GMDP academy

The Academy of Global Medicines Development Professionals

COURSE OFFERINGS 2025 - 2026

Note that all listed dates and tuition fees are subject to change.

Rev. 27October2025

Professional Certification in Medicines Development (CMD) - In Partnership with King's College London

Program Overview

This program is a unique partnership between academia, industry, and professional associations to foster competencies and improve your performance in medical affairs and other areas of medicines development. It is anchored by a strategic collaboration with King's College London, one of the world's leading research and teaching universities, located in London's heart.

The Certification in Medicines Development is ideal if:

- You are currently working in or looking to transition into Medicines Development related disciplines
- You want to gain invaluable knowledge of Medicines Development and learn from leading global industry experts.
- You are a biomedical professional seeking to increase your visibility at your company.

Students completing the six modules, and the End of Program Project (EPP), will receive their Certification in Medicines Development (CMD) from GMDP Academy and King's College London and are authorized to use the post-nominal letters CMD.

The program is ten months long, from January through November every year. Students are expected to complete six modules, each six weeks long, and the End of Program Project (EPP).
Students can expect to spend 5 - 12 hours per week among the various activities.

Tuition Costs:

Base Tuition: $9,800 USD

Corporate Sponsor Rates:

Tier and number of students	Tuition fee per student
Tier I (> 25)	$8,740
Tier II (15-24)	$9,000
Tier III (1-14)	$9,800

Special Pricing Groups:

1) King's College London Invitees:

- **Tuition:** $9,000
- Applicants must provide the following: referral from King's College London

2) National Associations of Medicines Development:

Members of a national medicines development association interested in partnership opportunities, including special pricing consideration and potential revenue-sharing, should contact us at admissions@gmdpacademy.org

3) Regulatory/government agencies:

- **Tuition:** $4,900
- Limited to 5% (including the financial support applicants) of final cohort
- A personal letter of intent
- A letter of recommendation from a supervisor that includes verification of the applicant's employment.

Self-Paid Students

- **Tuition:** $0 - $9,800
- Flexible payment plans are available.
- The Academy offers scholarships to self-paid students to provide educational opportunities in various countries with differing economic statuses. Up to two full scholarships may be awarded to exceptionally well-qualified applicants.
- Applicants interested in applying for a scholarship will find this option available within the application form. The application includes dynamic fields that adjust based on individual responses. Those who indicate they are self-paid students will have the opportunity to apply for a scholarship.

  Scholarship Application Requirements:

  - Applicants must not be employed by a pharmaceutical company at the time of application.
  - Applicants must be self-funded.
  - Submission of a personal letter of intent.
  - Submission of a letter of recommendation from a current or former supervisor or an academic advisor, preferably from individuals or organizations involved in medicines development or related disciplines.

Scholarship Determination Criteria

The GMDP Academy Admissions Board determines scholarship eligibility based on several factors, including:

- **Country of Residence**
- **Employment Status**
- **Employer**
- **Application Documents**

Partial Scholarships

Partial scholarships are limited to 5% of the final cohort at the Academy's discretion. This includes applicants from regulatory or government agencies.

Full Scholarships

We honor the legacies of pioneers in pharmaceutical medicine through two fully paid scholarships that may be awarded each academic year to highly qualified candidates:

- **The Herman Lahon Scholarship:**

  Named after Dr. Herman Lahon, a pioneer in pharmaceutical medicine and the founding President of IFAPP. Dr. Lahon, along with the other IFAPP founders, conceived the idea of holding an international meeting of Medical Advisers (as pharmaceutical physicians were then known), that would bring together physicians and scientists from the pharmaceutical industry with those working in research institutes and academic medicine. Their objective was to internationalize the advancement of knowledge of therapeutic agents and their actions, and also to foster the relationship between industry and academia. This scholarship supports young pharmaceutical physicians and drug development scientists from emerging regions.

- **The Fritz Bühler Scholarship:**

  Named in honor of Professor Dr. Fritz R. Bühler, a renowned cardiologist and founder of the European Center for Pharmaceutical Medicine (ECPM). Dr. Bühler was instrumental in developing and harmonizing educational programs in pharmaceutical medicine across Europe and globally, when he acted as the first President of PharmaTrain, a European Union “Innovative Medicines Initiative (IMI)” funded project aimed at the harmonization of educational programs in Medicines Development. This fellowship supports the education and promotion of young experts in pharmaceutical medicine.

Operational Dates

January - November

Online Application Link: **https://info.gmdpacademy.org/gmdpapplication**

Modules Included in the Certification in Medicines Development (CMD) Program:

1. Fundamentals in Medicines Development (Module 1)
2. Medical Affairs and Health Economics (Module 2)
3. Drug Discovery, Exploratory and Confirmatory Development (Module 3)
4. Clinical Trials: From Concept to Clinical Study Report (Module 4)
5. Regulatory Affairs, Drug Safety and Pharmacovigilance (Module 5)
6. Medical Affairs as a Strategic Business Partner (Module 6)

Individual Modules: All modules are available a la carte

To apply for one or more individual modules, please visit:
https://info.gmdpacademy.org/gmdpapplication

MODULE 1: Fundamentals in Medicines Development

Program Overview

This module will take you through the fundamentals of clinical pharmacology, health economics, exploratory and confirmatory clinical development and clinical research, regulations, and long-term safety, including the emerging role of patients and contributions of the Medical Affairs function in these arenas.

Dates – Time Commitment – Tuition Costs

2025: Jan 13 to Feb 23	5-12 hours per week	$2500
2026: Jan 12 to Feb 22	5-12 hours per week	$2500

Learning Outcomes

- Describe the drug development process using a Target Product Profile (TPP) and identify key factors and decision points critical to meeting stakeholder expectations.
- Describe the practical applications of pharmacokinetics and pharmacodynamics and the principles of clinical pharmacology.
- Describe how genetic factors can influence pharmacologic and toxic reactions and the molecular and cellular basis of these reactions in drug development and response.
- Explain the principles of translational research, from the bench to the bedside for human use including the value of clinical trials and statistics in medicines development.
- Conclude the importance of patients in drug development.
- Discuss the development of medicines regulation and the role of competent authorities in ensuring safety.
- Outline the principles of drug safety and risk management.
- Justify medical marketing and health economics principles, including the fundamentals of value in healthcare, Evidence-Based Medicine, Patient Reported Outcomes, and pharmacoeconomic metrics.
- Justify the importance of Medical Affairs in ensuring patients' availability and proper use of medicines through interaction with external stakeholders.

MODULE 2: Medical Affairs and Health Economics

Program Overview

This module will focus on how Medical Affairs functions as an effective interface with external stakeholders to ensure the right medicines are available for patient access and proper use. You will explore the processes involved in the evidence, data generation, health economics and commercialization and the application of digital technologies to ensure the candidate compound meets the desired profile to achieve regulatory approval and rapid entry into the healthcare system across countries.

Dates – Time Commitment – Tuition Costs

2025: Feb 24 to April 6	5-12 hours per week	$2500
2026: Feb 23 to April 5	5-12 hours per week	$2500

Learning Outcomes

- Summarize the principles of medical/marketing and the role of Medical Affairs.
- Understand the processes of developing and reviewing product information to ensure compliance with ethical, legal, and regulatory principles regarding Good Promotional Practices and marketing activities.
- Appraise the contributions of the various medical affairs-related functions (medical information, medical communication and education, medical service liaisons, external affairs, strategic alliances, etc.) to successful business conduct within the organization.
- Understand the life-cycle management of medicines (with clinical, regulatory, and marketing), different types of data generation, and the role of the medical affairs function.
- Outline the principles and practical applications of health economics, patient-reported outcomes, Health Technology Assessment, value generation, and communication.
- Discuss the role of generics and biosimilars.
- Describe the emerging use of digital technologies in Medicines Development.

MODULE 3: Drug Discovery, Exploratory and Confirmatory Development

Program Overview

This module covers the scientific approach to drug discovery, biopharmaceutical formulation and non-clinical safety evaluation, and early and confirmatory human trials of drugs and vaccines. The discussion of the statistical assessment of the results and their contribution to the principles of evidence-based medicine completes the program.

Dates – Time Commitment – Tuition Costs

2025: April 7 to May 18	5-12 hours per week	$2500
2026: April 6 to May 17	5-12 hours per week	$2500

Learning Outcomes

- Appraise the principles of rational design of chemical biological and nucleic acid based drugs.
- Outline the steps in the non-clinical toxicological pharmaceutical development of a drug substance and the final product (including chemical and biological compounds).
- Describe the planning of clinical trial supplies (active or placebo).
- Outline the design of clinical trials, including legal, regulatory, ethical, and practical aspects.
- Outline the specific principles of vaccine development.
- Describe the influence of genetic factors in drug development and drug response.
- Outline the early clinical drug development program, including micro-dose (phase 0), phase I dose finding, and phase II studies. Explain the importance of the proof of concept and its impact on the overall drug development plan.
- Outline the key operational and strategic issues in the Confirmatory Development Plan.
- Analyze and compare the principles and applications of statistics in clinical trials.
- Understand the importance of study design for conducting clinical trials.
- Communicate meaningfully with statisticians in project teams to ensure the aims of a trial are met.
- Understand the vital statistical issues when reading journal papers.
- Outline the principles of Evidence-Based Medicine and their relevance to drug development.

MODULE 4: Clinical Trials: From Concept to Clinical Study Report

Program Overview

This module will teach you how to conduct a quality clinical trial. It will examine ethics, subject protections, quality management, and governance. You will also learn the procedures supporting good data collection management and budgeting practices. We will conclude by discussing issues related to clinical trial failures and the latest decentralized trial approaches.

Dates – Time Commitment – Tuition Costs

2025: May 19 to June 29	5-12 hours per week	$2500
2026: May 18 to June 28	5-12 hours per week	$2500

Learning Outcomes

- Summarize the key documents related to the ethical conduct of clinical trials
- Outline the Investigators Brochure sections and describe its use, approval, and distribution
- Revise the principles and practical relevance of ethical issues in biomedical research and the legal and ethical provision for the protection of clinical trial subjects
- Identify the key issues involved in the conduct of a clinical study, including investigator and site selection, site management, and conflict resolution
- Describe the procedures for clinical trial data collection and data management to ensure optimal quality data and outline the various quality management issues in clinical trials
- Outline a study level feasibility plan and describe the structure of a study budget
- Outline the various quality management issues in clinical trials
- Discuss the collection, evaluation, and reporting of adverse event data in clinical trials
- Explain the role of the DSMB and other governance committees during the study conduct
- Discuss the evaluation and interpretation of clinical trial results

MODULE 5: Regulatory Affairs, Drug Safety and Pharmacovigilance

Program Overview

This module will focus on the regulatory framework for medicines and medical devices' development and approval in the US, EU, and emerging economies. It will also cover global initiatives for harmonization (e.g., ICH) and highlight some key topics of interest (e.g., specialized regulatory procedures) and their role in the overall regulatory strategy. Risk management and safety reporting will be evaluated from the vantage point of a medicine's life cycle.

Dates – Time Commitment – Tuition Costs

2025: June 30 to Aug 10	5-12 hours per week	$2500
2026: June 29 to Aug 9	5-12 hours per week	$2500

Learning Outcomes

- Categorize the general principles of medicines and device regulation and the regulatory process in the USA, Europe, and the rest of the world.
- Compare the role of national agencies and international bodies, such as the International Conference on Harmonization in medicines regulation
- Justify the impact of medicines legislative requirements on regulatory activities within a pharmaceutical company and its impact in planning and reviewing the product strategy
- Compare and contrast medical device regulation and drug regulations
- Value the role of pharmacoepidemiology and risk management in the lifecycle management of a medicine
- Appraise adverse events/adverse drug reactions in terms of severity and then describe the safety reporting requirements pre and post approval
- Calculate and interpret measures of risk
- Evaluate the ongoing management of drug safety issues pre and post approval (including risk management plans, periodic safety update reports, and post authorization safety studies) and the ongoing benefit/risk assessment throughout the lifecycle of a medicine
- Evaluate the factors influencing medication safety from the perspective of each stakeholder
- Devise a global regulatory strategy to maximize the probability of successfully gaining regulatory agency approval of a new pharmaceutical
- Explain the conditions for involving patients in medicines development.

MODULE 6: Medical Affairs as a Strategic Business Partner

Program Overview

This module will cover the evolving profile of Medical Affairs and Medicines Development professionals as key strategic pillars in the biopharmaceutical business. You will learn the ethics around working in multidisciplinary clinical research or therapeutic teams, the emerging preponderance of Real World Data / Real World Evidence, the responsibility of patients and professional organizations in health care, how to address and improve organizational effectiveness, the charge of medical affairs in medical education, the elements around public access to information, building trust in medicines development and in the biopharmaceutical industry, the importance of quality management, the value of strategic alliances, and how to critically review a clinical research paper.

Dates – Time Commitment – Tuition Costs

2025: Sept 1 to Oct 12	5-12 hours per week	$2500
2026: Aug 31 to Oct 11	5-12 hours per week	$2500

Learning Outcomes

- Understand the evolving profile of MA and medicines development professionals as strategic pillars in the biopharmaceutical business: purpose and career path.
- Characterize principles of professionalism, assessment of competence, and identity formation to guide the practice of medical affairs and medicines development.
- Describe ethical issues and ongoing tensions between the need for incentives for clinical research and medicines development and the global need for affordable medicines.
- Apply ethical behavioral framework for multidisciplinary clinical research and therapeutic teams.
- Discuss the responsibility of patients and professional organizations in healthcare.
- Appraise contributions of medical affairs and related medicines development functions to successful business conduct within organizations.
- Illustrate challenges and opportunities in the Real World Data / Real World Evidence arena and its increasing deployment in regulatory decision-making.
- Assess elements related to product information and public access to ensure compliance with ethical, legal, and regulatory principles.
- Define the rationale for the involvement of the Medical Affairs and related functions in Continuing Medical Education / Continuous Professional Development.
- Outline the value of networks and strategic alliances to meet business objectives.
- Evaluate concepts and principles to address organizational effectiveness.

- Reinforce the imperative of regaining and engendering trust in the medicines development enterprise and the biopharmaceutical industry
- Critically review a clinical research paper.

MODULE 7: Leadership in Medicines Development

Program Overview

Leadership has emerged as a critical competency in medicines development. This results from the increasing relevance of Medical Affairs and other functions related to Medicines Development in a dynamic healthcare environment with growing external and internal demands. Business success in today's Pharma industry requires strong Medical Affairs and Medicines Development teams. Existing programs on leadership help provide fundamentals but fall short of addressing the specific challenges and needs of the professional involved in Medical Affairs and related areas. This program intends to fill those gaps.

Dates – Time Commitment – Tuition Costs

2025: Sept. 29 - Nov. 21	3-5 hours per week	$3000
2026: Fall	3-5 hours per week	$3000

Lectures

1. The Why and What of Authentic and Courageous Leadership
2. Building and Applying Self-Awareness to Leadership
3. Becoming a Strategic Leader and Partner for the Business
4. Leading Teams and Change
    a. Leading in a Volatile, Uncertain, Complex, and Ambiguous (VUCA) World
    b. Stepping into a leadership role – transition guidance
5. Thought Leadership & Beyond: Being Influential with Peers and Stakeholders to Make the Right Things Happen
6. Being a Sustainable Leader

Learning Outcomes

- Enhanced Leadership Skills
    - By the end of the course, participants should be able to apply learned leadership styles and theories effectively in their roles.

- Strategic Application of Knowledge
    - Participants must apply course concepts to real-world scenarios, enhancing their strategic thinking and problem-solving skills.
- Improved Decision-Making Capabilities
    - The course empowers participants to make informed, ethical decisions that positively impact their teams and the organization.
- Increased Resilience and Adaptability
    - Training will equip participants to handle the stresses of the VUCA world, maintaining effectiveness and well-being.
- Development of a Personal Leadership Plan
    - As a capstone to the course, participants will create a detailed and personalized leadership plan reflecting their learning and professional development goals.

MODULE 8: Digital Technology in Medicines Development

Program Overview

In today's digital age, the healthcare and pharmaceutical industries are rapidly evolving, and so are how medical affairs professionals interact with healthcare stakeholders. To succeed in this dynamic landscape, staying current with the latest trends and developments in digital technologies is crucial. This course is designed to equip medical affairs and other professionals involved in medicines development in the pharmaceutical industry with the necessary knowledge and skills to navigate the digital world and leverage digital tools effectively in their work.

Dates – Time Commitment – Tuition Costs

2025: Sept. 29 - Nov. 9	3-5 hours per week	$3000
2026: Fall	3-5 hours per week	$3000

Lectures

1. Introduction to Digital Medicines Development
2. Digital Tools Explained
3. Digital Tools in Research and Clinical Development
4. Digital Tools in Medical Affairs
5. Digital Communications
6. The Emerging Regulation of New Technology in Healthcare
7. Digital Safety / Risk Management & Ethics
8. The Role of Patients in the Design of Digital Tools for Healthcare
9. Demonstrating the Value of Digital Approaches (Case Studies)
10. Future Technology - What's on the Horizon?

Learning Outcomes

- Understand the key concepts that digital technology affects within medicines development
- Identify various digital technologies to solve problems in medicines development
- Evaluate the opportunities and risks of using digital tools in Research and Clinical development plans
- Create an effective digital communication strategy and plan
- Understanding processes and guidance supporting the regulation of new technology in healthcare
- Explain how digital tools can support risk management planning and reporting and add value to pharmacovigilance/ Safety assessments
- Develop a patient-centric approach to digital technology within their company

- Apply the knowledge of the future digital tools to create a technology scanning plan to keep up to date with digital technology that could affect medicines development

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Short Course: HEOR (Health Economics and Outcomes Research)

Lectures / Webinars

1. The Principles of HEOR
2. Applying the Principles of HEOR
3. Introduction to HTA (Health Technology Assessment)
4. Value Evidence Plan
5. How to Develop and Leverage the Global Value Dossier
6. Value Generation and Communication
7. How to Generate and Communicate Value

Learning Outcomes

1. Define Health Economics and Outcomes Research (HEOR) and explain its use and methods.
2. Demonstrate how to apply HEOR methodologies and conduct analysis.
3. Explain what HTA is and how it is used to evaluate the value of drugs.
4. Explain how to develop and leverage a Value Evidence Plan.
5. Demonstrate how to generate and communicate value.

Dates – Time Commitment – Tuition Costs

Contact admissions@gmdpacademy.org if you are interested in attending this course.	3-5 hours per week	$1000

Short Course: Clinical Trials I - Basics of Clinical Trials

Lectures / Webinars

1. Ethical Aspects in Clinical Research
2. The Clinical Trial Protocol
3. Ethics and the Publication of Study Results
4. The Research Site
5. Adverse Event Reporting
6. Investigator Initiated Protocols
7. Study Monitoring

Program Overview

Participants in this short course will become familiar with the following:

1. The importance of Ethics in Research with human subjects.
2. Writing a scientifically sound clinical trial protocol.
3. Identification of the best research sites and the key selection criteria.
4. The importance of adverse events reporting and interpretation.
5. The significant improvement in quality caused by study monitoring.

Dates – Time Commitment – Tuition Costs

Contact admissions@gmdpacademy.org if you are interested in attending this course.	3-5 hours per week	$1000

Short Course: Clinical Trials II: The Optimal Management Of Clinical Trials

Lectures / Webinars

1. Project Management
2. Risk-Based and Patient-Centered Monitoring
3. Data Management
4. Quality Management
5. The Role of DSMB & CEC in Medicines Development
6. Study Report
7. Overall Issues in Medicines Development and Virtual Trials

Program Overview

Participants in this short course will become familiar with the following:

1. The importance of Project Management to keep control of all trial details.
2. How to manage massive amounts of clinical data.
3. The importance of quality in clinical research and how to implement it.
4. The final step of a clinical study: preparing the study report.
5. Some key aspects in clinical trials: failures and new horizons.

Dates – Time Commitment – Tuition Costs

Contact admissions@gmdpacademy.org if you are interested in attending this course.	3-5 hours per week	$1000