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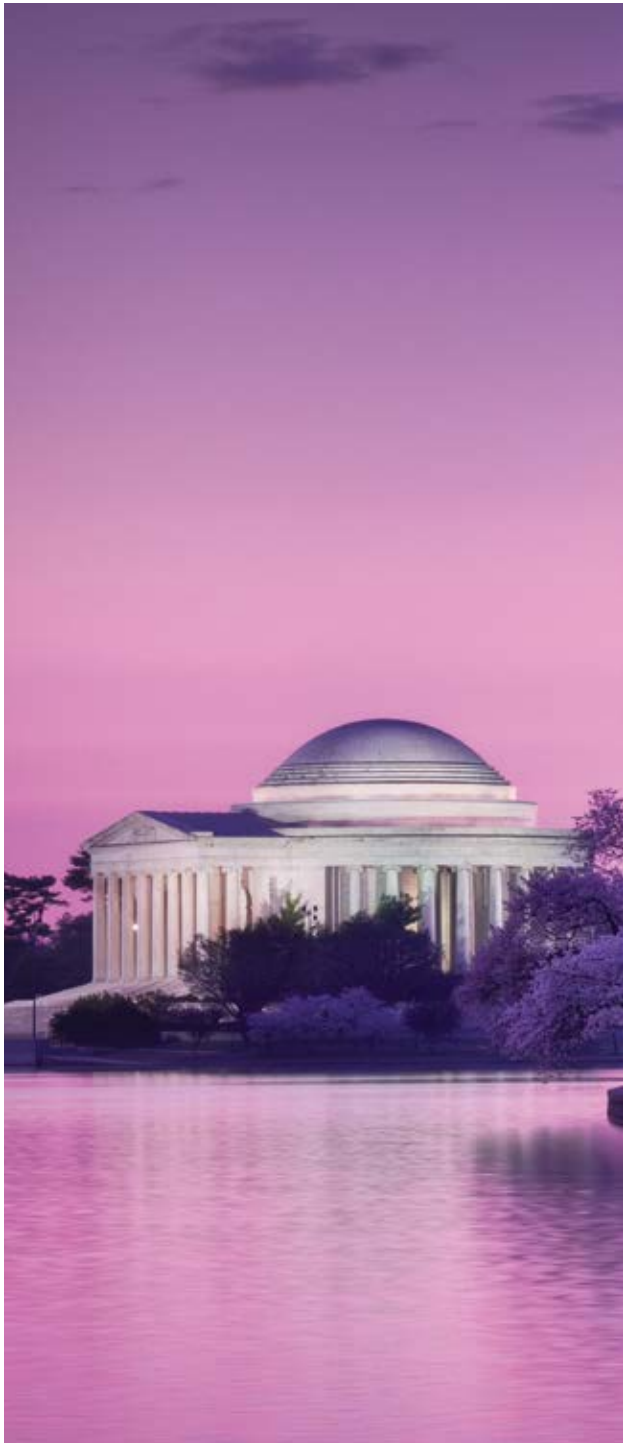
INSIDER UPDATE

e · newsletter

CMC Workshop: From Drug Development to Global Supply to Patients

April 15-17 | Washington, DC



Insider Update

This edition of *Insider Update* provides insights from experts about what Industry can expect from collaboration between regulatory agencies, drug storages and what are the most practical public websites to check for drug shortage information, as well as the regulatory pathway for biosimilars.

All of these key thought leaders will be presenting at this year's CMC Workshop: From Drug Development to Global Supply to Patients.

Get the Insider Scoop

#1

Jean-Louis Robert, PhD

Head, Medicines Control Laboratory
National Health Laboratory, Luxembourg

Q: Can Industry expect a benefit from collaboration between Regulatory Agencies?

A: "The answer to this question might at first sight seem obvious: The more regulators collaborate between each other, the more one can expect that this collaboration ends up in a more harmonized approach of evaluation of an application file for marketing authorization. But is there not a danger that this "harmonization" ends up in more and more additional "nice to know" questions without any real benefit to the patient? The true answer is more complex. Harmonization between regulators in a global world is a must, no doubt. However, harmonization means also that, first, regulators must not only achieve common understanding about pharmaceutical science, but also learn from each other and be prepared to revise a position if the other party has good arguments. Just adding up each party's views cannot and should not be considered true harmonization. Regulators need to also be open and create opportunities for scientific dialogue with industry. Having said that, industry has another role to play and a responsibility: Preparation of well-structured and transparent application files that enable regulators to achieve a sound assessment. In all cases, the patient's need should be our target."

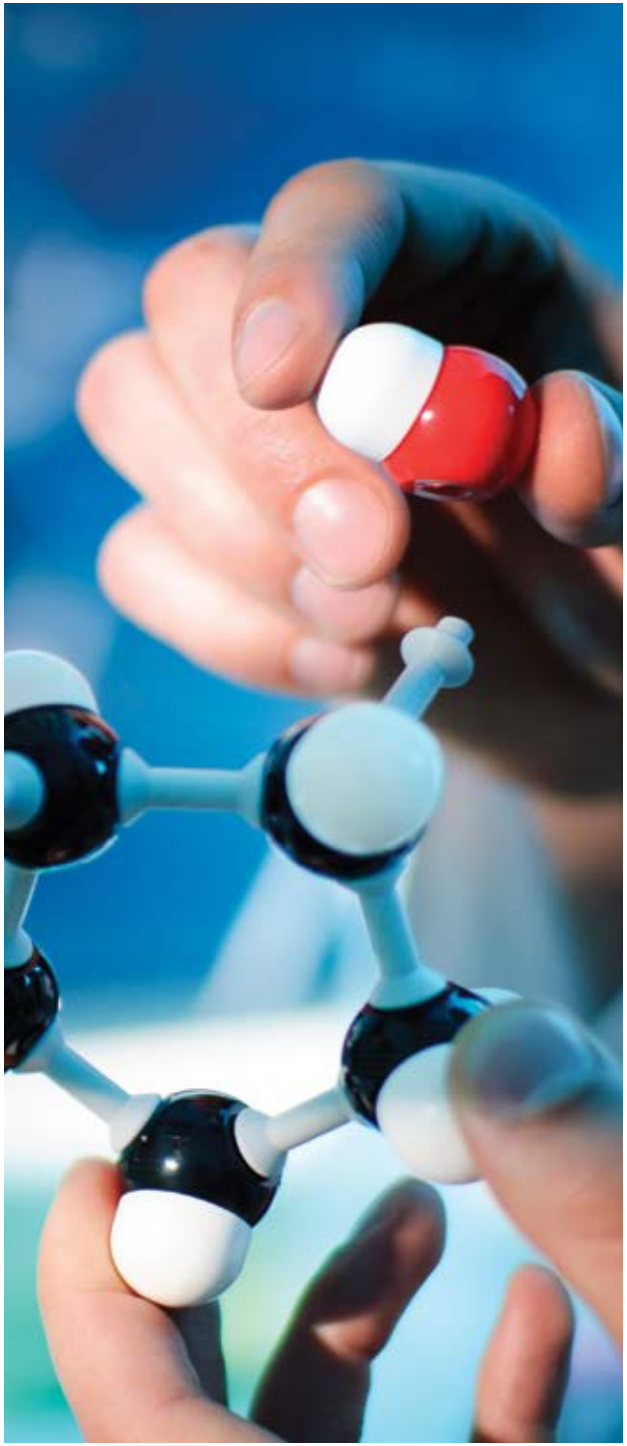
#2

Elaine Morefield, PhD

Deputy Office Director, Office of New Drug Quality Assessment
CDER, FDA, US

Q: What type of enhanced control strategies can be developed for pharmaceutical products?

A: "Having enhanced knowledge of your product and process can allow you to develop enhanced control strategies. Use of PAT tools such as NIR can assist in developing the process knowledge and can also be used for enhanced control strategy elements such as real time release testing."



#3

Gregory C. Davis, PhD

Consultant
Davis Consulting Services, US

Q: What have regulators learned regarding the approval of Biosimilars?

A: "Biosimilars are now a reality in most parts of the world. In nearly all instances, regulators are taking a pragmatic but scientifically cautious approach to their approval. FDA is just embarking on implementing a regulatory pathway for biosimilars. The regulatory speakers in this session will share learnings that have come out of that approval process and/or issues that still need to be addressed to ensure their safe and effective use."

#4

Erin Fox, PharmD

Director, Drug Information Service
University of Utah Hospitals & Clinics

Q: What are the public websites to check for drug shortage information?

A: "The most important websites are probably those of the US Food and Drug Administration and the American Society of Health-System Pharmacists. The FDA website focuses on medically necessary drugs. The ASHP website includes a broader list of products that impact pharmacy practice including drugs, biologics and some devices. The ASHP website also includes management strategies for clinicians to minimize the impact of drug shortages on patients. Both sites are updated regularly."

Are YOU Eager to Know More?

- What are the current CMC "hot topics" for chemical and biological products in a global environment?
- What are the current international initiatives in the area of impurities?
- How do you develop CMC documentation for clinical trials?
- What are the current issues related to the pharmaceutical supply chain?
- What are the trends for biorelevant specifications and bioequivalence studies?
- What are the latest strategies and practices for continuous manufacturing, control strategy and process validation?
- What helps you to adhere, and prevents you from adhering, to post-approval change management protocols?
- Would you like to ask the FDA and other international regulators your pressing questions in person?

There is only ONE place where you can get answers to these questions and more!

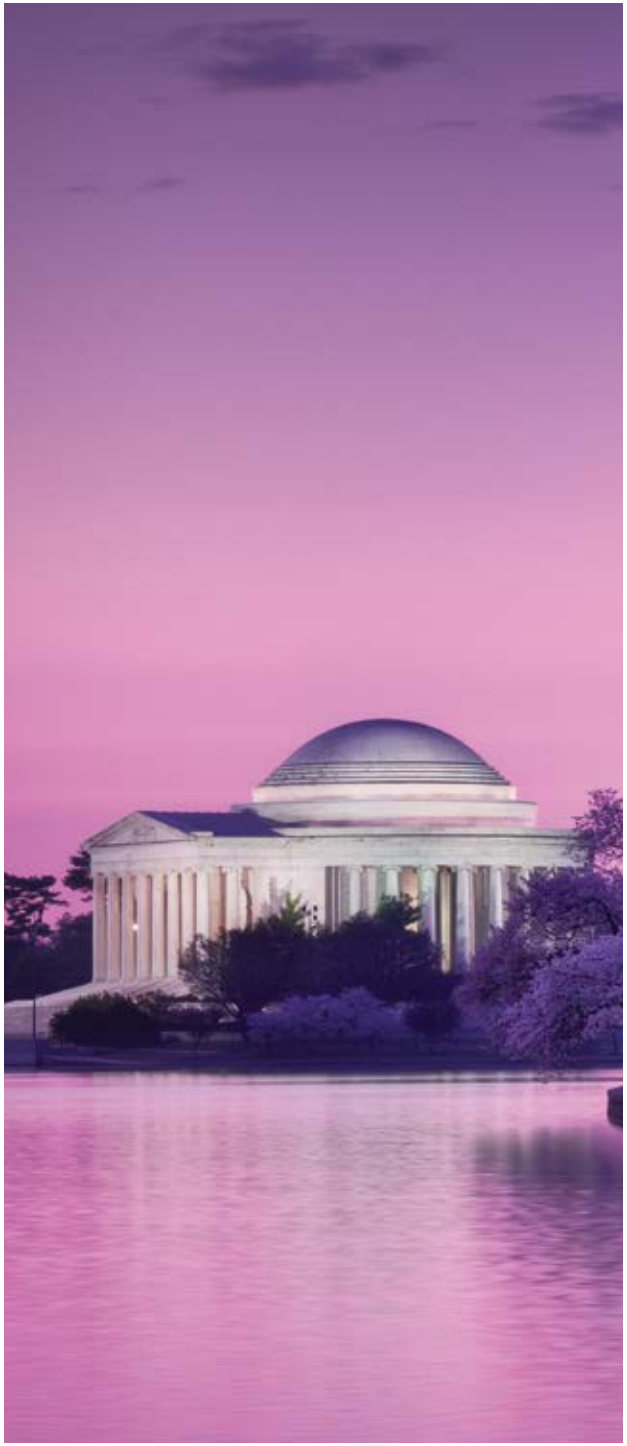
Your Special Invitation to the CMC Workshop

We would like to invite you to this year's CMC Workshop: From Drug Development to Global Supply to Patients, which will be **held April 15-17 in Washington, DC**. Join International Regulatory, Industry, and Academic experts, and come get answers to all your important CMC-related questions!

DIA, in cooperation with American Association of Pharmaceutical Scientists (AAPS), will host a two and a half-day workshop that will focus on the current Chemistry, Manufacturing, and Controls (CMC) challenges facing the global pharmaceutical and biopharmaceutical communities from development, implementation, and regulatory perspectives.

This interactive workshop offers plenary and breakout sessions, all of which feature cross-functional discussions on globalization of activities in the both CMC assessment and GMP inspections, antibody-drug conjugates, genotox impurities, registrations of biosimilars in Europe, Canada, and US, as well as drug shortages, plus much more.

To find out more or to register, visit diahome.org/CMC2013.



Workshop Highlights

Plenary Session Topics:
- Globalization in the CMC Area: Collaboration Between Regulatory Agencies
- Clinically Relevant Specifications
- New Technologies

Breakout Session Topics:
- Challenges and Opportunities for the API Supply Chain Following ICH Q11
- Global Supply Chain: Counterfeits
- Clinical Trials and Marketing Applications in Latin America CMC Considerations
- Clinical Trials Submissions in Asia Pacific Region
- Clinical Trials in the European Union (Biologicals)
- Drug Shortages
- Control Strategy – Lessons Learned
- Pediatrics: Challenges and Specific Requirements
- Biosimilars
- Postapproval Change Management Protocols
- Drug/Device Combination Products
- Plus much more!

Networking & Exhibits:
- Networking Reception: April 15 | 5:30-6:30PM
- Tabletop Exhibits: April 15-17

To find out more or to register, visit diahome.org/CMC2013.

Featured Regulatory Speakers:

Elaine Morefield, PhD
Deputy Office Director
Office of New Drug Quality Assessment
CDER, FDA, US

Jean-Louis Robert, PhD
Head, Medicines Control Laboratory
National Health Laboratory, Luxembourg

Diana Amador Toro, PhD
Director, New Jersey District
Office of Regulatory Affairs
FDA, US

Michael Wierer, PhD
Deputy Head, European Pharmacopoeia Department
European Directorate for the Quality of Medicines and HealthCare, France

Ana Carolina Araujo, PharmD
Sanitary Surveillance and Regulation Specialist Pharmacist, Post-Approval Coordination Group (COPRE) Pharmaceutical Technology General Office (GTFAR)
ANVISA, Brazil

Fanny Viana, PharmD
Sanitary Surveillance and Regulation Specialist Pharmacist
Research and Clinical Trials Coordination Group (COPEM)
Safety and Efficacy General Office (GESEF)
ANVISA, Brazil

Stephen Miller, PhD
CMC Lead, Office of New Drug Quality Assessment
CDER, FDA, US

Norman R. Schmuff, PhD
Associate Director for Product Quality
CDER, FDA, US

Marta Wosinska, PhD
Senior Economic Advisor, FDA, US

CAPT Valerie Jensen, RPh
Associate Director, CDER Drug Shortage Staff
CDER, FDA, US

John F. Kauffman, PhD, MBA
Research Chemist, Division of Pharmaceutical Analysis, Office of Pharmaceutical Science
CDER, FDA, US

Richard T. Lostritto, PhD, MS
Acting Deputy Office Director
Office of New Drug Quality Assessment, DPAMS
CDER, FDA, US

Jan Welink
Senior Pharmacokinetic Assessor
Medicines Evaluation Board, Netherlands

Sarah Pope Miksinski, PhD
Acting Director, Division 1
Office of New Drug Quality Assessment
CDER, FDA, US

Marjorie Shapiro, PhD
Chief of the Laboratory of Molecular and Developmental Immunology, OBP
CDER, FDA, US

Sharmista Chatterjee, PhD
Chemist, Office of New Drug Quality Assurance
CDER, FDA, US

Christine Moore, PhD
Acting Office Director
Office of New Drug Quality Assessment
CDER, FDA, US

Deborah A. Hursh, PhD
Senior Investigator
CBER, FDA, US

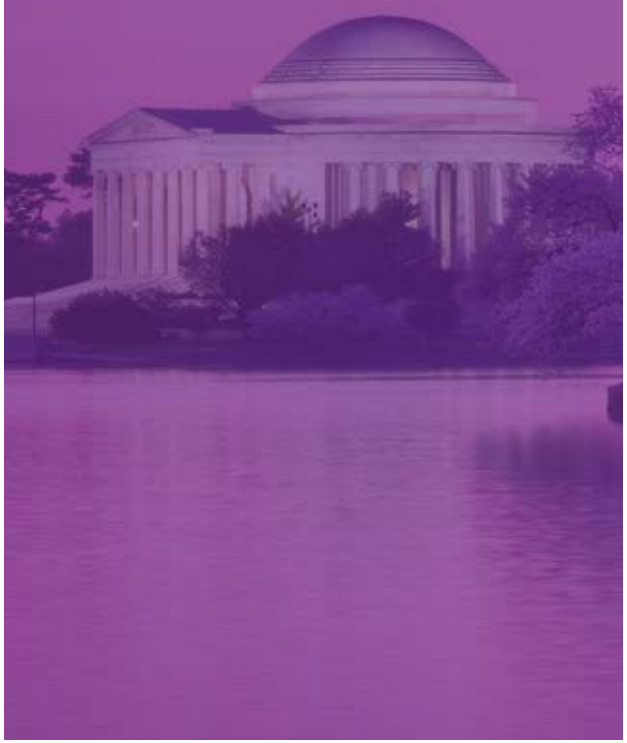
To find out more or to register, visit diahome.org/CMC2013.

REGISTRATION FEES:

Member
Member Academia $770
Member Government $615
Member Standard $1540
Early-bird $1390

Early-bird ends March 25!

Non-Member
Non-Member Academia $945
Non-Member Government $790
Non-Member Standard $1715



Workshop Highlights (Continued)

Who Should Attend?
Professionals involved in:
- CMC Regulatory Affairs
- CMC Writing
- Quality Assurance/Quality Control
- Regulatory Compliance
- API Development and Manufacturing
- Formulation Development and Manufacturing
- Analytical Development
- CMC Life Cycle Management
- CMC Project Management

Interested in Exhibiting?
Showcase your products and services to key decision makers. Submit your application today to exhibits@diahome.org.

We hope to see you in Washington, DC!

REGISTER ONLINE

You Might Also be Interested in:

DIA 2013 49th Annual Meeting: Advancing Therapeutic Innovation and Regulatory Science

June 23-27| Boston, MA

Search more than 250 sessions across 22 tracks on hot topics from key global thought leaders from the life sciences industry. This year's Pharmaceutical Quality Track highlights include:

- Chemistry, Manufacturing and Controls (CMC) Regulatory Landscape in Emerging Markets
- Update on Submission and GMP Expectations for Part 3 Combination Products
- GDUFA Update
- Strategies for the Development and Registration of Antibody Drug Conjugates
- Drug Shortages: Causes, Current State and Path Forward
- Implementation of Quality by Design: Progress, Challenges and Opportunities - Industry Perspective
- Implementation of Quality by Design: Progress, Challenges and Opportunities - FDA Perspective
- And More...

Archived Webinar Series: The Impact of Drug Shortages on the Pharmaceutical Industry

- Part 1: FDA Discusses Drug Shortages: Causes, Trends, Impact and Prevention
- Part 2: Drug Shortages within the Pharmaceutical Supply Chain: Impact on Patient Safety and Gray Market Control
- Part 3: Coordination and Communication with FDA and Worldwide Regulatory Authorities Regarding Manufacturing and Drug Shortage Issues
- Part 4: Potential Policy Solutions to Solve Drug Shortage Problem

Webinar:

- Certificates of Pharmaceutical Products for Regulatory Submissions
  May 23 | 10:00AM-12:00PM EST

Training Courses:

- Supplements and Other Changes to an Approved Application
  June 12 | 12:00-1:00PM
- Navigating Chemistry, Manufacturing & Controls Through the Drug Development Process
  November 4-5 | Horsham, PA

Join a DIA Community Today!

Interact and network with other professionals in your discipline through DIA's Communities. Here are related Communities to help you meet your needs:

- Chemistry, Manufacturing & Controls/Quality System
- Good Clinical Practices & Quality Assurance
- Clinical Research
- Regulatory Affairs

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- DrugInfoAssn DIA
- DrugInfoAssn
- DIA Annual Meeting

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