GMDP academy
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APPLICATIONS NOW AVAILABLE FOR WORLD-CLASS EDUCATION IN MEDICINES DEVELOPMENT

The GMDP Academy is pleased to announce that applications are now open for the highly acclaimed and prestigious Certification in Medicines Development (CMD) program, offered in collaboration with King's College London. The program, running from January 2024 to November 2024, offers a unique opportunity for academia, industry, and professional associations to come together to nurture competencies and elevate the roles of Medical Affairs and Medicines Development in the healthcare sector. Read more about this incredible opportunity on page 2.

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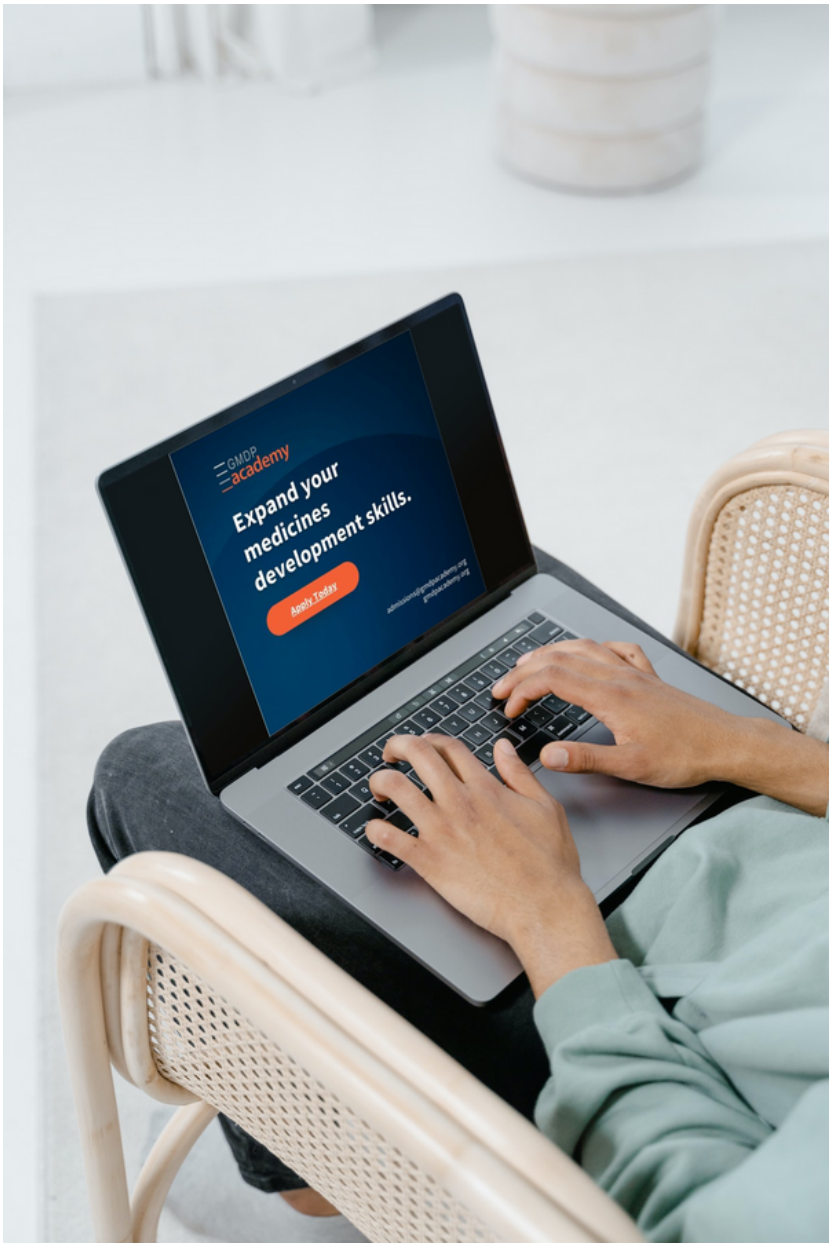

> The program's comprehensive curriculum, coupled with the chance to interact with industry leaders and expand my global network, has been truly exceptional. I am proud of the knowledge and skills I have gained through this program, and I am confident that it will equip me very well, in the long run, to make a meaningful impact in the field of Medicines Development that saves patients' lives and improve health care.

Rodgoun Attarian
Medical Advisor
Hospital Unit, Pfizer
current CMD student

IS THE CERTIFICATION IN MEDICINES DEVELOPMENT PROGRAM RIGHT FOR YOU?

The program is thoughtfully designed for professionals already working in Medicines Development who want to take their careers to the next level, as well as those looking to transition into a career in this up-and-coming industry. For biomedical professionals, the program offers a platform to increase visibility within their companies and beyond and showcase their proficiency. Upon completion of the program, students will receive their Certification in Medicines Development (CMD) from GMDP Academy and King's College London, and be authorized to use the post-nominal letters CMD.

Take advantage of this incredible opportunity and apply today! **Applications are due by December 4, 2023.**

Apply Today

EMA ENDORSES JOINT STATEMENT ON SAFETY OF COVID-19 VACCINES

EMA has just endorsed a joint statement on the safety of COVID-19 vaccines issued by the International Coalition of Medicines Regulatory Authorities (ICMRA).

Evidence from more than 13 billion doses of COVID-19 vaccines administered worldwide shows that these vaccines aimed at protecting people from severe outcomes of COVID-19 have a very good safety profile in all age groups, including children and people with underlying medical conditions, immunocompromised patients and pregnant women. The vaccines have saved millions of lives worldwide by significantly reducing the risk of severe disease, hospitalisation and death from infection with SARS-CoV-2.

While the vast majority of side effects of COVID-19 vaccines are mild and temporary, safety monitoring systems have identified some very rare (occurring in less than 1 in 10,000 people) but serious side effects.[1] Continue reading here.

FDA CONVERTS ALZHEIMER'S DISEASE TREATMENT

The U.S. FDA converted Leqembi (lecanemab-irmb), indicated to treat adult patients with Alzheimer's Disease, to traditional approval following a determination that a confirmatory trial verified clinical benefit. Leqembi is the first amyloid beta-directed antibody to be converted from an accelerated approval to a traditional approval for the treatment of Alzheimer's disease. The drug works by reducing amyloid plaques that form in the brain, a defining pathophysiological feature of the disease.

The new monoclonal antibody was approved in January under the Accelerated Approval pathway. This pathway allows the FDA to approve drugs for serious conditions where there is an unmet medical need, based on clinical data demonstrating the drug's effect on a surrogate endpoint.[2] Read more here.

NEWS FROM ICH: NEW GUIDELINE RELEASED

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) has released a new draft guideline, ICH E6(R3), on May 19, 2023.

This guideline is a revision of the previous ICH E6(R2) and aims to provide a unified standard for the European Union, Japan, the United States, Canada, and Switzerland to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions. The ICH E6(R3) guideline is designed to provide a framework for planning, designing, conducting, recording, and reporting trials that involve the participation of human subjects.

The guideline ensures the credibility and integrity of the data generated and the protection of trial subjects. The new guideline introduces several changes and updates to the previous version.[3] Read more here.

DEVELOPING A GUIDELINE ON QUALITY ASPECTS OF MRNA VACCINES

The European Medicines Agency has published for public consultation a concept paper on the development of a guideline on the quality aspects of mRNA vaccines.

This concept paper addresses the need to establish a guideline on the quality aspects of mRNA vaccines. The number of clinical trial applications for human products and marketing authorisation applications for mRNA-containing products significantly increased over the last few years and is expected to increase further in the future. Furthermore, a lot of experience with mRNA vaccines was gained during the COVID-19 pandemic. From an analytical and regulatory perspective, mRNA vaccines are interesting since their classification depends on the target and/or whether they are obtained chemically or biologically.[4] Comments should be provided using the EU Survey form by 30 September 2023.

UNDIAGNOSED DISEASES:NEEDS AND OPPORTUNITIES

Rare diseases (RD) are a health priority worldwide, as they affect hundreds of millions of people. Early and accurate diagnosis is crucial for clinical care, but remains challenging in low- and medium-income countries, leading to a significant burden of undiagnosed RD (URD) cases. To identify unmet needs and opportunities for URD patients, the Developing Nations Working Group of the Undiagnosed Diseases Network International (DNWG-UDNI) conducted a survey among members from 20 countries.

The results revealed that scientific and medical centers are making efforts to address patient needs, but resource scarcity remains a major hindrance, affecting-

diagnostic expertise and research availability. Inequities in service accessibility within and between countries were also observed. Continue reading here.[5]

FDA NEWS: COMPLEX INNOVATIVE TRIAL DESIGN MEETING PROGRAM

The FDA is continuing the Complex Innovative Trial Design (CID) Paired Meeting Program, originally established under PDUFA VI, to support the goal of facilitating and advancing the use of complex adaptive, Bayesian, and other novel clinical trial designs. The CID Paired Meeting Program fulfills a performance goal agreed to by the Prescription Drug User Fee Act (PDUFA) reauthorization for fiscal years (FYs) 2023-2027, known as PDUFA VII. This paired meeting program offers sponsors whose meeting requests are granted the opportunity for increased interaction with FDA staff to discuss their proposed CID approach. Meetings will be conducted by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) during fiscal years 2023 to 2027.
To promote innovation in this area, trial designs developed through the meeting program may be presented by FDA (e.g., in a guidance or public workshop) as case studies, including trial designs for medical products that have not yet been approved by the FDA.[6]

You can read more or apply for a meeting by clicking here.

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Thanks for reading!

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