VIRTUAL EVENT

DIA

Advancing CMC Workshop

Global Challenges, Global Opportunities

23-25 September 2020 | Timing in CEST

PROGRAMME COMMITTEE

Ben Thompson
Vice President, CMC and Non-clinical Regulatory Affairs, GlaxoSmithKline, UK

Frank Montgomery
Global Head Regulatory CMC, GRAPSQA, AstraZeneca, UK

Sara Torgal
Scientific Programmes Manager, DIA EMEA, Switzerland

Susanne Ausborn
Global Head International Regulatory Policy, F. Hoffmann-La Roche Ltd, Switzerland

Sylvie Meillerais
Director, Global CMC Policy, MSD (Europe) Inc., Belgium

Ursula Busse
Global Head of Quality Intelligence & External Affairs, Novartis, Switzerland

Overview

This workshop will focus on the currently most relevant topics in the CMC (Chemistry, Manufacturing and Controls) Regulatory space within the global pharmaceutical/ biopharmaceutical arena, including early **lessons learned from the COVID-19 emergency efforts** – including the perspective from 7 global Regulatory Authorities, reliance and global regulatory convergence, global ICH Q12 implementation (including emerging markets), challenges with innovative therapies, global case studies on medical devices and combination products, and many other topics. The format will allow participants to engage in constructive dialogue with experts from Regulatory Agencies, International Organisations and Industry, enabling interactive cross-functional discussions

Key Topics

- Lessons learned from COVID-19 in the CMC Regulatory space
- Enhanced Dialogue and Regulatory Flexibility
- eCPPs – electronic Certificates of Pharmaceutical Product
- Regulatory Frameworks to Support Innovation
- Innovation and its CMC Regulatory Challenges
- Challenges with Medical Devices and Combination Products
- Global ICH Q12 implementation
- Regulatory Convergence

Who Should Attend

Professionals involved in:

- CMC Regulatory Affairs
- CMC Writing
- CMC Policy
- Global Development
- Quality Assurance/Quality Control
- Quality Inteligence
- Regulatory Compliance
- Regulatory Policy
- API Development and ManufacturingS1S
- Formulation Development and Manufacturing
- Analytical Development
- Technical Research and Development
- ICH Guidelines implementation and development
- CMC Lifecycle Management
- CMC Project Management
- Medical Devices and Combination Products
- All professionals involved in CMC

DAY ONE | WEDNESDAY, 23 SEPTEMBER 2020

LESSONS LEARNED FROM COVID-19 IN THE CMC REGULATORY SPACE

12:30 LOG-IN

12:40 ORIENTATION AND INTRODUCTION TO THE ADVANCING CMC WORKSHOP

Sara Torgal, Scientific Programmes Manager, DIA EMEA

13:00 SESSION 1

ENHANCED DIALOGUE LEARNINGS AND REGULATORY AGILITY IN TIMES OF CRISIS

Session Chairs:
Susanne Ausborn, Global Head International Regulatory Policy, F. Hoffmann-La Roche Ltd, Switzerland
Sylvie Meillerais, Director, Global CMC Policy, MSD (Europe) Inc., Belgium

This session will gather various Stakeholders perspectives in times of crisis, as we are currently facing with the COVID-19 pandemic, and which has generated innovative ways of working, and communicating.

Panel Discussion with Q&A, with the participation of:
EMA - Fergus Sweeney, Head of Clinical Studies and Manufacturing Task Force, European Medicines Agency, EU
Vaccines Europe - Diane Wilkinson, Senior Director Regulatory CMC, Astrazeneca, UK
IFPMA - Janis Bernat, Director, Biotherapeutics & Scientific Affairs, IFPMA, Switzerland

14:00 BREAK

14:15 SESSION 2, PART I

AGENCIES EXPECTATIONS/OPPORTUNITIES AND INDUSTRY CHALLENGES AND PROPOSED OUTLOOK

Session Chairs:
Susanne Ausborn, Global Head International Regulatory Policy, F. Hoffmann-La Roche Ltd, Switzerland
Sylvie Meillerais, Director, Global CMC Policy, MSD (Europe) Inc., Belgium

Building on the previous session, this session will explore more specific CMC considerations moving forward and learnings from, for example, remote inspections, and will gather learnings, for example, remote inspections and will gather learnings on the use and benefits that electronic CPPs can provide in a time of crisis and beyond.

EFPIA White Paper on CMC development, manufacturing and supply of pandemic COVID-19 therapies and vaccines (available here)
Matt Popkin, Director, CMC Strategy, GlaxoSmithKline, UK

Remote Inspections
Stephan Roenninger, Director, Quality External Affairs, Amgen (Europe) GmbH, Switzerland

EMA Perspective on eCPPs
Alberto Ganan Jimenez, Head of Service, Procedure Management and Business Support Division, European Medicines Agency, EU

Industry Mapping on eCPP
Susanne Ausborn, Global Head International Regulatory Policy, F. Hoffmann-La Roche Ltd, Switzerland

IFPMA eCPP Position Paper
Nevena Miletic, Regulatory Policy Lead – EEMEA & Chair of IFPMA CPP Network, F. Hoffmann-La Roche Ltd, Switzerland

15:20 BREAK

15:30 SESSION 2, PART II

AGENCIES EXPECTATIONS/OPPORTUNITIES AND INDUSTRY CHALLENGES AND PROPOSED OUTLOOK

Session Chairs:
Susanne Ausborn, Global Head International Regulatory Policy, F. Hoffmann-La Roche Ltd, Switzerland
Sylvie Meillerais, Director, Global CMC Policy, MSD (Europe) Inc., Belgium

Building on the previous session, this session will explore more specific CMC considerations moving forward and learnings from, for example, remote insp Principal Quality Specialist, European Medicines Agency, EU ections.

Global Regulatory Authorities reflect on Lessons Learned, with the presence of:
EMA - Ragini Shivji, Principal Quality Specialist, European Medicines Agency, EU
ANVISA - Daniela Marreco Cerqueira, Deputy Director, ANVISA, Brazil
EAEU - Dzmitry Razhdzestvenski, Head, Division for Coordination of Common Market for Drugs and Medical Devices, Department of Technical Regulation and Accreditation, Eurasian Economic Commission, Russia

DAY ONE | WEDNESDAY, 23 SEPTEMBER 2020

Panel discussion with Q&A, with the additional participation of:
Matt Popkin, Director, CMC Strategy, GlaxoSmithKline, UK
Stephan Roenninger, Director, Quality External Affairs, Amgen (Europe) GmbH, Switzerland
Nevena Miletic, Regulatory Policy Lead – EEMEA & Chair of IFPMA CPP Network, F. Hoffmann-La Roche Ltd, Switzerland

16:40 BREAK

16:50 SESSION 3

PROGRESS OF THE EU-US COOPERATION ON THE MUTUAL RECOGNITION AGREEMENT FOR PHARMACEUTICAL GOOD MANUFACTURING PRACTICES

Session Chair:
Stephan Roenninger, Director, Quality External Affairs, Amgen (Europe) GmbH, Switzerland

Facilitating public health by freeing inspection resources for industry and national competent authorities and ensuring high quality medicines for patients in an environment of trade negotiations.

Introduction: Progress of the EU-US Cooperation on the Mutual Recognition Agreement for Pharmaceutical Good Manufacturing Practices
Stephan Roenninger, Director, Quality External Affairs, Amgen (Europe) GmbH, Switzerland

FDA International Engagement and the US-EU Mutual Recognition Agreement
Matthew Scherer, Assistant Attache, FDA-Europe Office, U.S. Food and Drug Administration, USA

EU-US MRA Practical Implementation
Andrei Spinei, Scientific Administrator, European Medicines Agency, EU

Panel discussion with Q&A

17:50 WRAP-UP

Susanne Ausborn, Global Head International Regulatory Policy, F. Hoffmann-La Roche Ltd, Switzerland
Sylvie Meillerais, Director, Global CMC Policy, MSD (Europe) Inc., Belgium

18:00 END OF DAY ONE

DAY TWO | THURSDAY, 24 SEPTEMBER 2020

REGULATORY FRAMEWORKS TO SUPPORT INNOVATION

11:30 WELCOME

Sara Torgal, Scientific Programmes Manager, DIA EMEA

11:40 SESSION 4

CATALYSING THE INTEGRATION OF SCIENCE AND TECHNOLOGY IN MEDICINES DEVELOPMENT

Session Chair:
Falk Ehmann, Chair of Innovation Task Force, European Medicines Agency, EU

Floodlight (Roche) RE digital challenges
Seya Colloud, Global Regulatory Director, F. Hoffmann-La Roche Ltd, Switzerland

Case study on Borderline/Combination product and consequent challenges for "joint" Pharma / Regulator / Notified Body assessment
Armin Ritzhaupt, Scientific Administrator, European Medicines Agency, EU

Example and view from the Notified Body's perspective
Astrid Hoepffner, Senior Product Specialist Clinical Data / Clinical Reviewer, TÜV SÜD Product Service GmbH, Germany

Support mechanisms from NCA, EU-IN and EMA side with a focus on Digital Technologies and Borderline Products
Laurence O'Dwyer, Scientific Affairs Manager, Health Products Regulatory Authority (HPRA), Ireland

EMA Innovation task force / EMA regulatory science strategy
Falk Ehmann, Chair of Innovation Task Force, European Medicines Agency, EU

Panel discussion with Q&A, on How to turn Challenges into Opportunities

Disclosure Policy

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

DAY TWO | THURSDAY, 24 SEPTEMBER 2020

13:00 BREAK

13:15 SESSION 5 & 6

INNOVATIVE MEDICINES AND ITS CMC REGULATORY CHALLENGES

Session Chairs:
Frank Montgomery, Global Head Regulatory CMC, GRAPSQA, AstraZeneca, UK
Ursula Busse, Global Head of Quality Intelligence & External Affairs, Novartis, Switzerland

The session will provide some insights on specific CMC challenges and opportunities for novel technologies such as gene therapy, radioligand therapies and oligomers. Considering high expectation from patients around the world for such innovative treatments to address unmet medical needs there is an urgent need for global approaches to drive for global regulatory requirements using the appropriate science and risk-based tools to address the CMC challenges. Industry will illustrate regulatory filings strategies considering the complexity for such type of medicines which will be discussed with regulators from different jurisdictions.

Gene Therapies
Adam Walker, Director, Biopharm CMC Global Regulatory Affairs, GSK, UK

Radio-Ligand Therapy: Is it a New Emerging Platform that Needs Specialized Regulations?
Jordi Vall-Llossera, Global Head of Quality, Advanced Accelerator Applications, a Novartis company, Switzerland
Camelia Cercel, Global Head Regulatory CMC, Advanced Accelerator Applications, a Novartis company, Switzerland

Oligonucleotides (siRNA & others)
Susanne Kindermann, Group lead Development Small Molecules, Technical Regulatory, F. Hoffmann-La Roche, Switzerland

ICH Quality Discussion Groups
Matt Popkin, Director, CMC Strategy, GlaxoSmithKline, UK

Panel discussion with Q&A, with the addtional participation of:
Evangelos Kotzagiorgis, Scientific Administrator, Quality of Medicines, Human Medicines Evaluation Division, European Medicines Agency, EU

14:40 WRAP-UP

15:00 SPEED NETWORKING

16:00 END OF DAY TWO

DAY THREE | FRIDAY, 25 SEPTEMBER 2020

GLOBAL HARMONISATION EFFORTS

13:00 WELCOME

Sara Torgal, Scientific Programmes Manager, DIA EMEA

13:15 SESSION 7

MEDICAL DEVICES AND COMBINATION PRODUCTS

Session Chairs:
Ben Thompson, Vice President, CMC and Non-clinical Regulatory Affairs, GlaxoSmithKline, UK
Susanne Ausborn, Global Head International Regulatory Policy, F. Hoffmann-La Roche Ltd, Switzerland

This session will provide updates on the MDR implementation in Europe, and provide an overview of the challenges in device registration and drug device combination products globally. The main objective of the session is to share industry experience with a view to enabling more efficient device registration.

MDR Updates - The Road to Implementation
Bjorg Hunter, Department Manager, RA NextGen Drug Device, Novo Nordisk, Denmark

Global Case Studies on Challenges with Medical Devices and Combination Products
Tim Chesworth, Senior Director Regulatory Affairs, Astra Zeneca, UK
Stephanie Horn, Technical Regulatory Manager, Device and Combination Products, F. Hoffmann La Roche Ltd., Switzerland

Approaches to implementing ICH Q12 for Drug/Biologic-Device Combination Products
Abhishek Telang, Senior Scientist, GRACS CMC Medical Devices & Combination Products, Merck, US

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Panel discussion with Q&A

14:30 BREAK

14:45 SESSION 8

ICH Q12 IMPLEMENTATION

Session Chairs:
Ben Thompson, Vice President, CMC and Non-clinical Regulatory Affairs, GlaxoSmithKline, UK
Frank Montgomery, Global Head Regulatory CMC, GRAPSQ, AstraZeneca, UK

The session will explore the experience and plans for implementation of ICH Q12 across all ICH markets from both an industry and regulatory agency perspective. A further aspect will be a consideration of how to implement Q12 beyond ICH and the challenges to achieve this. The objective is to share learnings and opportunities to enable more effective implementation of ICH Q12.

Industry Experience on ICH Q12
Stuart Finnie, Director, Regulatory CMC, AstraZeneca, UK
Gert Thurau, Global Head, Technical Regulatory Small Molecule Development, Roche, Switzerland

Emerging Markets Perspectives and Challenges - Feedback
Andrew Deavin, Director, Regulatory Affairs, GlaxoSmithKline Biologicals, Belgium

Health Authorities Perspective:
Brian Dooley, Quality Specialist, European Medicines Agency, EU
Mahesh Ramanadham, Division Director (Acting), Div. of Inspectional Assessment, OPF, OPQ, CDER FDA, USA

Panel discussion with Q&A

16:05 BREAK

16:20 SESSION 9

REGULATORY CONVERGENCE

Session Chairs:
Susanne Ausborn, Global Head International Regulatory Policy, F. Hoffmann-La Roche Ltd, Switzerland
Ursula Busse, Global Head of Quality Intelligence & External Affairs, Novartis, Switzerland

Panel discussion with representatives from different national/regional/global regulatory bodies & industry associations engaged in supporting global regulatory convergence. Topics addressed will include:
- Impact of data & digital on future collaboration/reliance
- Regulations for innovative treatments: what is/will be the approach to translate science into regulatory science in a globalized context?
- 'Agile' convergence - just another buzzword or reality?
- Reliance & collaboration - Vision for 2030

Panel Discussion with Q&A, with the presence of:

WHO - Samvel Azatyan, Group Lead, Regulatory Networks and Harmonization (RNH/RSS), World Health Organization (WHO)
EMA - Agnes Saint-Raymond, Head of Division International Affairs, European Medicines Agency, EU
EAEU - Dzmitry Razhdzestvenski, Head, Division for Coordination of Common Market for Drugs and Medical Devices, Department of Technical Regulation and Accreditation, Eurasian Economic Commission, Russia
IFPMA - Angelika Joos, Executive Director, Global Regulatory Policy, Merck Sharp & Dohme (Europe) Inc., Belgium
FIFARMA - Rebecca Lumsden, Director, Regulatory Policy, Pfizer, UK

17:10 WRAP-UP

Ben Thompson, Vice President, CMC and Non-clinical Regulatory Affairs, GlaxoSmithKline, UK
Frank Montgomery, Global Head Regulatory CMC, GRAPSQA, AstraZeneca, UK
Susanne Ausborn, Global Head International Regulatory Policy, F. Hoffmann-La Roche Ltd, Switzerland
Sylvie Meillerais, Director, Global CMC Policy, MSD (Europe) Inc., Belgium
Ursula Busse, Global Head of Quality Intelligence & External Affairs, Novartis, Switzerland
Sara Torgal, Scientific Programmes Manager, DIA EMEA

17:30 END OF THE WORKSHOP

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