Advanced Real-Time Release Testing (RTRT) Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

The pharmaceutical and biopharmaceutical industries are undergoing a paradigm shift towards more efficient and quality-centric manufacturing, driven by regulatory advancements like ICH Q8, Q9, and Q10. At the forefront of this evolution is Advanced Real-Time Release Testing (RTRT). This innovative approach moves beyond traditional end-product testing by integrating Process Analytical Technology (PAT), Quality by Design (QbD), and advanced multivariate data analysis (MVDA) to evaluate and ensure product quality continuously during the manufacturing process. RTRT significantly enhances product assurance, allowing for immediate corrective action, dramatically reducing cycle times, and fostering a culture of continuous process verification (CPV). Mastery of Advanced RTRT is crucial for modern manufacturers seeking to achieve operational excellence, supply chain resilience, and accelerated time-to-market for life-saving medicines.

Advanced Real-Time Release Testing (RTRT) Training Course delves into the strategic implementation and technical validation of comprehensive RTRT control strategies. Participants will gain deep expertise in designing, qualifying, and maintaining the complex analytical and informatics systems required for successful, globally compliant RTRT adoption. Key areas covered include the selection and integration of in-line/on-line sensors, the development of robust chemometric models, and navigating the regulatory landscape for seamless health authority acceptance. By leveraging case studies from both small molecule and biologics manufacturing, the training equips professionals with the practical skills to lead their organizations' digital transformation of quality control and manufacturing operations, securing a competitive edge in the global biomanufacturing arena.

Programme Curriculum

Advanced Real-Time Release Testing (RTRT) Training Course

Introduction

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Course Duration

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Course Objectives

1. Master the ICH Q8(R2), Q9, and Q10 regulatory frameworks and their direct application to Real-Time Release (RTR) strategies.
2. Design robust, compliant, and defensible RTRT control strategies by integrating Quality by Design (QbD) principles.
3. Implement and validate various Process Analytical Technology (PAT) tools including in-line/on-line/at-line sensors (NIR, Raman, FTIR).
4. Develop and qualify advanced multivariate data analysis (MVDA) and chemometric models for predicting Critical Quality Attributes (CQAs).
5. Establish comprehensive model lifecycle management (MLM) and model maintenance programs for sustained RTRT performance.
6. Apply Quality Risk Management (QRM) methodologies to identify and mitigate risks associated with RTRT implementation and process control.
7. Integrate RTRT with Continuous Manufacturing (CM) and Industry 4.0 digital technologies for end-to-end quality assurance.
8. Evaluate the utility and challenges of utilizing Mass Spectrometry (MAMs) and other emerging analytical technologies for real-time biopharma release.
9. Prepare and defend regulatory submissions for RTRT to global health authorities like FDA and EMA.
10. Optimize manufacturing processes for operational flexibility and reduced cycle time through the utilization of real-time data and control loops.
11. Conduct successful RTRT system validation including software validation and ensuring data integrity (ALCOA+).

12. Calculate the return on investment (ROI) and operational benefits of transitioning from traditional Quality Control (QC) to a full RTRT strategy.
13. Lead cross-functional teams for seamless RTRT project implementation and cultural change management.

Target Audience

1. Quality Control (QC) and Quality Assurance (QA) Professionals.
2. Process Development and R&D Scientists.
3. Manufacturing and Operations Engineers.
4. Automation and IT/Data Scientists.
5. Regulatory Affairs Specialists.
6. Senior Management and Technical Directors.
7. Analytical Method Development Scientists.
8. Validation Specialists.

Course Modules

Module 1: Foundational Principles of RTRT and Regulatory Drivers

- Deep dive into the ICH Q8(R2) & Q11 framework
- Regulatory expectations for RTRT
- Key differences between traditional release, parametric release, and Real-Time Release.
- Case Study: Transitioning a traditional small molecule tablet process to RTRT.
- Establishing the business justification and ROI for an RTRT program.

Module 2: Advanced Process Analytical Technology (PAT) Selection

- Criteria for selecting in-line/on-line/at-line sensors based on CQA measurement requirements.
- Focus on advanced spectroscopic techniques.
- Non-spectroscopic PAT tools.
- Case Study: Selection and qualification of an in-line Raman system for a biopharma protein purification step.
- Challenges in sampling interfaces and ensuring representative data collection in-process.

Module 3: Chemometrics and Multivariate Data Analysis (MVDA) for RTRT

- Principles of MVDAfor establishing a chemometric model predictive of CQA.
- Data preprocessing techniques.
- Model calibration strategy.
- Case Study: Developing a PLS model for blend uniformity or moisture content in a high-shear granulation process.
- Interpreting model outputs for process control and troubleshooting.

Module 4: RTRT Control Strategy Design and Implementation

- Developing the comprehensive RTRT Control Strategy Document as per ICH Q10.
- Integrating MVDA model predictions with Advanced Process Control systems.
- Defining real-time acceptance criteria and establishing appropriate alarm and action limits.
- Case Study: Designing a dynamic feedback control loop for dissolution rate using an in-line PAT tool.
- Strategies for handling process excursions and non-conforming material in a real-time environment.

Module 5: Model Lifecycle Management (MLM) and Maintenance

- Developing a proactive MLM plan to ensure the model remains fit for purpose over the product lifecycle.
- Defining criteria and frequency for model monitoring
- Model revalidation strategies.
- Case Study: Long-term performance monitoring and required model adjustments for a lyophilization moisture content model.
- Change control and documentation requirements for MVDA model revisions.

Module 6: Regulatory Submission and Health Authority Interaction

- Key elements of a successful RTRT regulatory submission package
- Addressing health authority concerns.
- Strategies for effective communication and negotiation with FDA and EMA reviewers on RTRT proposals.
- Case Study: Analyzing common deficiencies and successful approval pathways for biologics RTRT applications.
- Global regulatory convergence and divergence in RTRT acceptance.

Module 7: RTRT in Continuous Manufacturing (CM)

- RTRT as an enabler for fully integrated continuous manufacturing processes.
- Developing a control strategy for dynamic sampling and steady-state monitoring in CM.
- Implementation of process trending and real-time process verification in a continuous environment.
- Case Study: Establishing RTRT for a continuous solid dosage manufacturing line.
- Inventory management and release of material from a continuous flow process.

Module 8: Biopharmaceutical RTRT Applications

- Specific CQAs in biomanufacturing amenable to RTRT
- Utilizing Mass Spectrometry for real-time monitoring of protein attributes.
- Challenges in real-time sterility assurance and microbial control.
- Case Study: Implementing an at-line system for glycosylation profiling in a bioreactor harvest sample.
- RTRT for upstream and downstream processes.

Module 9: System and Software Validation (GAMP 5)

- Compliance with GAMP 5 guidelines for PAT and MVDA software validation.
- Ensuring data integrity (ALCOA+) across the entire RTRT informatics chain.
- Validation of PAT instruments
- Case Study: Full system validation of a commercial MVDA software package integrated with a SCADA system.
- Audit trail requirements and electronic records compliance

Module 10: Process Robustness and Risk Management

- Applying ICH Q9 to the RTRT lifecycle.
- Using FMEA and other risk tools to identify potential failure modes in RTRT systems.
- Strategies for minimizing the risk of false-positives and false-negatives in real-time predictions.
- Case Study: Risk assessment for sensor failure and its impact on batch release decisions.
- Developing Contingency Plans and fallback strategies for RTRT system downtime.

Module 11: RTRT Project Management and Change Leadership

- Establishing a cross-functional RTRT implementation team
- Developing a detailed project plan, budget, and resource allocation for RTRT adoption.
- Overcoming cultural resistance to moving away from traditional QC testing methods.
- Case Study: Managing stakeholder expectations and communication during a multi-site RTRT rollout.
- Upskilling the workforce.

Module 12: Data Infrastructure and Digitalization

- Architecture for collecting, storing, and analyzing high-volume real-time data
- Role of Industrial Internet of Things (IIoT) and Cloud Computing in RTRT.
- Advanced visualization tools for monitoring real-time process performance and model health.
- Case Study: Designing a secure and compliant data pipeline from PAT sensors to the RTRT release decision system.
- Leveraging AI/Machine Learning for predictive maintenance of PAT equipment.

Module 13: Advanced Analytical Method Validation for PAT

- Specific requirements for validating PAT analytical methods
- Developing the transfer function and correlating PAT data to the reference method.
- Strategies for defining the operating range and detection limits of in-line sensors.
- Case Study: Validating an NIR method for Potency/Assay equivalence to a complex HPLC test.
- Maintaining the validation status during process changes and scale-up.

Module 14: Integrating RTRT with PQS and CPV

- Alignment of RTRT with the overall Pharmaceutical Quality System and ICH Q10.
- Using RTRT data to support the Continuous Process Verification lifecycle stage.
- RTRT as a driver for continual improvement and process optimization.
- Case Study: Utilizing long-term RTRT trending data to justify a Process Optimization Project.
- Impact of RTRT on deviation management and investigation processes.

Module 15: Future Trends and Emerging Technologies

- Full integration with AI and Digital Twins.
- Dielectric Spectroscopy, micro-sensors, and single-particle analysis.
- Implementing RTRT in Advanced Therapy Medicinal Products and personalized medicine.
- Case Study: Exploration of digital twin technology for simulating process variations and testing RTRT strategies.
- Sustainable manufacturing and the role of RTRT in reducing waste and energy use.

Training Methodology

The course employs an Interactive Blended Learning Approach designed for maximum comprehension and practical skill development:

- Expert-Led Lectures.
- Real-World Case Studies & Group Discussions.
- Hands-on Workshops & Software Demonstrations.
- Interactive QRM and Regulatory Simulation.
- Practical Tools & Templates.

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
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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