DIA

Advancing CMC Workshop

Accelerated pathways, EU CMC trends and global opportunities

25-26 November 2019 | Radisson Blu, Basel, Switzerland

PROGRAMME COMMITTEE

Frank Montgomery
Global Head Regulatory CMC, GRAPSQA
AstraZeneca, UK

Helen Fitton
Vice President, Regional Regulatory Affairs
GlaxoSmithKline, UK

Susanne Ausborn
Regulatory Policy Lead
F. Hoffmann-La Roche, Switzerland

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

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

Overview

This workshop will focus on current challenging topics in chemical manufacturing and controls (CMC) within the global pharmaceutical/ biopharmaceutical arena, such as Accelerated Development Programmes, Global Regulatory Convergence, and new & future ICH topics. The format will allow participants to engage in constructive dialogue with experts from Regulatory Agencies and Industry, enabling interactive cross-functional discussions.

Objectives

- Understand how the companies and regulators deal with challenges for CMC in accelerated development programmes for biological and chemical molecules
- Gain insights of current CMC trends from international Regulators and their efforts to simplify the regulatory frameworks
- Have a clear overview on global/ regional harmonisation initiatives and how they drive regulatory convergence

Key Topics

- Regulators' Updates on CMC
- Opportunities for CMC in Accelerated Development Programmes
- Hot topics under Development - Experience with recent Regulatory Guidelines
- Reliance Programmes
- Devices & Combination products

Who Should Attend

Professionals involved in:

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

DAY ONE | MONDAY, 25 NOVEMBER 2019

09:30 REGISTRATION AND WELCOME COFFEE

10:45 WELCOME REMARKS

11:00 SESSION 1

ACCELERATED DEVELOPMENT PROGRAMMES AND PRODUCTS MEETING UNMET MEDICAL NEEDS: A PERSPECTIVE FROM REGULATORS WORLDWIDE

Session Co-Chairs:
Susanne Ausborn, Regulatory Policy Lead, F. Hoffmann-La Roche, Switzerland
Helen Fitton, Vice President, Regional Regulatory Affairs, GlaxoSmithKline, UK

The acceleration of clinical programmes for products addressing unmet medical need requires faster CMC development efforts to deliver the physical product both to clinical development and to support commercial launches. Multiple agency expedited pathways are in place across the world to support the accelerated access of new medicines to patients. In parallel with these programs, regulatory pathways using the concepts of reliance on approval by reference countries have been implemented by many countries enabling faster access of innovative new drugs.
This session will provide a **regulator perspective of acceptable accelerated development approaches from key agencies**. Discussions will focus on the level of harmonisation of data requirements and acceptance of scientifically driven approaches needed for more efficient accelerated development programs to be conducted.

The Pespective from Brazil
Bernardo Moreira, Second Directory Assessor (DIRE2), Brazilian Health Regulatory Agency (ANVISA), Brazil

The Pespective from Jordan
Ghadeer Al-Sheikh Salem, Senior Pharmacist, Head of the Originator and Biological Drugs Division, Registration Department, Drug Directorate, Jordan Food and Drug Authority (JFDA), Jordan

The Pespective from Eurasia
Dzmitry Razhdzestvenski, Head, Division for Coordination of Common Market for Drugs and Medical Devices, Department of Technical Regulation and Accreditation, Eurasian Economic Commission, Russia

The Pespective from the EU
Veronika Jekerle, Quality Specialist, European Medicines Agency, EU

13:00 LUNCH

14:00 SESSION 2

OPPORTUNITIES FOR CMC IN ACCELERATED DEVELOPMENT PROGRAMMES, PART 1

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

This session will explore current trends and novel approaches for CMC in accelerated development programmes. Case studies will illustrate CMC strategies, opportunities and challenges faced for different treatment modalities (small molecules, biotherapeutics, cell and gene therapies) both pre- and post-approval. Different means to accelerate development, such as the use of prior knowledge or predictive stability studies, will be discussed between industry and regulatory representatives.

Case Study: Small Molecules
Fabian Schwarb, Group Leader, CMC Regulatory Affairs - Small Molecule Development, F. Hoffmann-La Roche, Switzerland

Case Study: Biologics
T. G. Venkateshwaran, Associate Vice President, CMC Regulatory Affairs - Biologics, Device and Drug Device Combinations, MSD, USA

Case Study: Cell and Gene Therapy
Florence Salmon, Director Regulatory Affairs CMC, Novartis, Switzerland

Q&A and Panel discussion

16:00 COFFEE BREAK

16:30 SESSION 3

OPPORTUNITIES FOR CMC IN ACCELERATED DEVELOPMENT PROGRAMMES, PART 2

Session Co-Chairs:
Frank Montgomery, Global Head Regulatory CMC, GRAPSQA, AstraZeneca, UK
Susanne Ausborn, Regulatory Policy Lead, F. Hoffmann-La Roche, Switzerland

Panel Discussion and Q&A, with the participation of the Regulators present at Session 1 and the Industry Representatives from Session 2

Bernardo Moreira, Second Directory Assessor (DIRE2), Brazilian Health Regulatory Agency (ANVISA), Brazil
Ghadeer Al-Sheikh Salem, Senior Pharmacist, Head of the Originator and Biological Drugs Division, Registration Department, Drug Directorate, Jordan Food and Drug Authority (JFDA), Jordan
Dzmitry Razhdzestvenski, Head, Division for Coordination of Common Market for Drugs and Medical Devices, Department of Technical Regulation and Accreditation, Eurasian Economic Commission, Russia
Veronika Jekerle, Quality Specialist, European Medicines Agency, EU
Fabian Schwarb, Group Leader, CMC Regulatory Affairs - Small Molecule Development, F. Hoffmann-La Roche, Switzerland
T. G. Venkateshwaran, Associate Vice President, CMC Regulatory Affairs - Biologics, Device and Drug Device Combinations, MSD, USA
Florence Salmon, Director Regulatory Affairs CMC, Novartis, Switzerland

17:30 NETWORKING RECEPTION

18:30 END OF DAY 1

DAY TWO | TUESDAY, 26 NOVEMBER 2019

08:30 WELCOME COFFEE

09:00 SESSION 4

PREPARING FOR THE IMPLEMENTATION OF THE EU MEDICAL DEVICES REGULATION

Session Chair:
Sylvie Meillerais, Director, Global CMC Policy, MSD (Europe), Belgium
Helen Fitton, Vice President, Regional Regulatory Affairs, GlaxoSmithKline, UK

This session will focus on the actions required to implement the EU Medical Devices Regulation new rules, which impact industry and agency, and the complexities which must be navigated to be ready for May 2020. More specifically, this session will address the documentation expected for Drug Device Combinations in the Quality part of the dossier, as introduced in the draft guideline which has been released for public consultation through to August 31st 2019. This part of the programme will share agency, industry and Notified Body perspectives.

Introducing the Guideline and the Authority's Perspective
Abigail Moran, Senior Pharmaceutical Assessor, MHRA, UK

The Industry Perspective
Bjorg K. Hunter, Regulatory Manager, Devices, Global Regulatory Affairs, RD Chief Regulatory Office, GlaxoSmithKline, UK

The Notified Bodies Perspective
Jonathan Sutch, Medicinal Technical Specialist, BSI & Team NB group member, UK
Stephanie Göbel, Quality Manager MHS, TÜV SÜD Product Service GmbH, Germany

Panel Discussion and Q&A

10:30 COFFEE BREAK

11:00 SESSION 5

ICH TOPICS UNDER DEVELOPMENT, PART 1

Session Co-Chairs:
Sylvie Meillerais, Director, Global CMC Policy, MSD (Europe), Belgium
Ursula Busse, Global Head of Quality Intelligence & External Affairs, Novartis, Switzerland

This session will explore current and future ICH hot topics in the CMC/quality space. Through joint regulators/industry presentations, participants will learn about the most recent developments for ICH Q12, Q13 and Q14/Q2 and gain insights into the new concepts, their practical application and next steps. We will hear from leaders of the recently formed ICH Quality Discussion Group about current plans and future recommendations for ICH quality guidelines. Presentations will be followed by interactive discussions with industry and regulatory members of the different Expert Working Groups.

Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management - Post-ICH Meeting Update
Frank Montgomery, Global Head Regulatory CMC, GRAPSQA, AstraZeneca, UK

Q13: Continuous Manufacturing - Industry Expectations, Experience and Case Studies
Marta Antunes, Sr. Specialist, Regulatory Affairs, International CMC, EU/EEMEA Region, MSD, UK
Meike Vanhooren, Senior Director, Pfizer, Germany

Q14: Updates on the Guideline
Oliver Grosche, Director Collaborative Solutions, R&D Pharmaceutical and Vaccines Sciences and Technology, Elanco, Switzerland
Christof Finkler, Principle Advisor, Technical Development Biotech Europe, Hoffmann-La Roche Ltd, Switzerland

Panel Discussion and Q&A

12:30 LUNCH

13:30 SESSION 6

ICH TOPICS UNDER DEVELOPMENT, PART 2

Session Co-Chairs:
Sylvie Meillerais, Director, Global CMC Policy, MSD (Europe), Belgium
Ursula Busse, Global Head of Quality Intelligence & External Affairs, Novartis, Switzerland

ICH Survey on Guidelines Implementation
Giovanna Rizzetto, Senior Manager, Regulatory, Drug development and Manufacturing, EFPIA, Belgium

Guidelines Implementation: Lessons Learned from Tier 1 ICH Guideline Training (Q7) and Best Practices for Future Implementation
Frank Montgomery, Global Head Regulatory CMC, GRAPSQA, AstraZeneca, UK

Updates from the ICH Quality Discussion Group
Matt Popkin, Director, CMC Strategy, GlaxoSmithKline, UK

Implementation Q&A and Panel Discussion, with the additional participation of:
Hélène Bruguera, QWGG Chair & Head, Certification of Substances Department, European Directorate for the Quality of Medicines and Healthcare (EDQM), EU

DAY TWO | TUESDAY, 26 NOVEMBER 2019

15:00 COFFEE BREAK

15:30 SESSION 7

RELIANCE PROGRAMMES

Session Co-Chairs:
Frank Montgomery, Global Head Regulatory CMC, GRAPSQA, AstraZeneca, UK
Susanne Ausborn, Regulatory Policy Lead, F. Hoffmann-La Roche, Switzerland

Overview of the Reliance Programmes Available Globally
Rebecca Lumsden, Director, Emerging Markets Regulatory Policy, Pfizer Ltd, UK (on behalf of IFPMA)

The International Pharmaceutical Regulators Programme (IPRP) Quality Working Group for Generics
Hélène Bruguera, QWGG Chair & Head, Certification of Substances Department, European Directorate for the Quality of Medicines and Healthcare (EDQM), EU

Learning from Reliance Programmes - The ACSS Consortium
Chantal Walther, Case Manager Unit 2, Swissmedic, Switzerland

Q&A and Panel discussion, with the additional participation of:
Bernardo Moreira, Second Directory Assessor (DIRE2), Brazilian Health Regulatory Agency (ANVISA), Brazil

17:15 CLOSING REMARKS

17:30 END OF THE WORKSHOP

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.

Conference Venue

Radisson Blu Hotel
Steinentorstrasse 25
CH-4001 Basel
Switzerland

Phone: +41 61 227 2992
info.basel@radissonblu.com

Continuing Education

DIA meetings and training courses are approved by the SwAPP (Swiss Association of Pharmaceutical Professionals) Commission for Professional Development (CPD) and SGPM (Swiss Society of Pharmaceutical Medicine) and are honoured with credits for pharmaceutical medicine. All meeting and training course participants are eligible for applicable credits.

The CMC workshop has been accredited with 13,5 credits. The CMC Short Course has been accredited with 6,5 credits.

About DIA

DIA is the global connector in the life sciences product development process. Our association of thousands of members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China. For more information, visit www.DIAglobal.org or call DIA: +41 61 225 51 51.