automotive sector regulatory breach

Module 3: Hold-Release Procedures

- Definition of hold-release procedures
- Roles and responsibilities in release authorization
- Documenting product status effectively
- Handling restricted products in warehouses
- Ensuring segregation and labeling accuracy
- Case study: Food industry hold-release process

Module 4: Root Cause Analysis Tools

- Fishbone diagram for problem-solving
- 5 Whys technique application
- Failure Mode and Effects Analysis (FMEA)
- Statistical process control methods
- Corrective and preventive action integration
- Case study: Root cause analysis in electronics industry

Module 5: Digital Quality Management Systems

- Role of automation in quality control
- Digital traceability tools and platforms
- Cloud-based documentation and reporting
- Advantages of real-time monitoring
- Implementing e-signatures for compliance
- Case study: Implementation of digital QMS in healthcare

Module 6: Risk Management in Non-Conformance

- Identifying and assessing risks
- Applying risk-based decision-making frameworks
- Preventing recurrence of product failures
- Integrating risk registers in quality processes
- Balancing compliance and business objectives

- Case study: Supply chain disruption analysis

Module 7: Corrective and Preventive Actions (CAPA)

- Key components of CAPA systems
- Best practices for corrective actions
- Preventive actions for long-term improvements
- CAPA integration in QMS
- Tracking and closing CAPA effectively
- Case study: CAPA implementation in manufacturing

Module 8: Internal Audits and Monitoring

- Objectives of internal audits
- Audit planning and execution
- Compliance audit tools and checklists
- Continuous monitoring systems
- Audit reporting and follow-up actions
- Case study: Audit findings in a medical device company

Module 9: Communication and Reporting Protocols

- Effective reporting of non-conforming products
- Escalation pathways in organizations
- Interdepartmental communication strategies
- Customer communication during product holds
- Crisis management during recalls
- Case study: Recall communication in consumer goods

Module 10: Lean and Six Sigma Approaches

- Application of lean tools in non-conformance handling
- Six Sigma DMAIC methodology
- Reducing waste and inefficiency
- Value stream mapping for quality processes
- Statistical improvement models
- Case study: Lean Six Sigma in packaging industry

Module 11: Supply Chain and Non-Conformance

- Identifying supplier non-conformities
- Supplier audits and monitoring
- Supply chain risk management strategies
- Collaboration with vendors for compliance
- Contractual obligations in quality management
- Case study: Supplier non-conformance in retail sector

Module 12: Documentation and Record Management

- Importance of documentation in audits
- Designing effective records for compliance
- Digital vs paper-based records

- Traceability and retention policies
- Confidentiality and data protection
- Case study: Document management in logistics

Module 13: Product Recalls and Risk Mitigation

- Recall management procedures
- Stakeholder involvement in recalls
- Risk mitigation strategies
- Legal consequences of recalls
- Lessons learned from past incidents
- Case study: International recall in food sector

Module 14: Building a Quality Culture

- Role of leadership in quality culture
- Training employees on quality compliance
- Encouraging continuous improvement mindset
- Recognition and rewards for compliance
- Embedding accountability in workflows
- Case study: Culture transformation in aerospace industry

Module 15: Continuous Improvement and Future Trends

- Importance of Kaizen and innovation
- Emerging technologies in quality management
- Data analytics for continuous improvement
- Artificial intelligence in quality assurance
- Future challenges and opportunities
- Case study: AI adoption in pharmaceuticals

Training Methodology

- Interactive instructor-led sessions
- Real-life case study discussions
- Group exercises and role plays
- Simulation of hold-release processes
- Hands-on workshops with documentation tools
- Knowledge assessments and feedback sessions

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call *+254769199797*

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
21 Sep 2026	02 Oct 2026	Online	$2,000
21 Sep 2026	02 Oct 2026	Physical	$3,000
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0

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