Pediatric and Geriatric Drug Development Challenges 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 development of drugs for pediatric and geriatric populations presents unique scientific and ethical challenges that require specialized knowledge and understanding. Pediatric drug development is particularly complex due to the distinct physiological differences between children and adults, while geriatric drug development must address aging-related changes in pharmacodynamics and pharmacokinetics. Pediatric and Geriatric Drug Development Challenges Training Course equips professionals in the pharmaceutical industry, clinical research, and regulatory agencies with the essential skills to navigate these complexities. It delves into strategies for overcoming regulatory hurdles, designing clinical trials for these vulnerable populations, and ensuring the safety and efficacy of drugs across age groups. Participants will gain insights into innovative approaches and solutions to advance drug development for pediatrics and geriatrics, ensuring these populations receive tailored, effective therapies.

This course also explores the increasing global demand for pediatric and geriatric drug studies, which are growing due to an aging population and the rising need for age-specific medications. Learners will gain critical expertise in regulatory compliance, clinical trial design, and patient recruitment techniques. With an emphasis on regulatory frameworks, clinical trials, pediatric pharmacology, geriatric pharmacokinetics, and ethical considerations, this training will ensure participants are well-prepared to manage drug development programs from conception through to market approval. Advancing drug safety, optimizing patient care, and promoting scientific innovation in pediatric and geriatric drug development are core objectives that professionals will focus on throughout the course.

Programme Curriculum

Pediatric and Geriatric Drug Development Challenges Training Course

Introduction

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Course Duration

10 days

Course Objectives

1. Understand pediatric and geriatric drug development fundamentals and the need for age-specific therapies.
2. Explore regulatory frameworks and guidelines for pediatric and geriatric drug development.
3. Learn about clinical trial design challenges specific to pediatric and geriatric populations.
4. Examine pharmacokinetics and pharmacodynamics in pediatric and geriatric patients.
5. Analyze ethical considerations in clinical trials involving children and elderly individuals.
6. Gain expertise in patient recruitment and retention strategies for pediatric and geriatric trials.
7. Develop an understanding of pharmacovigilance and safety monitoring in vulnerable populations.
8. Address dosage forms and formulations suitable for pediatric and geriatric patients.
9. Investigate regulatory submissions and approval processes for pediatric and geriatric drugs.
10. Explore innovative solutions to overcome the underrepresentation of pediatrics and geriatrics in clinical trials.
11. Identify strategies for improving compliance and adherence to medication regimens in children and the elderly.
12. Study global challenges and regional differences in pediatric and geriatric drug development.
13. Master the integration of real-world evidence and patient feedback into pediatric and geriatric clinical trials.

Target Audience

1. Clinical Research Professionals
2. Regulatory Affairs Specialists
3. Pediatricians and Geriatricians

4. Pharmaceutical Scientists
5. Pharmacologists
6. Drug Safety and Pharmacovigilance Experts
7. Healthcare Administrators
8. Medical Affairs and Drug Development Teams

Course Modules

Module 1: Introduction to Pediatric and Geriatric Drug Development

- Overview of pediatric and geriatric drug development.
- Key regulatory frameworks (FDA, EMA).
- Common challenges in clinical trials.
- Importance of age-specific medications.
- Case studies on historical drug development challenges.

Module 2: Regulatory Guidelines for Pediatric and Geriatric Populations

- FDA and EMA pediatric regulations.
- Geriatric drug development guidelines.
- International harmonization of clinical trials.
- The Pediatric Research Equity Act (PREA).
- Case studies on regulatory approvals.

Module 3: Clinical Trial Design for Pediatric Populations

- Ethical concerns in pediatric trials.
- Pediatric dose-finding studies.
- Placebo use and alternative trial designs.
- Pediatric patient recruitment strategies.
- Case study on pediatric trial design.

Module 4: Clinical Trial Design for Geriatric Populations

- Key factors in geriatric trial design.
- Polypharmacy in elderly patients.
- Age-related physiological changes.
- Trial methods to improve elderly patient adherence.
- Case study on designing geriatric clinical trials.

Module 5: Pediatric and Geriatric Pharmacology

- Basic pharmacokinetics and pharmacodynamics.
- Age-related differences in drug absorption and metabolism.
- Pediatric-specific drug formulations.
- Geriatric-specific drug adjustments.
- Case studies on drug interactions.

Module 6: Ethical Considerations in Pediatric and Geriatric Trials

- Informed consent in vulnerable populations.
- Risk vs. benefit analysis.

- Legal and ethical challenges.
- Involvement of parents and guardians.
- Case studies on ethical dilemmas in clinical trials.

Module 7: Pharmacovigilance and Safety Monitoring

- Post-market surveillance in pediatric and geriatric drugs.
- Risk management strategies.
- Handling adverse drug reactions.
- Safety data collection and reporting.
- Case study on pharmacovigilance in pediatric/geriatric drugs.

Module 8: Patient Recruitment and Retention Strategies

- Targeting pediatric and geriatric patients.
- Addressing barriers to patient participation.
- Retention strategies for long-term studies.
- The role of caregivers in recruitment.
- Case study on effective recruitment strategies.

Module 9: Drug Formulations and Dosage Forms

- Dosage form selection for pediatrics and geriatrics.
- Liquid formulations vs. solids.
- Age-specific drug delivery systems.
- Overcoming challenges with swallowability in elderly patients.
- Case study on formulation development.

Module 10: Global Challenges in Pediatric and Geriatric Drug Development

- Variations in regulatory standards globally.
- Cultural differences in treatment response.
- Access to pediatric and geriatric healthcare in low-resource settings.
- Legal implications in international trials.
- Case studies on global trials in pediatrics and geriatrics.

Module 11: Advancing Pediatric and Geriatric Medicine

- Innovative treatments for pediatric and geriatric diseases.
- Personalized medicine in age-specific drug development.
- The role of gene therapy and precision medicine.
- Regulatory pathways for new therapies.
- Case study on breakthrough treatments.

Module 12: The Role of Real-World Evidence

- Integrating real-world data into clinical trials.
- Benefits of patient-reported outcomes.
- Patient-centric drug development.
- Regulatory acceptance of real-world evidence.
- Case studies on real-world evidence in clinical trials.

Module 13: Patient Compliance and Adherence

- Strategies for improving compliance in pediatric and geriatric populations.
- Overcoming age-related challenges.
- Role of caregivers in medication adherence.
- Digital tools to track patient adherence.
- Case study on improving adherence rates.

Module 14: Clinical Trial Monitoring and Data Management

- Data integrity and compliance in clinical trials.
- Monitoring pediatric and geriatric trials.
- Using technology for trial oversight.
- Adapting trial protocols for specific populations.
- Case study on trial monitoring and data analysis.

Module 15: Future Trends in Pediatric and Geriatric Drug Development

- Emerging therapeutic approaches.
- Impact of AI and machine learning on drug development.
- Trends in personalized medicine for age-specific therapies.
- Future regulatory changes.
- Case study on future trends in pediatric/geriatric drug research.

Training Methodology

- Lectures: In-depth knowledge transfer on drug development processes and regulations.
- Interactive Case Studies: Real-world scenarios to engage learners.
- Group Discussions: Collaborative learning on key challenges and solutions.
- Expert Guest Speakers: Insights from industry leaders and regulatory authorities.
- Hands-On Workshops: Practical application of knowledge in clinical trial designs.

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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