Advanced Biofilm Control in Bioprocessing 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

Biofilms complex microbial communities encased in a self-produced Extracellular Polymeric Substance (EPS) matrix are the most significant source of microbial contamination in cGMP bio manufacturing facilities. They lead to catastrophic batch failures, product safety concerns, and costly downtime for remediation, directly impacting the supply chain of critical therapeutics. Advanced Biofilm Control in Bioprocessing Training Course moves beyond standard cleaning protocols, offering an in-depth exploration of the latest scientific understanding of sessile cell physiology, quorum sensing (QS) dynamics, and the principles of Biofilm-Resistant Design. Attendees will master modern detection technologies, including Process Analytical Technology (PAT) for real-time monitoring, and learn to develop data-driven CAPA strategies that meet stringent FDA and EMA guidelines for microbial control.

This intensive, hands-on program equips engineers, microbiologists, and quality assurance specialists with the expertise to implement holistic contamination risk management systems. The curriculum emphasizes innovative solutions like enzymatic disruption, antimicrobial peptides, and surface modification techniques. By focusing on root cause analysis (RCA) and the validation of Cleaning-in-Place (CIP) and Sterilization-in-Place (SIP) cycles against mature biofilms, this course directly translates into reduced operational risk, enhanced process robustness, and increased facility throughput. Participants will leave prepared to champion a biofilm mitigation culture, ensuring the sustained sterility assurance level (SAL) of all critical bioprocess equipment.

Programme Curriculum

Advanced Biofilm Control in Bioprocessing Training Course

Introduction

Biofilms complex microbial communities encased in a self-produced Extracellular Polymeric Substance (EPS) matrix are the most significant source of microbial contamination in cGMP bio manufacturing facilities. They lead to catastrophic batch failures, product safety concerns, and costly downtime for remediation, directly impacting the supply chain of critical therapeutics. Advanced Biofilm Control in Bioprocessing Training Course moves beyond standard cleaning protocols, offering an in-depth exploration of the latest scientific understanding of sessile cell physiology, quorum sensing (QS) dynamics, and the principles of Biofilm-Resistant Design. Attendees will master modern detection technologies, including Process Analytical Technology (PAT) for real-time monitoring, and learn to develop data-driven CAPA strategies that meet stringent FDA and EMA guidelines for microbial control.

This intensive, hands-on program equips engineers, microbiologists, and quality assurance specialists with the expertise to implement holistic contamination risk management systems. The curriculum emphasizes innovative solutions like enzymatic disruption, antimicrobial peptides, and surface modification techniques. By focusing on root cause analysis (RCA) and the validation of Cleaning-in-Place (CIP) and Sterilization-in-Place (SIP) cycles against mature biofilms, this course directly translates into reduced operational risk, enhanced process robustness, and increased facility throughput. Participants will leave prepared to champion a biofilm mitigation culture, ensuring the sustained sterility assurance level (SAL) of all critical bioprocess equipment.

Course Duration

10 days

Course Objectives

Upon completion of this course, participants will be able to:

1. Differentiate the physiological and genetic characteristics of planktonic vs. sessile microbial states in a bioprocess context.
2. Apply advanced, non-destructive In-Situ Biofilm Detection methods, including ATP luminometry and Confocal Laser Scanning Microscopy (CLSM).
3. Evaluate and validate the effectiveness of CIP/SIP Cycles specifically against mature, multi-species biofilms.
4. Implement a robust Contamination Risk Assessment strategy for high-risk bioprocessing unit operations.
5. Design and integrate Biofilm-Resistant Surfaces and Aseptic Connection technologies into new and existing systems.
6. Analyze the molecular mechanisms of Quorum Sensing (QS) and explore Quorum Quenching (QQ) as a novel control strategy.
7. Select and optimize next-generation Anti-Biofilm Agents, such as enzymatic degraders and biosurfactants, for specific equipment materials.
8. Leverage Process Analytical Technology (PAT) and Multivariate Data Analysis (MVDA) for predictive, real-time Contamination Monitoring.
9. Conduct comprehensive Root Cause Analysis (RCA) for persistent microbial excursions and implement effective CAPA programs.
10. Ensure complete Regulatory Compliance with current FDA and EMA guidelines regarding Process Hygiene and Sterility Assurance.
11. Develop an effective Disinfectant Rotation plan to mitigate the risk of microbial resistance in a biomanufacturing environment.

12. Master the principles of Single-Use System (SUS) contamination control and end-to-end sterility maintenance.
13. Investigate the potential of emerging therapies, like Bacteriophage (Phage) Therapy and Nanotechnology, in biofilm eradication.

Organizational Benefit

- Significant Reduction in Batch Failures.
- Enhanced Regulatory Readiness.
- Optimized Operational Efficiency
- Extended Equipment Lifespan.
- Improved Product Safety and Quality.

Target Audience

1. Bioprocess Engineers and Manufacturing Scientists
2. Microbiology and Quality Control (QC) Analysts
3. Quality Assurance (QA) and Validation Specialists
4. Facilities and Utility Engineers
5. CIP/SIP and Equipment Cleaning Technicians/Supervisors
6. Research & Development (R&D) Scientists
7. Regulatory Affairs Professionals
8. Supply Chain and Vendor Management Personnel

Course Modules

Module 1: Foundational Biofilm Ecology and Bioprocess Relevance

- The life cycle of a biofilm: Initial attachment, maturation, and dispersal
- Structure and role of the Extracellular Polymeric Substance (EPS) matrix
- The critical physiological differences.
- Consequences in bioprocessing.
- Case Study: Analyzing a persistent Pseudomonas aeruginosa biofilm contamination in a bioreactor impacting a final drug product.

Module 2: High-Risk Areas and Biofilm-Prone Materials

- Identifying "dead legs," rough surfaces, seal interfaces, and gaskets as contamination hotspots.
- Material selection
- The role of fluid dynamics.
- Detailed review of high-purity water systems as primary vectors.
- Case Study: Mitigating biofilm formation in a pharmaceutical Water-For-Injection (WFI) Loop using flow optimization and sanitization frequency adjustments.

Module 3: Modern In-Situ Biofilm Detection Technologies

- Quantitative analysis using ATP Bioluminescence and its limitations in complex matrices.
- Principles and application of Confocal Laser Scanning Microscopy (CLSM) for 3D architecture visualization.
- Implementing Process Analytical Technology (PAT) probes for real-time, online monitoring.
- Advanced techniques.

- Case Study: A biomanufacturer uses a flow-cell sensor and online PAT to detect early-stage biofilm growth in a feed tank transfer line, preventing a batch infection.

Module 4: Optimizing Cleaning-in-Place (CIP) Validation

- The critical interplay
- Detergent chemistry.
- Riboflavin Tagging and other methods for demonstrating acceptable Surface Cleanliness.
- Designing and validating spray device coverage
- Case Study: Redesigning a vessel's CIP spray ball system after Riboflavin Mapping revealed inadequate coverage zones, leading to repeated microbial excursions.

Module 5: Sterilization-in-Place (SIP) and Heat Penetration

- Principles of Sterility Assurance Level (SAL) and the Bioburden Reduction goal.
- Effective steam sterilization.
- Thermal Mapping protocols.
- Validation documentation.
- Case Study: Analyzing a failed SIP validation in a lyophilizer, tracing the failure to a poorly designed steam trap that caused a persistent cold spot.

Module 6: Quorum Sensing (QS) and Novel Inhibition Strategies

- Understanding bacterial cell-to-cell communication and its role in biofilm maturity.
- Quorum Quenching (QQ).
- Development of small molecule inhibitors to block QS receptor sites.
- Translating QS/QQ research into practical, non-lethal industrial control measures.
- Case Study: A research pilot uses a novel Quorum Quenching enzyme to significantly delay the maturation and EPS production of a persistent Klebsiella pneumoniae biofilm.

Module 7: Next-Generation Anti-Biofilm Agents

- Enzymatic Disruption.
- Biosurfactants and their role in increasing surface tension and disrupting adhesion.
- Exploring the potential of Antimicrobial Peptides and other Host Defense Peptides
- Choosing the right agent.
- Case Study: Implementing an enzyme-based detergent as a pre-treatment step to enhance the efficacy of the standard chemical CIP in a tubular heat exchanger.

Module 8: Biofilm-Resistant Materials and Surface Engineering

- Mechanism of Anti-Adhesion Surfaces
- Strategies for Tethered Antimicrobials.
- The role of surface roughness, charge, and free energy in microbial colonization.
- Passivation and surface finish standards for cGMP surfaces.
- Case Study: Replacing a standard polymer O-ring with a low-surface-energy, anti-fouling material significantly reduced recurring contamination at a sampling port.

Module 9: Disinfectant and Sanitizer Rotation Programs

- The imperative for Disinfectant Cycling to prevent microbial tolerance and resistance.
- Classification of biocides.

- Validation of disinfectants
- Cleaning Agent Selection.
- Case Study: Developing a three-compound disinfectant rotation program that successfully eradicated a multi-drug resistant bacterial strain from a cleanroom floor biofilm.

Module 10: Microbial Risk and Single-Use Systems (SUS)

- Specific contamination risks in SUS.
- Validation of Gamma Irradiation and E-beam sterilization for SUS components.
- Best practices for Aseptic Connection and in-process sampling.
- Managing vendor qualification.
- Case Study: Investigating a process failure traced to a faulty sterile connector in a large-scale single-use bioreactor bag, leading to revised component testing protocols.

Module 11: Regulatory and Quality Systems (RCA and CAPA)

- FDA/EMA expectations
- Mastering the Root Cause Analysis (RCA) process for contamination events.
- Designing effective and sustainable Corrective and Preventive Actions (CAPA).
- Writing clear, defensible Out-of-Specification (OOS) investigation reports for microbial excursions.
- Case Study: Performing an RCA on a recurring fungal contamination in a fill-finish area, leading to a CAPA involving HEPA filter replacement and positive pressure adjustment.

Module 12: Advanced Process Analytical Technology (PAT)

- Integrating Real-Time Data into contamination control.
- Application of Multivariate Data Analysis (MVDA) for early warning of microbial deviations.
- Automated sampling systems and their role in reducing human-induced contamination.
- Using Spectroscopic Techniques for in-line bioprocess monitoring.
- Case Study: Implementing an automated Metabolic Profiling System that uses MVDA to predict a contamination event 24 hours before standard QC testing would have detected it.

Module 13: Facility Design and Aseptic Processing

- Principles of Zoning and Pressure Differentials for maintaining cleanroom integrity.
- HVAC system design.
- Aseptic gowning and Behavioral Risk Management in the cleanroom environment.
- Implementing Vaporized Hydrogen Peroxide (VHP) for room and isolator decontamination.
- Case Study: Evaluating the compliance of an Aseptic Processing Suite based on smoke studies and particle count data, identifying a critical design flaw near a material airlock.

Module 14: Emerging Technologies: Phage and Nanomedicine

- Bacteriophage Therapy.
- Nanotechnology.
- Electrochemical and Ultrasonic methods for biofilm dispersal
- Ethical and regulatory considerations for implementing novel biological controls.
- Case Study: Reviewing the successful use of a Phage Cocktail to eliminate a multi-drug resistant Staphylococcus biofilm on a pilot-scale fermentation system.

Module 15: Developing a Holistic Biofilm Mitigation Master Plan

- Integrating CIP/SIP Validation, RCA, and Disinfectant Rotation into a single program.
- Establishing a Preventive Maintenance (PM) schedule focused on biofilm-critical components.
- Creating a Standard Operating Procedure (SOP) for rapid response to contamination alerts.
- Training and Change Management for driving a facility-wide Process Hygiene Culture.
- Case Study: Developing a full Biofilm Control Master Plan for a new cell and gene therapy manufacturing facility from design to validation.

Training Methodology

The course employs an advanced, blended learning approach to ensure maximum knowledge retention and practical skill development:

1. Instructor-Led Presentations.
2. Interactive Workshops & Problem Solving.
3. Hands-On Simulations
4. Case Study Analysis.
5. Q&A/Expert Panel.

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

Ready to enroll or request a customized program? Book online or contact us:

Register Online Now

Email: info@fineskilltrainingcenter.com | Website: www.fineskilltrainingcenter.com