

Biodefense and Biosecurity in the Biotech Lab 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

In the age of Synthetic Biology and Rapid Genomic Sequencing, the Biotech Lab stands at the critical nexus of scientific progress and potential peril. The Dual-Use Dilemma where legitimate life sciences research could be repurposed for Bioterrorism or Biological Warfare has intensified the demand for rigorous Biorisk Management (BRM). This course addresses the urgent need to fortify Global Health Security by equipping personnel with Advanced Containment Strategies and a proactive Biosecurity Culture. We move beyond standard Biosafety Protocols to tackle the complex, intentional threats of unauthorized access, theft, or misuse of High-Consequence Biological Agents and Valuable Biological Materials (VBM). Participants will master the principles of Bio-Threat Reduction and Resilience Planning, essential for protecting laboratory assets, personnel, and national security from a spectrum of evolving Biothreats.

Biodefense and Biosecurity in the Biotech Lab Training Course is designed for immediate impact, transforming laboratory staff into informed Biosecurity Champions. Through a blend of theoretical knowledge and Real-World Case Studies, the curriculum provides mastery of Personnel Reliability Programs (PRP), Material Control & Accountability (MCA), and compliance with Select Agent Regulations. The focus is on establishing a Security-by-Design philosophy within BSL-3/BSL-4 Facilities and leveraging Next-Generation Surveillance technologies. By integrating Bioethical Governance with Cyber-Biosecurity best practices, this training ensures your organization maintains Regulatory Compliance and operational integrity against both traditional and emerging threats, securing the future of High-Risk Research.

Programme Curriculum

Biodefense and Biosecurity in the Biotech Lab Training Course

Introduction

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Course Duration

10 day

Course Objectives

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

1. Implement a comprehensive Biorisk Management system using the AMPER model.
2. Differentiate between Biosafety and Biosecurity and integrate their protocols.
3. Perform Threat, Vulnerability, and Risk Assessments (TVRA) specific to High-Consequence Biological Agents.
4. Master Material Control & Accountability (MCA) for tracking Valuable Biological Materials (VBM) from receipt to disposal.
5. Develop robust Personnel Reliability Programs (PRP) and insider threat mitigation strategies.
6. Analyze the Dual-Use Research of Concern (DURC) framework and establish effective oversight committees.
7. Ensure Regulatory Compliance with Select Agent Regulations and international conventions like the Biological Weapons Convention
8. Design laboratory security measures including Physical Security Systems and controlled access protocols for BSL-3/BSL-4 facilities.
9. Apply Cyber-Biosecurity principles to protect Genomic Data and intellectual property from digital threats.
10. Formulate comprehensive Emergency Response and Resilience Plans for biological spills, thefts, or intentional releases.
11. Evaluate the Bioethical Governance of emerging technologies such as Synthetic Biology and CRISPR gene editing.
12. Conduct internal Biosecurity Audits and Gap Analyses to continually enhance lab defense posture.
13. Integrate One Health surveillance concepts for early detection of Emerging Infectious Diseases (EID) and Zoonotic Spillover.

Target Audience

1. Research Scientists and Principal Investigators (PIs) in microbiology, virology, and synthetic biology.
2. Laboratory Directors and Managers responsible for facility operations and budget.
3. Biosafety Officers (BSOs) and Biosecurity Officers (BScOs) seeking advanced certification.
4. Facility Security Personnel and Physical Security Managers of high-containment laboratories.
5. Regulatory Affairs and Compliance Specialists dealing with Select Agents.
6. Public Health Officials and Emergency Responders involved in biological incident preparedness.
7. Government Officials and Policy Analysts in defense and health sectors.
8. Graduate Students and Post-Doctoral Fellows engaging in DURC.

Course Modules

Module 1: Foundations of Biorisk Management

- Biorisk, Biosafety and Biosecurity definitions.
- Introduction to the AMPER model
- Containment principles and BSL levels.
- Culture of Responsibility and ethical principles in the lab.
- WHO, OIE, and national regulatory landscapes.
- Case Study: Accidental SARS Release in Beijing ?Çô Failure of biosafety culture and containment.

Module 2: Threat, Vulnerability, and Risk Assessment

- Methodologies for identifying High-Consequence Biological Agents.
- Analyzing Adversary Capabilities and intentions
- Systematic identification of laboratory Vulnerabilities
- Quantifying risk and prioritizing mitigation strategies.
- Developing a facility-specific Biosecurity Risk Register.
- Case Study: The Sarin Gas Attack ?Çô Analyzing non-state actor motivation and delivery methods.

Module 3: Physical Security & Access Control

- Layered approach to Physical Security
- Design principles for high-containment facilities
- Implementing Controlled Access using biometrics, key card systems, and CCTV.
- Intrusion detection systems and surveillance technologies.
- Security of transport and transfer points.
- Case Study: USAMRIID Anthrax Thefts ?Çô Evaluating physical controls and insider access during a high-profile incident.

Module 4: Material Control & Accountability (MCA)

- Classification and inventory of Valuable Biological Materials
- Developing a secure, auditable Chain of Custody system.
- Tracking and inventory technology
- Procedures for material transfer, storage, and secure destruction/waste management.
- Annual inventory reconciliation and discrepancy resolution.
- Case Study: The Texas A&M Foot-and-Mouth Disease Samples Incident ?Çô Failure of inventory control and material tracking.

Module 5: Personnel Reliability Program & Insider Threat

- Defining the Insider Threat
- Personnel screening, vetting, and continuous evaluation processes.
- Strategies for building a positive Biosecurity Culture and reporting.
- Managing access to VBM and sensitive information
- Employee behavioral monitoring and crisis intervention.
- Case Study: Case of Dr. Thomas Butler ?Çô Analysis of insider behavior, theft, and legal consequences.

Module 6: Select Agent Regulations & Compliance

- Understanding the Select Agent and Toxin List (SATL) criteria.
- Registration, certification, and inspection procedures
- Security plans, incident response, and required drills.
- Record-keeping, reporting, and non-compliance penalties.
- International regulations and export control requirements.
- Case Study: NIH-Funded Research Non-Compliance Cases ?Çô Review of common regulatory violations and corrective actions.

Module 7: Dual-Use Research of Concern Governance

- Definition and identification of DURC criteria and experiments of concern.
- Establishing an institutional DURC oversight and review committee.
- Strategies for mitigating risks while promoting scientific freedom.
- Responsible communication of DURC results and data sharing policies.
- Role of scientific journals and publishers in DURC oversight.
- Case Study: H5N1 Gain-of-Function Research Controversy ?Çô Ethical debate and policy reaction to potential dual-use science.

Module 8: Cyber-Biosecurity & Data Protection

- The convergence of IT, OT, and biological systems.
- Securing Genomic Data, research records, and LIMS
- Protecting laboratory equipment from remote manipulation.
- Threats from Ransomware and espionage on biotech IP.
- Developing an integrated Cyber-Physical Security strategy.
- Case Study: Digital Theft of Pharmaceutical IP ?Çô Illustrating the financial impact of data breach in the biotech sector.

Module 9: Synthetic Biology & Emerging Biothreats

- Current and future capabilities of Synthetic Biology
- Genome Editing technologies and their dual-use potential.
- Screening protocols for synthetic DNA orders
- Rapid Diagnostic and Countermeasure development as a defense.
- Policy challenges of a decentralized, accessible biotechnology.
- Case Study: The Recreation of Horse Pox Virus ?Çô Examining the technical feasibility and ethical implications of synthetic virus creation.

Module 10: Transport Security & Export Control

- Compliance with IATA and DOT regulations for infectious substances.
- Proper packaging, labeling, and documentation for Category A and B agents.

- Security procedures during domestic and international transport.
- Developing Contingency Plans for transport accidents or theft.
- Understanding Export Control licensing for biological materials and technology.
- Case Study: Anthrax Letters ?Çô Failure of postal system security and the consequences of agent misuse in transport.

Module 11: Emergency Response & Crisis Management

- Developing a detailed Biological Incident Response Plan
- Effective internal and external Risk Communication strategies during a crisis.
- Protocols for post-incident clean-up, decontamination, and forensic sampling.
- Interagency Cooperation
- Psychological first aid and personnel resilience planning.
- Case Study: The Ebola Outbreaks ?Çô Analyzing the public health security response and coordination challenges.

Module 12: Bioethical Governance and Responsible Conduct

- Ethical obligations of life scientists in the Dual-Use context.
- Principles of Responsible Research and Innovation
- The role of Institutional Biosafety Committees and their mandate.
- Handling issues of conflicts of interest and academic freedom.
- Promoting a culture of transparency and accountability.
- Case Study: He Jiankui?Çôs CRISPR Babies Experiment ?Çô Reviewing failure of ethical oversight and international reaction.

Module 13: Audit, Inspection, and Continuous Improvement

- Conducting internal Biosecurity Audits and self-assessments.
- Preparing for external regulatory inspections and gap analyses.
- Developing Corrective and Preventive Actions
- Performance measurement and metrics for the BRM system.
- Documentation control and training refreshment cycles.
- Case Study: WHO Laboratory Audit Failures ?Çô Lessons learned from documented breaches and subsequent systemic fixes.

Module 14: Zoonotic Threats and One Health Security

- Understanding the risk of Zoonotic Spillover and Emerging Infectious Diseases
- The One Health concept.
- Surveillance methods for pathogen detection in the environment and animals.
- Agricultural Biosecurity and its link to laboratory risk.
- Policies for handling animal biosafety levels
- Case Study: COVID-19 Pandemic Origin Debate ?Çô Emphasizing the need for robust lab security and zoonotic threat tracking.

Module 15: Policy & Future of Biodefense

- Analysis of national Biodefense Strategies and funding priorities.
- The role of the Biological Weapons Convention in global security.
- Policy implications of CRISPR and Gene Drive technology.

- Future trends in Bio-Threat Intelligence and countermeasure development.
- Advocacy for global Biosecurity Harmonization and cooperation.
- Case Study: The Sverdlovsk Anthrax Leak ?Çô Political cover-up and the critical need for international verification.

Training Methodology

The course utilizes a Blended Learning approach focused on Competency-Based Training (CBT):

- Interactive Lectures & Workshops.
- Simulation & Role-Playing.
- Case Studies
- Practical Demonstrations.
- Tabletop Exercises.

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

- The participant must be conversant with English.
- Upon completion of training the participant will be issued with an Authorized Training Certificate
- Course duration is flexible and the contents can be modified to fit any number of days.
- The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.
- One-year post-training support Consultation and Coaching provided after the course.
- 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

Start Date	End Date	Location	Price
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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