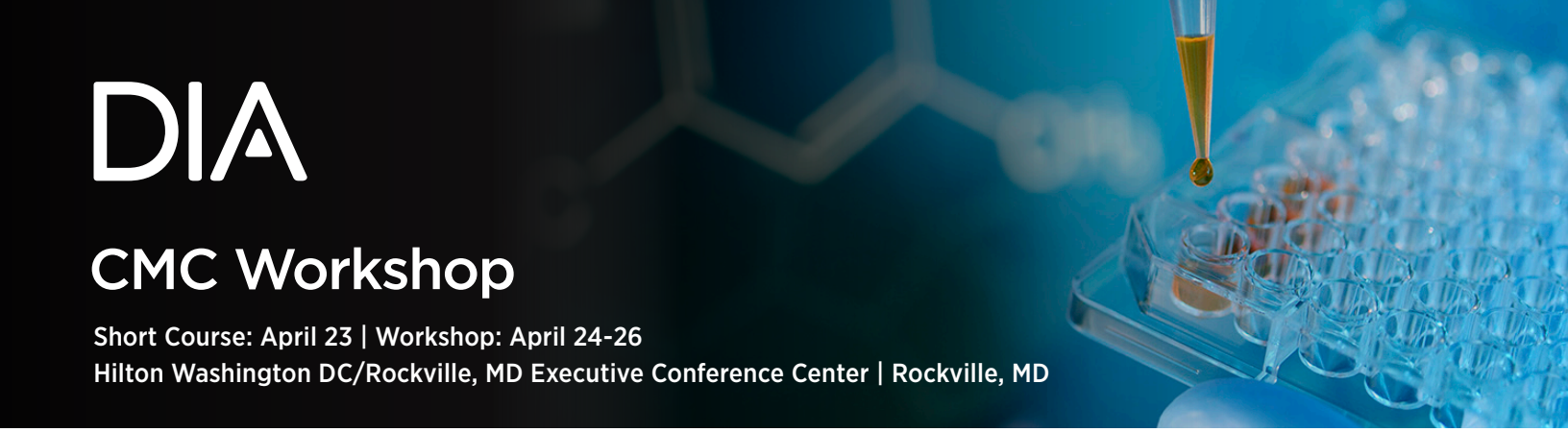

DIA

CMC Workshop

Short Course: April 23 | Workshop: April 24-26
Hilton Washington DC/Rockville, MD Executive Conference Center | Rockville, MD

PROGRAM CHAIR

Yasmin de Faria Krim, PharmD
Chairperson of the CMC Working Group
DIA Regulatory Affairs Community

PROGRAM COMMITTEE

Lin-Jau (Christine) Wu Anderson, MS, RAC
Senior Research Scientist, Global Regulatory, CMC
Eli Lilly and Company

Lynn Gold, MS, PhD
Vice President, Scientific and Regulatory Affairs
Camargo Pharmaceutical Services, LLC

Elaine Morefield, PhD, RPh
Vice President Regulatory Affairs
VaxForm, LLC.

Moheb M. Nasr, PhD, MS
Vice President, CMC Regulatory Strategy
GlaxoSmithKline

Peter Richardson, PhD
Head of Quality, Human Medicines Evaluation Division
European Medicines Agency, European Union

Jean-Louis Robert, PhD
CHMP (EMA) Co-Opted Member / CHMP (EMA) QWP Chair
CHMP (EMA), Luxembourg

Overview

Sound chemistry, manufacturing, and controls (CMC) are fundamental to the manufacture of safe, high quality, reliable biopharmaceuticals and devices. The growing complexity of products and technologies, along with increasing globalization and other factors, creates manufacturing challenges that can be difficult to resolve. Through three parallel tracks, DIA's *CMC Workshop* will provide a thorough understanding of the regulatory, technical, and quality requirements and strategies needed to support problem-solving as well as continuous improvements and innovation in biopharmaceutical manufacturing. Opportunities for interactive sharing of information and approaches will be an important part of the program.

Highlights

- Laser focus on regulatory applications and translations to technical and quality processes – the strategy behind the science
- Facilitated discussions with a highly global, regulatory focus, concentrating on regulations and guidelines from multiple ICH and non-ICH regions by regulatory authorities from those regions
- Multiple tracks with truly comprehensive content that will meticulously cover regulatory, technical, and GMP/Quality processes and how they work together
- In-depth discussions on a broad array of innovative products including: drugs (small molecule), complex products/generics, large molecules (biologics), biosimilars, and drug device combination products

Who Should Attend

Professionals involved in:

- All areas of CMC
- Quality Assurance/Quality Control
- Regulatory Compliance
- API Development and Manufacturing
- Formulation Development and Manufacturing
- Analytical Development

aaps® *This program is co-sponsored with the American Association of Pharmaceutical Scientists*

Schedule At-A-Glance

Track A: GMP/Quality **Track B:** Regulatory/Dossier **Track C:** Technical Aspects of CMC

SHORT COURSE | SUNDAY, APRIL 23

7:00AM-5:00PM	Short Course Registration	Madison Foyer
7:00-8:00AM	Short Course Continental Breakfast and Networking	Madison Foyer
8:00AM-5:00PM	**Short Course:** Regulatory CMC Training – The Basics to Prepare for the CMC Workshop	Madison

DAY ONE | MONDAY, APRIL 24

7:30AM-5:30PM	Registration	Plaza Ballroom Foyer
7:30-8:30AM	Continental Breakfast, Exhibits, and Networking	Plaza Ballroom Foyer
8:30-8:45AM	**Welcome and Opening Remarks**	Plaza Ballroom
8:45-10:15AM	**Session 1:** Accelerated Programs	Plaza Ballroom
10:15-10:45AM	Refreshments, Exhibits, and Networking Break	Plaza Ballroom Foyer
10:45AM-12:15PM	**Session 2:** Breakout Sessions	
	Track A: Joint Inspections	Plaza A
	Track B: QbD Approaches to Accelerated Drug Development	Plaza C
	Track C: Drug/Device – Part 1: Human Factor Studies	Regency
12:15-1:30PM	Luncheon	Atrium
1:30-3:30PM	**Session 3:** Innovative Technologies	Plaza Ballroom
3:30-4:00PM	Refreshments, Exhibits, and Networking Break	Plaza Ballroom Foyer
4:00-5:30PM	**Session 4:** Breakout Sessions	
	Track A: Global Landscape of Falsified Medicines and Global Landscape of Serialization	Plaza A
	Track B: Dissolution Techniques Challenges	Plaza C
	Track C: Drug/Device – Part 2: Technical Challenges	Regency
5:30-6:30PM	**Networking and Exhibits Reception**	Plaza Ballroom Foyer

DAY TWO | TUESDAY, APRIL 25

7:00AM-5:30PM	Registration	Plaza Ballroom Foyer
7:00-8:00AM	Continental Breakfast, Exhibits, and Networking	Plaza Ballroom Foyer
8:00-10:00AM	**Session 5:** Breakout Sessions	
	Track A: Leveraging CDMOs to Optimize Biologics Product Development and Manufacturing Strategies	Plaza A
	Track B: Challenges in Development and Approval of Generic Non-Biological Complex Drugs (NBCDs)	Plaza C
	Track C: Drug/Device – Part 3: Global Regulatory Updates	Regency
10:00-10:30AM	Refreshments, Exhibits, and Networking Break	Plaza Ballroom Foyer
10:30AM-12:00PM	**Session 6:** ICH Q12 Life Cycle Management: Benefits and Challenges	Plaza Ballroom
12:00-1:30PM	Luncheon	Atrium
1:30-3:30PM	**Session 7:** Breakout Sessions	
	Track A: Science, Risk-Based Approaches to Post-Approval Stability Testing	Plaza A
	Track B: Biosimilars	Plaza C
	Track C: Regional Updates – Part 1: Latin America Regional Convergence Opportunities and Challenges	Regency
3:30-4:00PM	Refreshments, Exhibits, and Networking Break	Plaza Ballroom Foyer
4:00-5:30PM	**Session 8:** Breakout Sessions	
	Track A: Process Validation/Continuous Verification for APIs: Challenges and Potential Benefits	Plaza A
	Track B: Update on ICH M9 Gaps	Plaza C
	Track C: Regional Updates - Part 2: Asia-Pacific	Regency

DAY THREE | WEDNESDAY, APRIL 26

7:00AM-12:00PM	Registration	Plaza Ballroom Foyer
7:00-8:00AM	Continental Breakfast, Exhibits, and Networking	Plaza Ballroom Foyer
8:00-9:30AM	**Session 9:** Breakout Sessions	
	Track A: Process and Product Monitoring for Sustained Quality	Plaza A
	Track B: The Divide Between Small and Large Molecule Drugs: Myths and Realities…	Plaza C
	Track C: Regional Updates – Part 3: Middle East	Regency
9:30-10:00AM	Refreshments, Exhibits, and Networking Break	Plaza Ballroom Foyer
10:00AM-12:00PM	**Session 10:** Regulators Update	Plaza Ballroom

Learning Objectives

At the conclusion of this Workshop, participants should be able to:

- Discuss the current CMC topics for chemical and biological products in a globalized environment
- Explain challenges and opportunities for accelerated drug development
- Describe recent ICH updates
- Compare challenges in the area of drug delivery devices
- Outline challenges in preventing falsified medicines in a global landscape
- Assess current situation for biosimilars approval
- State regulatory updates in International markets
- Discuss process monitoring for CMC

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Workshop ..... 1.7 CEUs

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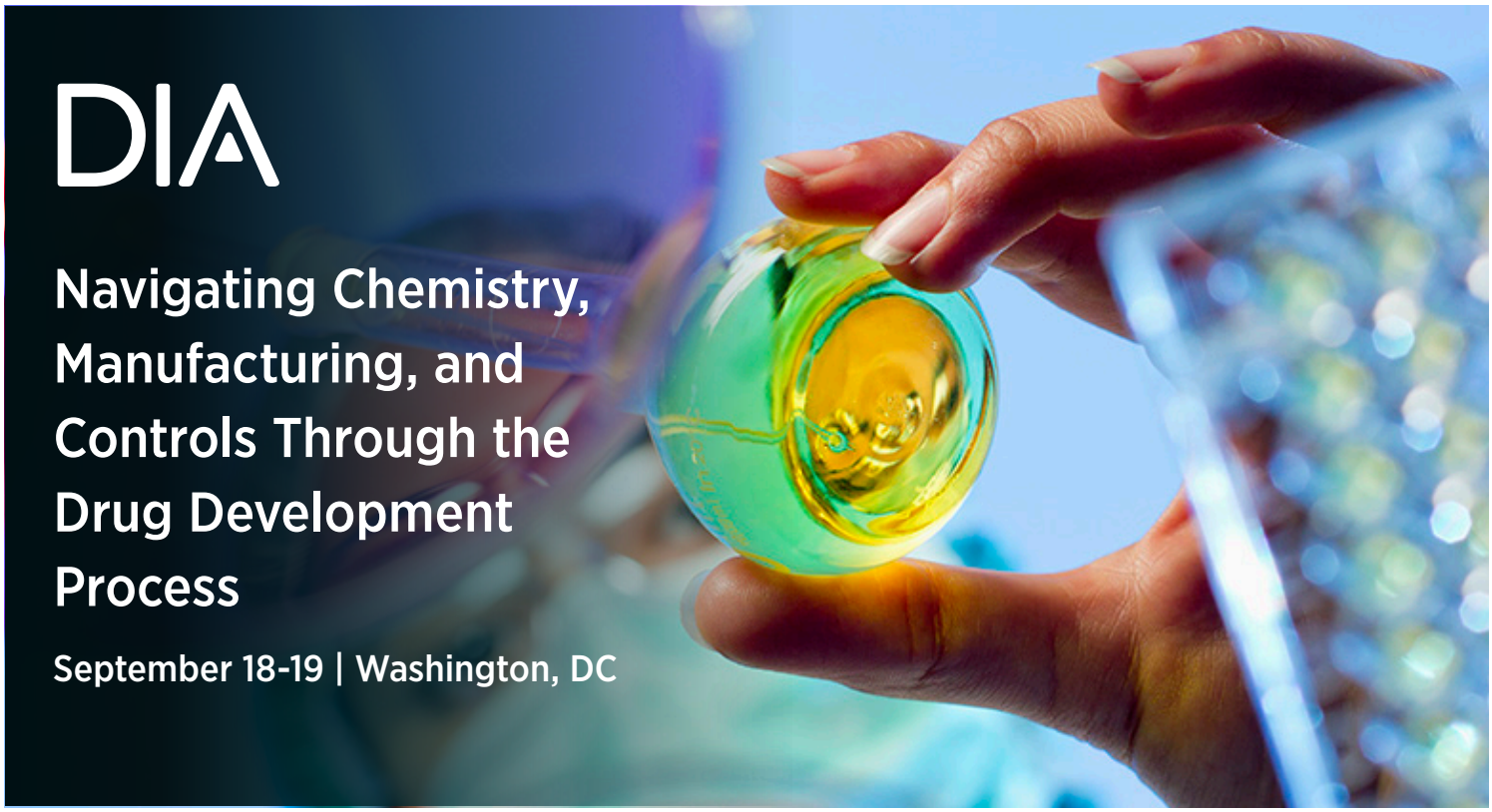
SHORT COURSE | SUNDAY, APRIL 23

7:00AM-5:00PM	**Short Course Registration**
7:00-8:00AM	**Short Course Continental Breakfast and Networking**
8:00AM-5:00PM *DIA will provide lunch 11:45AM-12:45PM*	**Short Course** Regulatory CMC Training - The Basics to Prepare for the CMC Workshop **Instructors** **Elaine Morefield, PhD** Vice President Regulatory Affairs VaxForm, LLC. **Lin-Jau (Christine) Wu Anderson, MS** Senior Research Scientist, Global Regulatory, Chemistry, Manufacturing, and Control Eli Lilly and Company This course will cover the basics of regulatory CMC topics that will be covered during the Workshop at a higher level. It will allow you to gain a better understanding about regulatory applications in the US and abroad, stability requirements, and inspections. The course will jump start your knowledge to allow you to make the most of your time during the full Workshop. **Learning Objectives** At the conclusion of this short course, participants should be able to: • Review the basics of Chemistry and manufacturing controls • Interpret and analyze CMC regulations to facilitate better understanding of the topics in the CMC Workshop • Improve skills in the CMC regulatory area to enhance work performance



DAY ONE | MONDAY, APRIL 24

7:30AM-5:30PM	**Registration**
7:30-8:30AM	**Continental Breakfast, Exhibits, and Networking**
8:15-8:45AM	**Welcome and Opening Remarks** **Sudip Parikh, PhD** Senior Vice President & Managing Director DIA Americas **Program Chair** **Yamin de Faria Krim, PharmD** Chairperson of the CMC Working Group DIA Regulatory Affairs Community
8:45-10:15AM	**Session 1** Accelerated Programs **Session Chair** **Silke Klick, PhD** Regulatory CMC Director AstraZeneca, Sweden This session will give an overview of accelerated programs in a global regulatory environment. Challenges in the CMC area will be illustrated by case studies, providing both industry and regulator perspective. **Expedited Programs – Implications and Innovations in Quality Assessment** **Sarah Pope Miksinki, PhD** Director, Office of New Drug Products, Director (Acting), Office of Surveillance, OPQ CDER, FDA **Accelerated Programs – Experiences from a Small Molecule NME Global Roll-Out** **Silke Klick, PhD** Regulatory CMC Director AstraZeneca, Sweden **Manufacturing Challenges and Opportunities for Accelerated Development Programs** **Earl Dye III, PhD** Director, Technical Regulatory Policy Genentech, A Member of the Roche Group
10:15-10:45AM	**Refreshment and Networking Break**

DAY ONE | MONDAY, APRIL 24

10:45AM-12:15PM

Session 2: Concurrent Breakout Sessions

TRACK A

Joint Inspections

Session Chair
Zedong Dong, PhD
Quality Assessment Lead (Acting)
FDA

Frequently, new drug applications and post-approval CMC changes may require facility inspections. In addition to the investigator(s), reviewers and subject matter experts may also participate in the audit. Speakers from regulatory agencies and industry will share their knowledge and experience on manufacturing facility inspections. A brief panel discussion will follow to address your questions and discuss approaches for a successful inspection from both the regulatory and industry perspectives.

CDER Participation on Pre-Approval and Post-Approval Inspections

Thuy Thanh Nguyen, MPH
Quality Assessment Lead (Acting)
FDA

Pre-Approval and Post-Approval Inspections – ORA Role

CAPT. Sharon K. Thoma, PharmD, RPh
National Expert of Pharmaceutical Inspections, ORA, OMPTO
FDA

Development and Current State of Joint Inspections: Review and Inspection – Industry Perspective

Joseph C. Famulare
Vice President, Global Compliance and External Collaboration
Genentech, A Member of the Roche Group

Joint Review and Inspection, an Industry Perspective

John Groskoph
Senior Director, New Products CMC, Global CMC
Pfizer Inc

TRACK B

QbD Approaches to Accelerated Drug Development

Session Chair
Elaine Morefield, PhD
Vice President Regulatory Affairs
VaxForm, LLC.

Breakthrough Therapy Designation (BTD), Priority Medicines (PRIME), Sakigake, and other accelerated pathways facilitate earlier patient access to innovative medicines. The timing of the accelerated pathway designation and corresponding marketing application can impact CMC as well as current Good Manufacturing Practice (GMP) development strategies and activities. This session will discuss how implementing a QbD paradigm can facilitate accelerated drug development and approval. Timing of development milestones in early phases, the use of risk to focus development decisions, how novel manufacturing techniques can support speed to market, various approaches for life cycle management that leverage enhanced product and process understanding, and regulatory approaches to meet the rapid development timelines for accelerated approvals will be discussed. During the panel discussion, you will have the opportunity to ask questions and share ideas on using QbD approaches for meeting accelerated timelines.

Leveraging QbD Paradigm for Accelerated Product Development: A Regulatory Perspective

Sharmista Chatterjee, PhD
Division Director (Acting), OPF, OPQ
CDER, FDA

Expedited Drug Development with Quality by Design

James Bush
Associate Director
Syner-G Pharma Consulting, LLC

CMC QbD Strategies for Accelerated Pathways

Terrance Ocheltree, PhD, RPH
Senior Director Regulatory Policy & Intelligence
AbbVie Inc.

TRACK C

Drug/Device – Part 1: Human Factors Studies

Session Chair
Andrew Chang, PhD
Vice President, Quality and Regulatory Compliance, Product Supply Quality
Novo Nordisk, A/S

This session will address the current regulatory landscape of Human Factors usability testing for drug/device combination products. The development of advanced drug delivery technologies is bringing new regulations and technical requirements with regards to usability of these devices. Last year, the FDA and the MHRA published draft guidelines for Human Factors studies. The session will provide recommendations/expectations for Human Factors analysis and testing, based also on experience with the existing CDRH FDA HFE Guide from 2016 and IEC62366-1 Usability for Medical Devices.

Irene Z. Chan, PhD
Associate Director, Divison of Medication Error, Prevention and Analysis, OSE
CDER, FDA

Usability and Human Factors Engineering: Integration with Risk Management and Design Controls

Peter Boge
Senior R&D Engineer, Design and Controls
Novo Nordisk, Denmark

Regulatory Perspectives on Planning Human Factors Studies of Combination Products

Becky Leibowitz, PhD
Associate Director, Regulatory Affairs, CMC Medical Devices and Combination Products
Janssen Research & Development

12:15-1:30PM

Luncheon and Networking

1:30-3:30PM

Session 3
Innovative Technologies

Session Chair
Peter Richardson, PhD
Head of Quality, Human Medicines Evaluation Division
EMA, United Kingdom

This session will look at innovative technologies for the manufacture of pharmaceutical products, with a focus on continuous manufacture (CM). Over recent years, CM has become of increasing interest for manufacturers, offering many potential benefits. Experience is growing in this field and a number of CM processes have been approved by regulators and with many companies considering applying this process technology, this will continue to grow. Challenges such as batch definition and traceability, dynamic control strategies, use of Process Analytical Technologies, validation strategies, and specifications are some of the areas which can require new perspectives from both industry and regulators. The session will give broad ranging perspectives from regulators and industry participants for small and large molecule examples.

Session introduction and EU Regulatory Perspectives on Innovative Technologies

Peter Richardson, PhD
Head of Quality, Human Medicines Evaluation Division
EMA, United Kingdom

US FDA Regulatory Perspectives on Innovative Technologies

Sau "Larry" Lee
Deputy Director (Acting), OPQ Emerging Technology Team Chair, Office of Testing and Research, OPQ
FDA

Industry Perspective for Implementing Continuous Manufacturing for Small Molecules

Diane Zezza, PhD
Vice President, Head Regulatory Affairs Global Drug Development CMC
Novartis Pharmaceuticals Corporation

Industry Perspective for Implementing Continuous Manufacturing for Biopharmaceuticals

Nick Keener III, PhD
Director of Process Development
Amgen

Panelist
(Joining Session Speakers)
Yoshihiro Matsuda, PhD
Senior Scientist (for Quality), Pharmacist
PMDA, Japan

3:30-4:00PM — **Refreshment and Networking Break**

4:00-5:30 PM

Session 4: Concurrent Breakout Sessions

TRACK A

Global Landscape of Falsified Medicines and Global Landscape of Serialization

Session Chair
Terrance Ocheltree, PhD
Senior Director Regulatory Policy and Intelligence
AbbVie Inc.

To combat the increasing risk of falsified medicines in the global market many countries have or plan to initiate serialization and traceability requirements. The lack of coordination of these efforts has the potential to create conflicting requirements and complex operational challenges for all stakeholders in the pharmaceutical supply chain. This session will highlight the current challenges facing the pharmaceutical industry to track and trace global medicinal products, discuss harmonized approaches pertaining to serialization, and provide a regulator's perspective to addressing falsified medicines. During the panel discussion, you will have the opportunity to ask questions and share ideas on approaches to secure pharmaceutical products supply chains to ensure that patients receive safe and effective medicinal products.

Supply Chain Integrity: FDA Perspective on Falsified Medicines and Serialization

CDR Eleni Anagnostiadis
Director, Division of Supply Chain Integrity
CDER, FDA

Global Development in Serialization and the Need for Harmonization

Eric M. Marshall, JD
Senior Director
Leavitt Partners

DSCSA - Drug Supply Chain Security Act

Lloyd Mager
Global Traceability Lead, Supply Chain Traceability Operations
AbbVie

TRACK B

Dissolution Techniques Challenges

Session Co-Chairs
Lynn Gold, PhD
Vice President, Scientific and Regulatory Affairs
Camargo Pharmaceutical Services, LLC

Kathy Kemme
Associate Director of CMC Services
Camargo Pharmaceutical Services, LLC

Innovation is essential to the development of novel pharmaceutical drug products, such as Non-Biologic Complex Drugs (NBCDs), such as nanoparticles, microspheres, parenterals and suspensions, which present unique challenges to the development program, impacting the design of a meaningful dissolution method. There are many challenges to dissolution for the standard drug products and the drug product complexity increases the dissolution method challenges become more complex as well. The challenges take many forms such as sampling, apparatus, parameters, optimum statistical analysis, and regulatory acceptability. This session will explore various aspects of these challenges from historical, scientific, and regulatory perspectives.

Challenges in Developing Dissolution Methods for Non-Conventional Suspensions, Implants, and Stents

Vivian Gray
President
V.A. Gray Consulting, Inc.

Statistics for Dissolution Methods for Novel Dosage Forms/Non-Biologic Complex Drugs

Helen Strickland
Senior Statistical Consultant
GlaxoSmithKline

Regulatory Challenges for Dissolution Methods for Novel Dosage Forms/Non-Biologic Complex Drugs

Okpo Eradiri, PhD
Acting Quality Assessment Lead
FDA

TRACK C

Drug/Device – Part 2: Technical Challenges

Session Chair
Douglas Mead
Director, CMC Global Regulatory Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson

Technical challenges in co-developing a delivery device with a drug or biologic are often underestimated and addressing them early on can mitigate delays later in development. The expected Design Controls approach will lead to user and technical design requirements and a "combination product design" with performance specifications that must be documented, verified in bench testing, and validated against user needs. We must also define control strategies for the design and manufacture of combination products to ensure quality attributes for safety and performance are established and confirmed. "Platform" delivery devices suitable for multiple drugs can be an important goal to streamline across product development programs, and ensuring high volume manufacturability for launch can raise significant challenges while providing life cycle advantages. This session will include a mixed discussion of technical challenges associated with the development control strategies, manufacturing considerations, and bridging strategies with Q&A.

Combination Product Control Strategy Development

Suzette Roan
Associate Director, Regulatory Affairs CMC Combination Products
Biogen

Technical Challenges and Opportunities in Device Development

E. Guan
Director, Drug Delivery and Device Development
MedImmune

Clinical and Quality Considerations Applicable to Combination Product Bridging Principles

Douglas Mead
Director, CMC Global Regulatory Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson

5:30-6:30PM

Networking and Exhibits Reception

DAY TWO | TUESDAY, APRIL 25

7:00AM-5:30PM Registration

7:00-8:00AM Continental Breakfast and Networking

8:00-10:00AM **Session 5:** Concurrent Breakout Sessions

TRACK A

Leveraging CDMOs to Optimize Biologics Product Development and Manufacturing Strategies

Session Chair
Mike Jenkins, PhD
Senior Consultant
BioProcess Technology Consultants, Inc.

One of the strategic decisions that must be made during product development is how and where to develop and manufacture the product. Manufacturing in-house, partnering with a company with excess capacity, and working with a CMO are common options. This session focuses on the best practices and the advantages of working with CDMO that go beyond accessing capacity. A good CDMO has extensive expertise in areas such as cell line, process and method development QbD, continuous manufacturing, and accelerated development programs, and will apply this expertise as appropriate to optimize the long-term manufacturing strategy for their client.

José Ochoa
JD Chief Business Officer
IDT Biologika

Selecting a CDMO: Perspective from a Small Biopharma Company

Karen Cui, MD, PhD
Head, Drug Development
Precision Biologics

Getting to Win-Win: Reflections from CMO and Client Perspectives

Manoj Menon, PhD
Director, New Products, Biologics Global Technical Operations
AstraZeneca

TRACK B

Challenges in Development and Approval of Generic Non-Biological Complex Drugs (NBCDs)

Session Chair
Yu Chung Tsang, PhD
Chief Science Officer, Biopharmaceuticals and Biostatistics, Apobiologix
Apotex, Inc., Canada

Non-biological complex drugs (NBCDs) are defined scientifically as not being a biological medicinal product where the active substance is not a homo-molecular structure, but consists of different closely related and often nanoparticulate structures that cannot be isolated and fully quantitated, characterized and/or described by physicochemical analytical means, where the structural elements that might impact the therapeutic performance are unknown. Nanomedicines, such as liposomes, polymeric micelles, glatiramoids, iron-carbohydrate complexes and nanocrystals are examples of NBCDs. The challenges in developing analytical methodologies to characterize these products, as well as assuring safety and efficacy of generic NBCDs for regulatory approval will be presented and discussed in this session.

Regulatory Perspective on Demonstrating Analytical and Therapeutic Similarities of Complex Generic Products

Rob Lionberger, PhD
Director, Office of Research and Standards, Office of Generic Drugs
FDA

Challenges in Manufacture of NBCDs and Assuring Analytical Similarity

Olu Aloba, PhD
Senior Director, Pharmaceuticals
Camargo Pharmaceutical Services

The Need of Conducting Clinical Study for Assuring Safety and Efficacy, as Well as a Lack of Immunogenicity for Generic NBCDs

Ajaz S. Hussain, PhD
President and CEO
Insight Advice & Solutions, LLC

TRACK C

Drug/Device – Part 3: Global Regulatory Updates

Session Chair
LeeAnn Chambers, MS, RAC
Principal Research Scientist, Global Regulatory Affairs, CMC-Devices
Eli Lilly and Company

This session will provide overviews of drug/device combination product regulations and development strategies. Topics include an update on the status of the EU Medical Device Regulations and how they will impact manufacturers, an overview of combination product development strategies for registering these products in China, and an overview of global regulation of oral liquid pharmaceutical products.

Revolution in Europe — What Changes Can You Expect Regarding Drug-Device Combinations?

Jaap Laufer, MD, PhD
Vice President of Clinical and Regulatory Affairs
Emergo Group

Combination Product Development: A Harmonized Roadmap for Efficiency, Compliance, and Speed to Market in Asia

Winston R. Brown
Vice President of Globabl Quality and Regulatory Affairs
Phillips Medisize Corporation

Regulations and Design/ Development Strategies for Oral Liquid Packaging and Device

Matthew S. Thomas
Packaging Design and Development Manager
Eli Lilly and Company

10:00-10:30AM **Refreshments and Networking Break**

10:30AM-12:00PM

Session 6
ICH Q12 Life Cycle Management: Benefits and Challenges

Session Co-Chairs
Jean-Louis Robert, PhD
CHMP (EMA) Co-Opted Member / CHMP (EMA) QWP Chair
CHMP (EMA), Luxembourg

Moheb M. Nasr, PhD
Vice President, CMC Regulatory Strategy
GlaxoSmithKline

While the concepts in ICH Q8, Q9, Q10, and Q11 provided opportunities for a more science- and risk-based approach for assessing changes across the life cycle, several gaps exist which limit full realization of expected regulatory flexibility. These gaps include harmonized change management best practices that effectively evaluates the impact of change on quality, clarity of the regulatory commitments (established conditions) in regulatory files and distinguishing them from supporting information, and the development and submission of product specific life cycle management strategy document in regulatory files.

ICH Q12 industry and regulatory experts will share their perspectives on ICH Q12 and provide an update on progress made to date. Presentations will be followed by panel discussions.

An Industry Perspective
Moheb M. Nasr, PhD
Vice President, CMC Regulatory Strategy
GlaxoSmithKline

EU Regulatory Perspective
Jean-Louis Robert, PhD
CHMP (EMA) Co-Opted Member / CHMP (EMA) QWP Chair
CHMP (EMA), Luxembourg

12:00-1:30PM — **Luncheon and Networking**

DAY TWO | TUESDAY, APRIL 25

1:30-3:30PM

Session 7: Concurrent Breakout Sessions

TRACK A

Science, Risk-Based Approaches to Post-Approval Stability Testing

Session Chair
Chi-wan Chen, PhD
Executive Director, Global CMC
Pfizer Inc

This session will examine the need for, and the benefit of, establishing an ICH guideline on science- and risk-based approaches to stability testing for post-approval CMC changes or stability commitment. An outline of a proposal for an ICH guideline on this topic will be described. Predictive tools such as statistical modeling, and Accelerated Stability Assessment Program (ASAP), will be discussed. Utility of prior knowledge to justify reduced stability protocols for legacy products will be presented.

The Case for a New ICH Guideline on Science- and Risk-Based Approaches to Stability Testing for Post-Approval CMC Changes

Chi-wan Chen, PhD
Executive Director, Global CMC
Pfizer Inc

Predictive Stability Approaches to Assessing Critical Attributes of Pharmaceutical Products

Brian Regler, PhD
Associate Principle Scientist
Merck

Leveraging Stability Profiles to Justify a Reduced Stability Program for Legacy Products

Anthony Rainosek
Senior Manager, Stability
Baxter Healthcare

Right-Sizing Post-Approval Stability Commitments: A Case-Study and Considerations

Donnie Pulliam
Manager, Global Stability
Biogen

TRACK B

Biosimilars

Session Chair
Anthony Ridgway, PhD
Acting Director, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics, Biologics and Genetic Therapies Directorate, Health Products and Food Branch
Health Canada

The development of biosimilars is continuing at a fast pace. This session will provide regulatory updates from the US and EU covering recent biosimilar approvals as well as changes to the regulatory frameworks and guidances in these regions (e.g. FDA draft guidance on interchangeability). Perspectives from industry speakers will include case studies illustrating obstacles for biosimilars in the CMC area and how these might be circumvented. During the panel discussion, CMC regulatory considerations for global development and the potential for a global regulatory submission will be explored.

Regulatory Update from Europe and IPRF Biosimilars Working

Peter Richardson, PhD
Head of Quality, Human Medicines Evaluation Division
EMA, United Kingdom

Constructing a Comprehensive Analytical Similarity Assessment Program

Juhong Liu
Scientist, OPQ, OBP, DBRRII
CDER, FDA

Biosimilar Development: Understanding Structure Function Relationships is Key

Hansjeorg Toll, PhD
Head RegCMC Immunology Products
Sandoz Pharmaceuticals, Austria

Case Study - CMC Challenges when a Small Biosimilar Developer Must Rely on Outsourcing for Development and Manufacturing Activities

Patricia M. Seymour
Senior Consultant
BioProcess Technology Consultants, Inc.

TRACK C

Regional Updates – Part 1: Latin America Regional Convergence Opportunities and Challenges

Session Chair
Rebecca E. Thomas
Owner
Bekki Thomas Consulting, Inc.

This session will be a discussion of regional convergence opportunities and challenges in Latin America. The session will focus on clinical trials through all facets of development and commercialization-full life cycle of the product. The session will include an industry representative and invited PAHO and Health Authority representatives with overview presentations with an opportunity for audience participation.

Challenges and Opportunities from Initial Application Through Life Cycle in Latin America

Maria Cristina Mota Pina
Director, Scientific Regulatory Policy and Intelligence, Latin America
Abbvie

Regulatory Challenges and Scenarios in Brazil

Tatiana Gaban
Director, Regulatory Affairs
CMC International, Latin America
Merck, Brazil

3:30-4:00PM **Refreshment, Exhibits, and Networking Break**

4:00-5:30PM

Session 8: Concurrent Breakout Sessions

TRACK A

Process Validation/Continuous Verification for APIs: Challenges and Potential Benefits

Session Chair
Jean-Louis Robert, PhD
CHMP (EMA) Co-Opted Member / CHMP (EMA) QWP Chair
CHMP (EMA), Luxembourg

A major element of the new paradigm in pharmaceutical quality, besides science and risk management, is the life cycle approach as described in ICH Q10. Continuous verification strategies form the basis for handling life cycle maintenance. These strategies can enable continuous improvement and process optimization by continuously collecting information, allowing for better scientific understanding of both process and product. The session will present the regulatory expectation for process validation and process verification. Two drug substance examples, chemical and bio, will highlight the benefit of continuous verification strategies compared to traditional process validation.

Process Validation/Process Verification: A Regulatory Perspective

Jean-Louis Robert, PhD
CHMP (EMA) Co-Opted Member / CHMP (EMA) QWP Chair
CHMP (EMA), Luxembourg

A Risk-Based Approach to Process Validation Using QRM Principles and Practices

Thomas Gervais, PhD
Associate Director, Process Life Cycle Management
Bristol-Myers Squibb

Process Validation and Continuous Verification; Leveraging Process Models for the Manufacture of a Small Molecule Semi-Continuous Process

Kevin Seibert, PhD
Senior Research Advisor, Chemical Product R&D
Eli Lilly and Co.

TRACK B

Update on ICH M9 Gaps

Session Chair
Roger Nosal
Vice President and Head, Global CMC
Pfizer, Inc.

The ICH M9 EWG intends to harmonize criteria and definitions for Biopharmaceutics Classification System (BCS)-Based Biowaivers. While BCS-based biowaivers may be applicable to BCS Class I and III drugs, definitions of these two classes are not regionally consistent or recognized globally. This session will describe differences in classification definitions of solubility, and permeability as well as differences in the data required to justify a waiver in various regions and provide proposals for reconciling those differences.

Definition of Solubility (Maximum Therapeutic Dose vs. Highest Strength) and Requirement of Dose-Proportionality (Dose Exposure)

Jack Cook
Vice President, Clinical Pharmacology
Pfizer Inc.

Definition of Permeability (Relative Value of In Vitro Data)

Mehul Mehta, PhD
Director
FDA

Dissolution and Formulation Criteria (Justification for Dissolution Criteria/Media; Excipient Impact on BA)

Patrick Marroum, PhD
Senior Research Fellow
AbbVie

TRACK C

Regional Updates – Part 2: Asia-Pacific

Session Co-Chairs
Lin-Jau (Christine) Wu Anderson, MS
Senior Research Scientist, Global Regulatory, Chemistry, Manufacturing and Control
Eli Lilly and Company

Xiling Song
Senior Quality Product Leader
Genentech, A Member of Roche Group

There are numerous new and innovative regulatory developments coming to light in the Asia-Pacific region. In order to have a successful clinical trial application and/or MAA submission in this region, sponsors need to be made aware of these changes and requirements and how to adapt. This session will cover the latest hot topics in the Asia-Pacific region including Japan, China, and many other countries, regarding the regulatory submissions. A closing panel discussion and Q&A will allow for more in-depth discussions on these topics.

Regulatory Updates and Hot Topics – Japan

Issei Takayama, PhD
Reviewer, Office of New Drug IV
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Regulatory Updates and Hot Topics - China

Yang (Frank) Gao
Associate Regulatory Affairs Director,
Eli Lilly and Company, China

Regulatory Updates and Hot Topics – Other Asia-Pacific Countries

Xiling Song
Senior Quality Product Leader,
Genentech, A Member of Roche Group

Panelist
(Joining Session Speakers)
Chi-wan Chen, PhD
Executive Director, Global CMC
Pfizer Inc.

DAY THREE | WEDNESDAY, APRIL 26

7:00AM-12:00PM Registration

7:00-8:00AM Continental Breakfast, Exhibits, and Networking

8:00-9:30AM **Session 9:** Concurrent Breakout Sessions

SESSION 9A

Process and Product Monitoring for Sustained Quality

Session Chair
Christine M. V. Moore, PhD
Global Head and Executive Director, GRACS CMC - Policy
Merck Research Laboratories

This session will describe the advantages of product and process monitoring beyond minimal GMP requirements. Such efforts are aligned with FDA efforts to modernize manufacturing and can aid in sustained process performance, that may be reflected in quality metrics. Industry speakers will discuss implementing a comprehensive system to monitor process performance and support continual improvement and how multivariate analysis of process data can aid fault diagnosis and correction. Additionally, an FDA speaker will provide a perspective of the advantages of process monitoring over the product life cycle.

Improving Process Robustness via Continuous Process Monitoring in Drug Product Manufacturing – Case Studies

Stelios Tsinontides, PhD
Senior Director and Head, Drug Product Technical Services, SM Operating Unit, Technical Operations
Shire

The Application of Real-Time Multivariate Data Analysis to Improve Equipment Health and Process Consistency

Louis Obando, PhD
Principle Scientist
Merck Research Laboratories

Design and Implementation of Process Monitoring Tools for Continuous Improvement

Christina Capacci-Daniel, PhD
Quality Assessment Lead (Acting), OPF
CDER, FDA

SESSION 9B

The Divide Between Small and Large Molecule Drugs: Myths and Realities...

Session Chair
Wassim Nashabeh, PhD
Vice President, Regulatory Policy and International Operations
F. Hoffmann-La Roche Ltd.

This session will feature an interactive panel discussion on the similarities and differences between small and large molecule drugs development and regulatory approaches. Are these two classes of molecules so uniquely different that warrant different scientific and regulatory principles. What shared lessons can we learn between them when it comes to enhanced process and product understanding, quality risk management, establishment of control strategy, science-based regulatory framework and international regulations and harmonization. The panel will explore these themes with active engagement and participation from the audience. Come prepared with your questions and keep an open curious mind.

Panelists
Joseph C. Famulare
Vice President, Global Compliance and External Collaboration
Genentech, A Member of the Roche Group

Peter Richardson, PhD
Head of Quality, Human Medicines Evaluation Division
EMA, United Kingdom

Nirdosh Jagota, PhD
Global CMC Regulatory Head
Merck

Laurie Graham
Acting Director, DIPAP, OPPQ, OPQ
CDER, FDA

SESSION 9C

Regional Updates – Part 3: Middle East

Session Chair
Ihab Attia
RAWG Chair
Eli Lilly (suisse) S.A., United Arab Emirates

This session will discuss CMC regulatory requirements in the Middle East/Near East region focusing on recent updates.

Ihab Attia
RAWG Chair
Eli Lilly (suisse) S.A., United Arab Emirates

Inas Chehimi
Head DRA Middle East and North Africa
Novartis Pharma Services AG, United Arab Emirates

9:30-10:00AM **Refreshment, Exhibits, and Networking Break**

10:00-12:00PM

Session 10
Regulators Update

Session Chair
Moheb M. Nasr, PhD
Vice President, CMC Regulatory Strategy
GlaxoSmithKline

To conclude the workshop, this last session will provide updates from experts from regulatory agencies as well as a true opportunity for a dialogue with the audience.

Issei Takayama, PhD
Reviewer, Office of New Drug IV
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Jean-Louis Robert, PhD
CHMP (EMA) Co-Opted Member / CHMP (EMA) QWP Chair
CHMP (EMA), Luxembourg

Peter Richardson, PhD
Head of Quality, Human Medicines Evaluation Division
EMA, United Kingdom

Anthony Ridgway, PhD
Acting Director, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics, Biologics and Genetic Therapies Directorate, Health Products and Food Branch
Health Canada

Sarah Pope Miksinki, PhD
Director, Office of New Drug Products, Director (Acting), Office of Surveillance, OPQ
CDER, FDA

Helen Saccone, PharmD
Senior Advisor, Global Regulatory Operations and Policy, OIP, OC
FDA

12:00PM

Workshop Adjourns