



LAST CHANCE TO REGISTER: MODULE 8 – DIGITAL TOOLS IN MEDICINES DEVELOPMENT

🚨 Final Call! Don't miss out on Module 8: Digital Tools in Medicines Development - [enroll](#) now to explore cutting-edge advancements.

🚨 Registration is open until May 8, granting you a final chance to seize this opportunity.

📚 Designed for pharmaceutical professionals in the healthcare sector, this course offers an in-depth examination of how emerging technologies such as AI, Digital Therapeutics, and digital Biomarkers are reshaping the medical research landscape and clinical practice. Click [here](#) to learn more and read a message from the Module Chair, Dr. Mark Lightowler.

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FDA LAUNCHES CDER QUANTITATIVE MEDICINE CENTER OF EXCELLENCE

The FDA's Center for Drug Evaluation and Research (CDER) is excited to introduce the new CDER Quantitative Medicine (QM) Center of Excellence (CoE).

QM involves leveraging exposure-based, biological, and quantitative modeling and simulation approaches from various sources, including nonclinical, clinical, and real-world data. These methods play a crucial role in shaping drug development, regulatory decisions, and patient care, enriching our understanding of a drug's benefits and risks.

The primary objective of this CoE is to streamline and enhance the integration of QM practices throughout CDER.



Dr. Patrizia Cavazzoni, Director of CDER, expressed, "CDER has long championed QM approaches for premarket product reviews and post-market assessments. With the expanding scope of QM, we recognize ample opportunities to foster collaboration within CDER. By centralizing outreach, education, scientific and regulatory policies, we aim to promote the uniform adoption of QM methodologies in drug development and regulatory deliberations."¹ Read more [here](#).

FDA SAFETY COMMUNICATION: EVALUATING PLASTIC SYRINGES MADE IN CHINA FOR POTENTIAL DEVICE FAILURES



The FDA is intensifying actions regarding plastic syringes from China due to quality issues. Import alerts have been issued for Jiangsu Shenli Medical Production Co. Ltd., preventing their syringes from entering the U.S. Additional recommendations advise transitioning away from these syringes unless absolutely necessary. Warning letters have been sent to entities involved in distributing unauthorized syringes.

The FDA urges vigilance, recommending monitoring for potential failures and reporting any issues. The agency assures an adequate supply of syringes from other sources and pledges ongoing evaluation and communication on the matter.²

Read the full safety announcement [here](#).

ASSESSING THE ROLE OF LARGE LANGUAGE MODELS IN SCIENTIFIC PUBLISHING

The debut of ChatGPT in November 2022 stirred anticipation and apprehension within the scientific realm. The advent of this artificial intelligence (AI) tool, alongside other applications built on large language models (LLMs), prompted questions about their potential benefits and pitfalls in scientific and medical publishing. Would these AI tools aid researchers, peer reviewers, editors, and publishers in addressing the growing demands of writing, evaluating, publishing, and comprehending research? Could they alleviate challenges for non-native English speakers? Or would they inadvertently foster unethical practices like paper mills, plagiarism, and fraud?

As the landscape evolved, the quest for answers persisted. Nearly 1.5 years later, it's prudent to reflect on the impact LLMs have had thus far.



Capable of generating scientific text, from abstracts to entire papers, LLMs have proven versatile. Related tools can even produce figures and data, raising the question of whether LLMs could serve as authors.³ Continue reading [here](#).

CONSULTATION OPEN: EUROPEAN MEDICINES AGENCY'S PROPOSAL FOR NON-INFERIORITY AND EQUIVALENCE COMPARISONS GUIDELINE



The European Medicines Agency is seeking public input on a Concept Paper outlining the framework for a Guideline on Non-Inferiority and Equivalence Comparisons in Clinical Trials. In drug development, non-inferiority comparisons to active comparators play a pivotal role, particularly in phase 3 trials aimed at supporting marketing authorization applications. Addressing specific considerations unique to non-inferiority and therapeutic equivalence comparisons, distinct from those encountered in superiority trials, is crucial.

Stakeholders are invited to submit their comments by May 31, 2024, utilizing the EU survey form.⁴ Access the draft document [here](#).

FDA'S POST-MARKET SURVEILLANCE: SAFEGUARDING DRUG SAFETY

The FDA operates a robust system of post-market surveillance and risk assessment programs to uncover adverse drug reactions and medication errors not detected during drug development. Through analyzing reports of adverse events—issues patients face after drug intake, irrespective of causality—the FDA evaluates if these events are drug-related. CDER utilizes these reports, alongside other safety data, to monitor approved drugs and biologic products.

When new safety concerns arise, the FDA conducts thorough reviews before deciding on appropriate actions. Understanding the difference between adverse events and adverse drug reactions is vital: adverse events encompass any unexpected medical occurrences, while adverse drug reactions denote harmful responses caused by medication.



Read more about the role of CDER and the FDA in post-market surveillance by clicking [here](#).⁵

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Thanks for reading!

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