Immunogenicity Assessment of Biologics 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

Immunogenicity assessment of biologics plays a crucial role in the development and safety evaluation of biologic drugs, ensuring their efficacy and minimizing adverse immune responses. With increasing global demand for biologics, it is essential for pharmaceutical and biotechnology professionals to acquire advanced skills in immunogenicity testing, regulatory compliance, and risk assessment. Immunogenicity Assessment of Biologics Training Course equips professionals with the latest tools, techniques, and methodologies to assess the immunogenic potential of biologic products throughout their lifecycle. By exploring state-of-the-art approaches in bioanalytical methods, immunoassays, and regulatory standards, participants will gain comprehensive knowledge needed to address the immunogenicity challenges in biologic development.

As biologics become a larger part of the pharmaceutical landscape, understanding immunogenicity is more vital than ever. This course also emphasizes the application of Quality by Design (QbD) principles for continuous manufacturing in biologics, ensuring better quality control and process optimization. Participants will learn to implement these methodologies to enhance product quality and reduce costs in manufacturing processes. By focusing on trending concepts like biosimilars, novel biologics, and continuous manufacturing systems, the course offers a practical approach to overcoming common obstacles in biologic development and manufacturing, aligning with both regulatory and industry standards.

Programme Curriculum

Immunogenicity Assessment of Biologics Training Course

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Course Duration

10 days

Course Objectives

1. Comprehend the role of immunogenicity in biologic drug development and its implications for safety.
2. Understand the regulatory requirements for immunogenicity testing of biologics.
3. Develop proficiency in bioanalytical methods used for immunogenicity testing.
4. Analyze immune responses induced by biologics and assess their clinical relevance.
5. Master the application of highly sensitive immunoassays for detecting anti-drug antibodies.
6. Integrate Quality by Design (QbD) principles to optimize biologics manufacturing.
7. Learn how to implement continuous manufacturing systems in biologic production.
8. Apply strategies for minimizing immunogenicity risk in the design phase of biologics.
9. Gain insight into biosimilars and their immunogenicity concerns.
10. Understand the global regulatory landscape for biologics and biosimilars.
11. Evaluate the impact of process variations on immunogenicity.
12. Assess the immunogenicity testing guidelines set by major health authorities like the FDA and EMA.
13. Explore the future of biologics and potential immunogenicity challenges in emerging therapies.

Target Audience

1. Pharmaceutical professionals.
2. Biotechnology researchers.
3. Regulatory affairs experts.
4. Clinical researchers.
5. Manufacturing engineers.
6. Quality control/assurance professionals in the biologics industry.
7. Regulatory compliance officers in the biopharma sector.
8. Product managers and developers in biologics companies.

Course Modules

Module 1: Introduction to Immunogenicity of Biologics

- Overview of biologics and their immunogenicity.
- Key immunogenicity factors in biologics.
- Regulatory requirements and standards.
- Role of immunogenicity testing in biologics development.
- Case Study: Immunogenicity concerns in monoclonal antibodies.

Module 2: Regulatory Guidelines and Immunogenicity Testing

- FDA and EMA immunogenicity guidelines.
- Designing immunogenicity tests.
- Case Study: Regulatory approval challenges.
- Immunogenicity risk assessment frameworks.
- Practical examples of non-compliance risks.

Module 3: Bioanalytical Methods for Immunogenicity Testing

- Overview of immunoassays.
- Sensitivity and specificity in testing.
- ELISA, ligand-binding assays, and cell-based assays.
- Case Study: Immunoassay selection in a drug development program.
- Comparison of various testing methods.

Module 4: Immunoassay Technologies

- Enzyme-linked immunosorbent assays (ELISA).
- Cell-based assays and their applications.
- High-throughput screening methods.
- Data interpretation and validation.
- Case Study: ELISA in biosimilar testing.

Module 5: Anti-Drug Antibodies (ADAs)

- Mechanism of anti-drug antibody formation.
- Impact of ADAs on biologics safety.
- Monitoring ADAs in clinical trials.
- Case Study: ADA detection in a biosimilar product.
- ADA neutralization assays.

Module 6: Immunogenicity and Clinical Relevance

- Clinical consequences of immunogenicity.
- Impact on drug efficacy and safety.
- Immunogenicity in post-market surveillance.
- Case Study: Post-market safety of a biologic.
- Long-term monitoring of immunogenic responses.

Module 7: Quality by Design (QbD) in Biologics Manufacturing

- Introduction to QbD principles.
- Implementing QbD for biologic drugs.
- Process design and optimization.
- Case Study: Application of QbD in monoclonal antibody production.

- Regulatory considerations for QbD.

Module 8: Continuous Manufacturing in Biologics

- Benefits of continuous manufacturing.
- Integrating continuous manufacturing into biologics production.
- Process analytical technology (PAT).
- Case Study: Continuous biologics production in a commercial setting.
- Overcoming operational challenges.

Module 9: Process Optimization and Immunogenicity

- Identifying sources of process variation.
- Impact of process variations on immunogenicity.
- Strategies to minimize immunogenicity risk.
- Case Study: Process optimization in biologic manufacturing.
- Role of process control in reducing immunogenic responses.

Module 10: Regulatory Challenges in Biosimilars Development

- Immunogenicity considerations in biosimilars.
- Regulatory pathway for biosimilars approval.
- Comparability studies for biosimilars.
- Case Study: Immunogenicity testing in a biosimilar approval process.
- Risk management for biosimilars.

Module 11: Immunogenicity Risk Mitigation Strategies

- Early-stage risk assessment.
- Control strategies for minimizing immunogenicity.
- Long-term strategies for risk reduction.
- Case Study: Risk mitigation in antibody-drug conjugates.
- Regulatory expectations for risk management.

Module 12: Case Studies of Immunogenicity in Biologic Development

- Immunogenicity issues in a therapeutic antibody.
- Immunogenicity in gene therapy.
- Immunogenicity of enzyme replacement therapy.
- Lessons learned from immunogenicity failures.
- Case Study: Immunogenicity testing in cell-based therapies.

Module 13: Post-Marketing Surveillance and Immunogenicity

- Importance of post-market monitoring.
- Methods for tracking immunogenic responses.
- Regulatory guidelines for post-market surveillance.
- Case Study: Long-term monitoring of a biologic product.
- Safety reporting in biologic drugs.

Module 14: Emerging Trends in Immunogenicity Testing

- Latest advances in immunoassay technologies.

- Personalized medicine and immunogenicity.
- Impact of genetic factors on immunogenicity.
- Case Study: Immunogenicity testing in CAR-T cell therapies.
- Emerging regulatory guidelines.

Module 15: Future of Biologics and Immunogenicity Assessment

- Advancements in biologics development.
- Future trends in immunogenicity testing.
- Regulatory shifts in biologic approval processes.
- Case Study: Cutting-edge biologics and immunogenicity concerns.
- Predictive models for immunogenicity assessment.

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

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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