Agricultural Biotechnology and GMO Regulation 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 an era defined by global food security and the imperative of sustainable agriculture, the field of Agricultural Biotechnology stands as a pivotal driver of innovation. This technology, encompassing genetic engineering and modern breeding techniques, offers unprecedented solutions to address critical challenges like climate-resilient crops, pest resistance, and enhanced nutritional value. The ability to precisely modify crop genomes has unlocked higher yields and reduced reliance on chemical inputs, promising a greener, more efficient food production system. However, this transformative power is intrinsically linked to complex, often divergent, GMO Regulation frameworks worldwide.

The increasing adoption of Genetically Modified Organisms (GMOs) and new tools like CRISPR-Cas9 gene editing necessitate a robust understanding of both the underlying science and the intricate biosafety and regulatory compliance landscape. International agreements such as the Cartagena Protocol on Biosafety and national food and environmental safety laws create a highly technical and dynamic environment. Professionals must be equipped to navigate risk assessment, manage co-existence with conventional agriculture, interpret food labeling requirements, and engage in informed stakeholder communication to ensure the responsible and ethical commercialization of these vital technologies. Agricultural Biotechnology and GMO Regulation Training Course is specifically designed to bridge the gap between scientific advancement and regulatory mastery.

Programme Curriculum

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Course Objectives

The course is designed to equip participants with a comprehensive understanding of the scientific, regulatory, and socio-economic dimensions of agricultural biotechnology and GMOs.

1. Differentiate modern gene-editing techniques from classical genetic engineering.
2. Evaluate the role of Biotechnology in achieving Global Food Security and Sustainable Development Goals
3. Analyze the scientific principles and applications of Recombinant DNA Technology in crop improvement.
4. Interpret the scope and obligations of the Cartagena Protocol on Biosafety and its impact on international trade.
5. Master the process of GMO Risk Assessment, covering environmental, human, and animal health aspects.
6. Assess and manage risks related to Gene Flow and the Co-existence of GM and non-GM crops.
7. Identify and compare the diverse National Regulatory Frameworks for GMO approval
8. Formulate strategies for Public Engagement and effective Risk Communication regarding biotech products.
9. Examine the complexities of Intellectual Property Rights (IPR) and Patent Landscape in Ag-Biotech.
10. Discuss the Socioeconomic Impact of GMO adoption on Smallholder Farmers and global markets.
11. Understand the regulatory status and implications of New Breeding Techniques (NBTs) and their differentiation from traditional GMOs.
12. Apply principles of Molecular Diagnostics for the detection and traceability of GM products.
13. Debate the key Ethical and Labeling considerations surrounding biotech-derived foods and crops.

Target Audience

1. Regulatory Affairs Specialists
2. R&D Scientists and Plant Breeders
3. Government Policy Makers and Biosafety Officials
4. Trade and Export/Import Compliance Managers

5. Agricultural Extension Officers
6. Legal Professionals specializing in IPR and Ag-Law
7. NGO and Civil Society Representatives focused on food and environment
8. Corporate Communications and Public Relations Managers in Agribusiness

Course Modules

1. Fundamentals of Agricultural Biotechnology

- Overview of classical breeding vs. modern Genetic Engineering.
- Key components of Recombinant DNA Technology
- Understanding the mechanism of Agrobacterium-mediated transformation.
- Different generations of biotech crops
- Case Study: Development and global adoption of Bt Cotton and its impact on pesticide use.

2. Advanced Genome Editing Technologies

- In-depth science of CRISPR-Cas9, TALENs, and ZFNs.
- Mechanism of action and distinction between SDN-1, SDN-2, and SDN-3 categories.
- The concept of New Breeding Techniques (NBTs) and their products.
- Regulatory challenges in distinguishing NBTs from traditional GMOs.
- Case Study: Using CRISPR to develop drought-resistant corn and the policy debate in different jurisdictions.

3. Global GMO Regulatory Landscape

- Comparison of major regulatory approaches
- Analysis of the USA's Coordinated Framework and the EU's Directive 2001/18/EC.
- Regulatory frameworks in major exporting nations.
- Challenges posed by Asynchronous Approvals and their effect on global trade.
- Case Study: The prolonged approval of a new GM soybean variety and trade blockages with the EU.

4. The Cartagena Protocol on Biosafety

- Core principles, objectives, and scope of the international agreement.
- Advance Informed Agreement procedure for transboundary movement of Living Modified Organisms
- The role of the Biosafety Clearing-House in information exchange.
- Review of documentation requirements for export/import of LMOs.
- Case Study: A developing country invoking the Precautionary Principle to halt a GM crop import.

5. Environmental Risk Assessment (ERA)

- Methodology and tiered approach for conducting a robust ERA.
- Assessment of potential impacts on non-target organisms.
- Risk evaluation of gene flow to wild relatives and development of superweeds.
- Post-release monitoring and surveillance protocols.
- Case Study: The environmental monitoring program for GM canola in Canada to manage gene flow.

6. Food and Feed Safety Assessment

- The concept of Substantial Equivalence and its application in risk analysis.
- Assessing the potential for Toxicity and Allergenicity of new proteins.

- Nutritional composition analysis and comparison with the conventional counterpart.
- Protocols for animal feeding studies and long-term health monitoring.
- Case Study: FDA and EFSA review of Golden Rice for its safety and nutritional benefits

7. Co-existence and Contaminant Management

- Defining Co-existence and its significance for conventional and organic farming.
- Policy measures and practical strategies for segregation and minimizing commingling.
- Liability and redress mechanisms for adventitious presence (AP) of GM material.
- Technical methods for Identity Preservation (IP) and seed-to-shelf traceability.
- Case Study: German and Spanish national rules for the distance between GM and non-GM maize fields.

8. Intellectual Property Rights (IPR) in Ag-Biotech

- Types of IPR protection for biotech products: Patents for genes/traits and Plant Variety Protection (PVP).
- Understanding and navigating Freedom to Operate (FTO) analyses.
- Licensing agreements, Technology Use Agreements, and seed saving policies.
- Ethical and access issues related to the patenting of life forms.
- Case Study: Monsanto and Bowman case on patent infringement and the saving of patented seeds.

9. Socioeconomic and Ethical Considerations

- Impact of biotech crops on Smallholder Farmers and income disparity.
- Debate over Seed Monopoly and access to technology in developing nations.
- Philosophical and religious perspectives on Genetic Modification.
- The role of biotechnology in achieving Sustainable Agriculture and addressing climate change.
- Case Study: Socioeconomic impact analysis of Bt brinjal introduction in South Asia.

10. Public Perception and Science Communication

- Understanding the factors driving Public Acceptance and Resistance to GMOs.
- Strategies for effective and transparent Risk Communication.
- Addressing misinformation, fear, and anti-biotech campaigns in the media.
- Building trust with consumers, civil society, and stakeholders.
- Case Study: Handling public backlash following the unauthorized discovery of a GM rice line in a non-GM supply chain.

11. GMO Detection and Traceability

- Methods for Molecular Diagnostics for GMO detection.
- Reference materials and standards for quantitative and qualitative analysis.
- Setting thresholds and Labeling Regulations for mandatory and voluntary GMO labeling.
- Developing robust supply chain traceability systems.
- Case Study: Implementing China?ÇÖs mandatory labeling regime and its technical and trade implications.

12. Biotechnology in Animal and Microbe Agriculture

- Applications of Biotechnology in Livestock
- Regulation of Genetically Engineered Animals
- Use of microbial biotech in farming.
- Regulatory oversight for new biotech inputs beyond crop varieties.

- Case Study: The regulatory pathway for approval of AquaAdvantage salmon

13. Regulatory Trends and Future of Ag-Biotech

- Global push for differentiated regulation of CRISPR-edited products.
- Emerging issues in Synthetic Biology and its agricultural applications.
- The potential of RNA interference in pest control.
- Regulatory considerations for Climate-Resilient Crops development.
- Case Study: Analysis of the UK's post-Brexit approach to New Breeding Techniques regulation.

14. National Biosafety System Development

- Components of a functional National Biosafety Framework
- Establishing and operating a National Biosafety Committee
- Capacity building for scientific risk assessors and regulators in developing countries.
- Integration of biosafety regulations into existing national laws
- Case Study: The process of South Africa developing its comprehensive biosafety law and its regional influence.

15. Risk Management and Crisis Scenarios

- Developing and implementing a Biosafety Emergency Response Plan.
- Procedures for the safe conduct of Confined Field Trials.
- Strategies for product recall and managing non-compliant GM presence.
- Best practices for internal and external Crisis Communication.
- Case Study: A simulated crisis scenario involving the accidental release of an unapproved GM research line.

Training Methodology

The course will utilize a highly interactive, blended learning approach to ensure practical mastery and deep understanding of complex topics:

- Expert-Led Lectures.
- Case Studies and Debates.
- Interactive Workshops
- Practical Demonstrations.
- Panel Discussions.

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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