

Ethical and Social Issues in Genetic Engineering 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 rapid evolution of Biotechnology and Genome Editing tools, particularly CRISPR-Cas9, has unlocked unprecedented power to manipulate life, offering transformative potential in human health, agriculture, and sustainability. This progress, however, is deeply entangled with complex Bioethical Dilemmas and profound Societal Implications that demand rigorous, informed engagement. From the specter of Germline Editing and Designer Babies to issues of Equitable Access and Biodiversity protection, the moral compass of scientific innovation is being tested. Professionals, policymakers, and the public must cultivate a shared Ethical Framework to navigate this revolutionary landscape and ensure that Genetic Technologies are applied for the good of all, rather than exacerbating existing Social Inequality.

Ethical and Social Issues in Genetic Engineering Training Course provides a critical, comprehensive analysis of the Socio-ethics of Genetic Engineering, moving beyond the scientific capabilities to address the essential questions of Moral Responsibility and Responsible Innovation. Participants will explore fundamental ethical theories, dissect modern regulatory challenges like Genetic Privacy and Intellectual Property, and develop the Critical Thinking and Accountability skills necessary to lead with integrity in the age of gene editing. The goal is to establish a culture of Ethical Stewardship within the biotechnology sector, promoting Global Governance and transparent Public Engagement to steer the future of these powerful tools toward a Just and Sustainable world.

Programme Curriculum

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Introduction

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Course Objectives

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

1. Analyze the Bioethical Frameworks governing the development of CRISPR-Cas9 and next-generation gene-editing tools.
2. Differentiate between Somatic and Human Germline Editing and evaluate the Intergenerational Consequences of heritable genetic changes.
3. Evaluate the risks of Genetic Discrimination and the societal threat of a Two-Tier Healthcare System resulting from unequal access.
4. Debate the core ethical tension between Therapeutic Gene Editing and Genetic Enhancement
5. Apply the principles of Informed Consent and Autonomy in complex scenarios involving vulnerable populations and experimental therapies.
6. Assess the Environmental Impact of Genetically Modified Organisms (GMOs) and Gene Drives on Biodiversity and ecosystem stability.
7. Identify and mitigate the molecular risks of Unintended Consequences, such as Off-Target Effects and Mosaicism, in clinical trials.
8. Formulate strategies to address Distributive Justice and promote Equitable Access to life-saving genetic technologies globally.
9. Examine the complexities of Gene Patenting and Intellectual Property rights over biological materials and genetic data.
10. Discuss the role of Participatory Governance and public dialogue in shaping Biotechnology Policy and regulatory oversight.
11. Develop an organizational culture of Responsible Innovation and scientific transparency to enhance public trust.
12. Compare and contrast the varying Global Governance Challenges and national regulations concerning human genome editing.
13. Communicate complex genetic and ethical concepts effectively for transparent Science Communication and stakeholder engagement.

Target Audience

1. Biotechnology Researchers & Scientists:
2. Pharmaceutical and Biotech Executives:
3. Medical & Healthcare Practitioners
4. Policymakers and Regulators
5. Bioethics and Philosophy Students/Scholars.
6. Legal Professionals
7. Journalists and Science Communicators.
8. Patient and Disability Advocates

Course Modules

Module 1: The Foundations of Genetic Power

- Defining Genetic Engineering.
- Core Bioethical Principles.
- Technological Capabilities and Ethical Boundaries.
- Introduction to Somatic and Germline Editing and the threshold of heritability.
- Case Study: The discovery and initial public reaction to recombinant DNA technology

Module 2: The CRISPR Revolution and Safety

- Mechanism of CRISPR-Cas9 and its unparalleled precision and accessibility.
- Off-Target Effects, Mosaicism, and unintended genomic changes.
- Precautionary Principle.
- Ethical duty to monitor and disclose long-term Unintended Consequences.
- Case Study: Analysis of early-phase CRISPR clinical trials for sickle cell disease, focusing on safety and adverse event reporting.

Module 3: Human Germline Editing (HGE)

- The profound ethical debate surrounding heritable genetic changes.
- Intergenerational Consequences.
- Global consensus and the call for a mandatory, sustained moratorium on HGE.
- Regulatory challenges of enforcing national and international bans.
- Case Study: The He Jiankui case and the global scientific fallout from unauthorized germline modification.

Module 4: The Enhancement and Therapy Divide

- Drawing the Blurring Line between medical treatment and Genetic Enhancement.
- The ethics of seeking Non-Therapeutic traits
- Impact on social norms, human nature, and the value of human life.
- Philosophical debate on Human Dignity and the concept of a 'programmable' entity.
- Case Study: Discussion on gene editing to eliminate the gene for deafness is it a cure or an attack on Deaf culture?

Module 5: Genetic Discrimination and Privacy

- Defining Genetic Discrimination in employment, insurance, and social contexts.
- The need for robust Genetic Privacy and data protection protocols.

- Policy solutions: Review of the Genetic Information Nondiscrimination Act (GINA) and its limitations.
- Protecting vulnerable populations from coercion and genetic profiling.
- Case Study: Hypothetical scenario of an employer demanding genetic screening data to assess future health risk.

Module 6: Equitable Access and Distributive Justice

- Addressing Access Inequality and the risk of creating a Genetic Underclass.
- The high cost of Precision Medicine and specialized Gene Therapy delivery.
- Moral obligation for Affordable Solutions and global resource distribution.
- Examining the role of public funding and pharmaceutical pricing in equity.
- Case Study: Comparative analysis of access to gene therapies for β -thalassemia or sickle cell anemia in high-income and low-income countries.

Module 7: Informed Consent and Vulnerability

- The complexity of achieving truly Informed Consent in cutting-edge, experimental trials.
- Consent challenges for non-autonomous individuals
- The concept of Uncertainty in genetic outcomes and its disclosure to patients.
- Ensuring transparency and avoiding technical jargon and therapeutic misconception.
- Case Study: The ethical process for enrolling a pediatric patient in an experimental in vivo gene therapy trial.

Module 8: GMOs and Agricultural Bioethics

- The ethics of creating Genetically Modified Organisms for pest resistance and yield.
- Concerns over Monoculture, seed dependence, and Corporate Control of the food supply.
- Debating mandatory Labeling and consumer's right to know.
- Risk of Gene Flow and unintentional transfer to wild-type species.
- Case Study: The controversy surrounding Bt-cotton in developing nations, focusing on economic and ecological impact.

Module 9: Gene Drives and Environmental Ethics

- The mechanism and power of Gene Drives for permanent species alteration
- The ethical concept of Ecological Responsibility and "playing God."
- Potential for irreversible damage to Biodiversity and ecosystem balance.
- Need for controlled release protocols and public involvement in field testing.
- Case Study: Proposals for using gene drives to eradicate invasive species or malaria-transmitting mosquitos, analyzing the risk/benefit to the entire ecosystem.

Module 10: Animal Welfare and Xenotransplantation

- Ethical status of animals in genetic research
- The moral responsibility concerning Animal Suffering from genetic modifications.
- Xenotransplantation.
- Debate over the creation of Transgenic animals and changes to their intrinsic worth.
- Case Study: The use of genetically modified pigs to harvest organs for human transplant, and the Zoonotic Disease risks involved.

Module 11: Patenting Life and Intellectual Property

- The ethics and legality of patenting genes, cell lines, and engineered organisms.
- Impact of IP Rights on access to research and affordability of treatments.
- The historical shift from discovery-based to invention-based patent eligibility.
- Balancing the incentive for innovation with the public good.
- Case Study: The legal history of gene patenting and its effect on diagnostics.

Module 12: Regulatory Frameworks and Global Governance

- Overview of national regulatory approaches
- The need for Harmonized International Standards and collaboration.
- Challenges of Fragmented Governance and 'ethics shopping' between countries.
- The role of international bodies like UNESCO and WHO in setting norms.
- Case Study: Comparing the restrictive regulatory approach to human cloning vs. the evolving stance on somatic gene therapy.

Module 13: Responsible Innovation and Organizational Culture

- Implementing Ethical Impact Assessments (EIA) in research and development.
- Fostering a culture of Accountability and ethical leadership.
- Managing Conflicts of Interest in academic and industry research.
- Strategies for proactive engagement with ethicists and social scientists.
- Case Study: Developing an internal ethics charter for a biotech startup focused on genetic sequencing and data storage.

Module 14: Public Engagement and Science Communication

- Methods for Transparent and effective Science Communication on complex topics.
- Strategies for combating Misinformation and fostering public trust.
- The importance of Participatory Governance
- Understanding and addressing Religious and Cultural Objections to genetic manipulation.
- Case Study: Developing a public outreach campaign to explain the risks and benefits of mRNA Vaccines and their underlying genetic technology.

Module 15: Ethical Decision-Making Workshop

- Scenario-based training using complex, multi-stakeholder ethical dilemmas.
- Practicing the application of Utilitarianism and Deontology in a final judgment.
- Developing a personal and organizational Ethical Action Plan.
- Techniques for leading effective Ethical Dialogue within a professional team.
- Case Study: A comprehensive capstone simulation involving a scientist seeking approval for a Gene Drive release in a sovereign nation.

Training Methodology

The course will employ a dynamic, blended methodology designed for maximum engagement and practical application:

- Interactive Lectures & Discussions.
- Case Study Analysis.
- Ethical Role-Playing.
- Group Policy Drafting.
- Expert Guest Speakers.

Register as a group from 3 participants for a Discount

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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 commencement 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

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