DIA

CMC Workshop

20-21 June 2018
CMC Short Course: 19 June 2018
Radisson Blu Hotel, Basel, Switzerland

PROGRAMME CHAIR

Yasmin de Faria Krim
Chair, CMC Working Group,
DIA Regulatory Affairs Community, France

PROGRAMME COMMITTEE

Ursula Busse
Head of Quality Intelligence, External Engagement
Novartis, Switzerland

Sabine Kopp
Group Lead, Medicines Quality Assurance
World Health Organization (WHO), Switzerland

Frank Montgomery
Global Head Regulatory CMC, GRAPSQA
AstraZeneca, United Kingdom

Elaine Morefield
Vice President, Regulatory Affairs
VaxForm, United States

Moheb Nasr
Principal, Nasr Pharma Regulatory Consulting, United States

Peter Richardson
Head of Quality, Specialised Scientific Disciplines Department
European Medicines Agency (EMA), European Union

Jean-Louis Robert
Former CHMP/CVMP QWP Chair
Luxembourg

Overview

This workshop, through plenary and parallel sessions, will focus on current challenging topics within the global pharmaceutical/biopharmaceutical arena. Attendees from the different CMC (chemistry, manufacturing and controls) areas will be able to interact with peers from Regulatory Agencies and Industry in sessions enabling interactive cross-functional discussions.

This programme was developed by the CMC Working Group of the DIA Regulatory Affairs Community.

Objectives

- Address technical challenges for biological and chemical molecules
- Discuss regulatory updates in a globalised environment
- Outline regulatory harmonisation initiatives

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 Lifecycle Management
- CMC Project Management

PRE-WORKSHOP SHORT COURSE | TUESDAY, 19 JUNE 2018

CMC SHORT COURSE | *BERLIN 3*

Instructors: **Elaine Morefield**, Vice President, Regulatory Affairs, VaxForm, United States
Yasmin de Faria Krim, Chair, CMC Working Group, DIA Regulatory Affairs Community, France

OVERVIEW

This course will provide a full introduction to CMC with regards to regulatory submissions. This CMC course will be a combination of lectures and practical examples. It will be an interactive course with an opportunity for questions and answers.

The course will be of valuable interest to individuals working in CMC Regulatory Affairs and to those working in start-ups looking to gain knowledge in the CMC area. Furthermore, it will serve as an introductory course for the following 2-day CMC Workshop.

LEARNING OBJECTIVES

- Discuss CMC submissions to support drug development and beyond
- Identify expectations and requirements for CMC submissions
- Describe CMC challenges during drug development
- Compare guidelines in the CMC area
- Identify GMP requirements in CMC submissions
- Consolidate CMC knowledge to build a good foundation for the CMC Workshop

KEY TOPICS

- CMC submissions (IMPD, IND, MAA, NDA/BLA, variations and supplements)
- CMC development plan (product target profile, CMC teams)
- CMC guidelines (ICH, EU, US)
- GMP requirements for regulatory submissions

WHO SHOULD ATTEND

- Professionals in CMC Regulatory Affairs
- CMC project management
- Individuals in product development, including start-ups
- Quality Assurance/Control/Compliance

Level: beginner

The Short Course requires a separate registration

AGENDA

07:30 REGISTRATION | *FOYER*

08:00 SESSION 1

INTRODUCTION/TYPES OF SUBMISSIONS AFFECTED BY CMC

- Global Health Authorities and Regulatory Review
- Briefing Package
- Investigational New Drug Application (IND)
- Investigational Medicinal Product Dossier (IMPD)
- Marketing Authorisations (NDA/BLA/MAA)
- Drug Master Files (DMF)/Active Substance Master Files (ASMF)
- Amendments to an IND/IMPD
- Post Approval Changes
- IND/NDA Annual Reports

09:00 SESSION 2

FROM CLINICAL TRIAL MATERIAL TO COMMERCIAL PRODUCT

- CMC Teams
- Begin with the End in Mind
- What is a Target Product Profile?
- Design Your Ideal Label
- TOC for a Target Product Profile
- References (Navigating CMC Guidelines)

09:45 COFFEE BREAK | *FOYER*

10:15 SESSION 3

THE GLOBAL DEVELOPMENT PLAN

- Components of a Global Development Plan (GDP)
- Manufacturing Strategy (CMC Development Plan)
- Risks and Issues

11:15 SESSION 4

COMMON TECHNICAL DOCUMENT: MODULE 3

- Organisation of the CTD
- Organisation of Module 3

12:15 LUNCH | *FOYER*

13:15 SESSION 5

COMMON TECHNICAL DOCUMENT SUMMARIES: MODULE 2

- Organisation and Review of Module 2

13:45 SESSION 6

CMC REQUIREMENTS FOR AN NDA/BLA/MAA

- Application Summary
- Drug Substance and Product
- Deficiencies that Cause Delays

14:30 SESSION 7

GMP REQUIREMENTS/INSPECTIONS

- Good Manufacturing Practice (GMP)
- General Considerations
- What is a PAI and Objectives of a PAI?
- Inspectional Procedures
- Qualified Person (QP)

15:30 COFFEE BREAK | *FOYER*

16:00 SESSION 8

BEYOND APPROVAL – POST APPROVAL CHANGES/VARIATIONS

- Specificities for the US and EU
- ICH Q12

17:00 END OF THE SHORT COURSE

WORKSHOP | WEDNESDAY, 20 JUNE 2018

07:45 REGISTRATION AND WELCOME COFFEE | *FOYER*

08:15 WELCOME REMARKS | *BERLIN 3*

Inka Heikkinen, Senior Scientist, DIA, Switzerland
Yasmin de Faria Krim, Chair, CMC Working Group, DIA Regulatory Affairs Community, France

08:30 SESSION 1 | *BERLIN 3*

INNOVATION AND NEW TECHNOLOGIES – CHALLENGES AND OPPORTUNITIES

Session Chair:
Peter Richardson, Head of Quality, Specialised Scientific Disciplines Department, European Medicines Agency (EMA), European Union

The session will review digitalisation (Pharma 4.0), from development and manufacture to patient use. Enablers and controls needed to define and implement a Holistic Control Strategy, delivery systems and engagement with regulatory authorities on innovation will be presented.

Bridging Industry 4.0 and Pharma 4.0 – the Holistic Control Strategy
Christian Wölbeling, Senior Director, Global Accounts, Werum IT Solutions, Germany

Digitalisation of Biotech Processes
Patrick Sagmeister, Chief Technology Officer, Exputec, Austria

Perspectives of Digitalisation: Continuous Manufacturing to Patient Interface
Gordon Muirhead, Visiting Professor of Pharmaceutics, Leicester School of Pharmacy, De Montfort University, United Kingdom

10:30 COFFEE BREAK | *FOYER*

11:00 SESSION 2 - PARALLEL SESSIONS

SESSION 2A | *BERLIN 3*

DRUG/DEVICE COMBINATIONS

Session Chair:
Ursula Busse, Head of Quality Intelligence, External Engagement, Novartis, Switzerland

The number, scope and complexity of Drug/Device combinations is expanding exponentially while regulations are evolving worldwide. This session will provide an overview of the challenges faced with a focus on the impact of the EU Medical Device Regulation (MDR). Speakers from industry, regulators and EU notified bodies will provide insights and point to possible solutions.

Drug/Device Combinations - Challenges and Opportunities
Marc Rohrschneider, Head of New Technologies, TRD Device Development and Commercialisation, Novartis, Switzerland

EU Regulatory Considerations for Drug/Device Combinations
Nick Lee, Executive Pharmaceutical Assessor, Health Products Regulatory Authority (HPRA), Ireland

EU MDR Implementation for Combination Products – the Role of Notified Bodies
Bassil Akra, Vice President, Global Focus Teams (Cardiovascular, Orthopedic and Clinical), TÜV SÜD Product Service, Germany

SESSION 2B | *BERLIN 2*

PROCESS VALIDATION/PROCESS VERIFICATION

Session Chair:
Andrew Chang, Vice President, Quality and Regulatory Compliance, Quality Intelligence and Inspection, Novo Nordisk, United States

There is a lack of clear, comprehensive harmonised guidance on process validation for drug substance and finished pharmaceuticals. In this session, participants will hear both an industry and regulatory viewpoint on globally harmonised expectations including some possible opportunity areas to address current perceived challenges and opportunities for improvement. Additionally, Process Validation considerations for new manufacturing technologies, e.g. Continuous Manufacturing will be discussed.

Robust and Lean Process Validation - Compliant with Regulatory Requirements: Novo Nordisk as a Case Study
Jens Peter Gundorf, Principal Validation Specialist, Novo Nordisk, Denmark

Practical Considerations Towards Process Validation for Continuous Manufacturing (PCMM)
Christoph Wabel, Director/Team Leader Process Management, Product and Process Development, Pfizer, Germany

12:30 LUNCH | *FOYER*

13:30 SESSION 3 - PARALLEL SESSIONS

SESSION 3A | *BERLIN 3*

CONTRACT MANUFACTURING (PART I)

Session Chair:
Oliver Schläfli, Head Quality External Supply Organization NTO, Novartis, Switzerland

Pharmaceutical supply chain set-ups are becoming increasingly complex within a changing regulatory environment. This session will introduce to the role of outsourced operations in future manufacturing settings, discuss challenges that contract manufacturing relationships can bring and share examples of some strategies that can be applied.

Manufacturing of the Future – the Role of Outsourced Operations
Morten Munk, Global Technology Partner, Global Best Practice, NNE, Denmark

Quality Assurance Agreements for a Complex Supply Chain, Benefits and Opportunities to Simplify
Sarah Hockey, Global Head, ESO Systems and Compliance Oversight, Novartis, Germany

Ensuring Quality of Outsourced Operations Throughout the Lifecycle
Maria Loeflund, Head Global Technical Functions/Operations, BU Operations, Lonza, Switzerland

SESSION 3B | *BERLIN 2*

ENHANCED CONTROL STRATEGY

Session Chair:
Elaine Morefield, Vice President, Regulatory Affairs, VaxForm, United States

This session will explore the benefits and challenges of using enhanced control strategies approaches such as using PAT for real time release and using statistical process control. The GMP aspects of advanced control strategy will be discussed. A panel Q&A session will give attendees a chance to participate in the discussion.

Ensuring Regulatory Compliance and Data Integrity with Big Data for Your PAT System Whilst Also Providing Knowledge Management & Closed Loop Control
Martin Gadsby, Owner & Director, Optimal Industrial Automation, United Kingdom

Developing an Economically Sustainable Control Strategy - How to Use Statistics More Responsibly
Jeff Gardner, President & Principal Consultant, DataPharm SDMS, United States – *presenting remotely*

Smart Processes Optimization and Control Using Bayesian Predictive Modeling
Eric Rozet, Director Statistics, Arlenda, Belgium

15:00 COFFEE BREAK | *FOYER*

15:30 SESSION 4 - PARALLEL SESSIONS

SESSION 4A | *BERLIN 3*

CONTRACT MANUFACTURING (PART II)

Session Chair:
Sabine Kopp, Group Lead, Medicines Quality Assurance, World Health Organization (WHO), Switzerland

The session will provide insights, by sharing practical experience and examples, on what can go wrong and how this can be prevented. Perspectives will be shared by speakers representing a manufacturer from a company with international hubs, a regulatory agency and a UN agency involved in international procurement.

Pharmaceutical Contract Manufacturing
Ron Ogilvie, CMC Advisor, Pfizer, United Kingdom

MRA Agreements and Contract Manufacturing
Piotr Krauze, Principal Scientific Administrator Compliance and Inspections, European Medicines Agency (EMA), European Union – *presenting remotely*

Aspects and Consequences for Prequalification and Major Procurement Agencies
Dimitrios Catsoulacos, Technical Officer (Inspector), Regulation of Medicines and other Health Technologies, World Health Organization (WHO), Switzerland

SESSION 4B | *BERLIN 2*

MEDICAL ERRORS DUE TO PRODUCT DESIGN AND DEVELOPMENT

Session Chair:
Diana van Riet-Nales, Senior Assessor, Medicines Evaluation Board, The Netherlands; Member of EMA Quality Working Party

Medication errors may result in patient harm or death. Risk is known to increase when the product design is insufficiently tailored to patient needs e.g. children, (older) patients. Demographic changes strengthen the importance to identify and mitigate risk in science, regulation and drug development.

Medication Safety in the Hospital – Challenges and Hurdles
Martin Hug, Professor, Chief Pharmacist, University Medical Center Freiburg, Germany

Considering the Human Factor When Mitigating Risks of Medication Errors - an Industry Perspective
Isabel Menz, Managing Director Germany, Medical Human Factors, Germany

Medication Errors: How the Drug Design May Mitigate Risk - a Regulatory Perspective
Diana van Riet-Nales, Senior Assessor, Medicines Evaluation Board (MEB), The Netherlands; Member of EMA Quality Working Party

Panel Discussion
All speakers and
Sven Stegemann, Professor, Patient Centric Drug Development and Manufacturing, Graz University of Technology; Director, Pharmaceutical Business Development, Capsugel, Austria

17:00 NETWORKING RECEPTION | *FOYER*

18:00 END OF DAY 1

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WORKSHOP | THURSDAY, 21 JUNE 2018

08:00 SESSION 5 | *BERLIN 3*

REGULATORY HARMONISATION

Session Chair:
Jean-Louis Robert, Former CHMP/CVMP QWP Chair, Luxembourg

This session will focus on ICH and WHO activities and will provide a candid assessment of progress to date, current challenges and future opportunities. A panel discussion will follow three presentations from global experts representing industry, regulators and WHO.

WHO Harmonisation Initiatives
Luther Gwaza, Technical Officer, World Health Organization (WHO), Switzerland

Regulatory Harmonisation – Progress, Challenges and Opportunities
Jean-Louis Robert, Former CHMP/CVMP QWP Chair, Luxembourg

Regulatory Landscape – Balancing Innovation, Acceleration and Global Regulatory Harmonisation
Ron Ogilvie, CMC Advisor, Pfizer, United Kingdom

09:30 COFFEE BREAK | *FOYER*

10:00 SESSION 6 - PARALLEL SESSIONS

SESSION 6A | *BERLIN 3*

POST APPROVAL CHANGES - ICH Q12

Session Chair:
Jean-Louis Robert, Former CHMP/CVMP QWP Chair, Luxembourg

This session will present the challenges related to regulatory management of post approval changes. Many of the challenges are due to differences in the global regulatory requirements and complexities associated with supply chain. Can ICH Q12 address these challenges? Is Q12 by itself sufficient? How can Q12 be accepted worldwide?

Post Approval Changes from a Regulatory Perspective
Jean-Louis Robert, Former CHMP/CVMP QWP Chair, Luxembourg

Post Approval Changes with Emphasis on Biological Products
Markus Goese, Lead EU CMC Regulatory Policy, F. Hoffmann-La Roche, Switzerland

Post Approval Changes with Emphasis on Chemical Products with Global Supply Chains
Frank Montgomery, Global Head Regulatory CMC, GRAPSQA, AstraZeneca, United Kingdom

SESSION 6B | *BERLIN 2*

BIOLOGICS: STATISTICAL METHODOLOGY FOR COMPARATIVE ASSESSMENT OF QUALITY ATTRIBUTES IN DRUG DEVELOPMENT

Session Chair:
Martin Schiestl, Chief Science Officer, Sandoz Biopharmaceuticals, Sandoz, Austria

EMA issued a draft Reflection Paper in March 2017 and discussed the draft in a stakeholder workshop in May 2018. The scope of it includes manufacturing process changes for biologicals, biosimilar evaluation and generics. FDA on the other hand published a relatively prescriptive biosimilar specific draft guidance on "Statistical approaches to evaluate analytical similarity". The session will highlight the main aspects of this guideline development and will also reflect the outcome of the EMA May workshop.

Meaningful Statistical Approaches in the Comparison of Quality Attributes
Martin Schiestl, Chief Science Officer, Sandoz Biopharmaceuticals, Sandoz, Austria

EMA Workshop on the Draft Reflection Paper: Outcome, Learnings and Next Steps
Thomas Lang, Senior Statistical Assessor, Austrian Agency for Health and Food Safety (AGES), Austria

12:00 LUNCH | *FOYER*

13:00 SESSION 7 - PARALLEL SESSIONS

SESSION 7A | *BERLIN 3*

LEVERAGING PRIOR KNOWLEDGE DURING LIFECYCLE

Session Chair:
Seán Barry, Executive Pharmaceutical Assessor, Health Products Regulatory Authority (HPRA), Ireland

Prior Knowledge represents a relatively untapped resource, which can be used to support a broad range of regulatory submissions. This session will aim to explore a common understanding of Prior Knowledge and provide examples of where it can be used in support of new product applications and life cycle management.

Use of Prior Knowledge in the Development of Monoclonal Antibody
Kowid Ho, Pharma Technical Regulatory Policy, F. Hoffmann-La Roche, Switzerland

Use of Prior Knowledge in Life Cycle of Vaccines
Nancy Cauwenberghs, Senior Director Regulatory Affairs, Global Regulatory Affairs & Clinical Safety, MSD, Belgium

How to Maximise the Effectiveness of Prior Knowledge in CMC Submissions
Seán Barry, Executive Pharmaceutical Assessor, Health Products Regulatory Authority (HPRA), Ireland

Panel Discussion
All speakers and
Peter Richardson, Head of Quality, Specialised Scientific Disciplines Department, European Medicines Agency (EMA), European Union,
Ron Ogilvie, CMC Advisor, Pfizer, United Kingdom

SESSION 7B | *BERLIN 2*

BIOLOGICS: MONOGRAPHS AND STANDARDISATION

Session Chair:
Paul Varley, Vice President, Biopharmaceutical Development (Cambridge) Site Lead, MedImmune, United Kingdom

The question of how standardisation and Pharmacopeial monographs can be used to ensure the quality of biological medicines remains a complex and challenging one. This session will aim to review this progress and discuss future challenges in this area.

Industry View of Pharmacopoeial Monographs and Standardisation
Lionel Randon, Head – GRA CMC Regulatory Intelligence & Ops, Merck Serono, Switzerland

MHRA Perspectives on Pharmacopoeial Standards for Biological Medicines
James Pound, Group Manager - British Pharmacopoeia & Laboratory Services, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

European Pharmacopoeia Texts for Biotherapeutic Products
Mihaela Buda, Scientific Programme Manager, European Pharmacopoeia Department, European Directorate for the Quality of Medicines & HealthCare (EDQM), France

WORKSHOP | THURSDAY, 21 JUNE 2018

14:30 COFFEE BREAK | *FOYER*

15:00 SESSION 8 | *BERLIN 3*

UPDATES FROM HEALTH AUTHORITIES

Session Chair:
Frank Montgomery, Global Head Regulatory CMC, GRAPSQA, AstraZeneca, United Kingdom

This session features regulatory updates from members of national, regional and global health associations sharing recent trends and changes anticipated for the future. The session will allow discussion on the evolving global regulatory environment.

Speakers:

Sabine Kopp, Group Lead, Medicines Quality Assurance, World Health Organization (WHO), Switzerland

Peter Richardson, Head of Quality, Specialised Scientific Disciplines Department, European Medicines Agency (EMA), European Union

Ingo Matthes, Head of Division Quality Review/Sector Marketing Authorisation, Swissmedic, Swiss Agency for Therapeutic Products, Switzerland

Mihaela Buda, Scientific Programme Manager, European Pharmacopoeia Department, European Directorate for the Quality of Medicines & HealthCare (EDQM), France

17:00 END OF THE WORKSHOP

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 generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits. The CMC Workshop has been accredited with 13,5 credits. The CMC Short Course has been accredited with 6,5 credits.

SwAPP | Swiss Association of Pharmaceutical Professionals

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Register 3 individuals from the same company and receive a 50% discount for a 4th! All 4 individuals must register and prepay at the same time without exception. DIA will apply the value of the lowest applicable fee to this discounted registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. Group registration is not available online and only available for the industry rate.

To take advantage of this offer, please print the registration form for each of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA. For groups of 5 or more individuals, please contact Zsofia.Molnar@DIAglobal.org for a custom group rate.

Access Presentations

As a benefit of your registration, presentations are made available on the DIA website.

To access presentations, go to www.DIAglobal.org and click on ***Sign in*** at the very top. Once you have successfully logged in, click on ***Welcome*** on the top, then ***My Account*** and on the left, go to ***My Presentations***
No paper copies of the presentations will be provided.

NOTE: If a presentation is not available, the speaker either did not agree to publish it or did not provide us with their presentation. Updated versions of the slides will be made available shortly after the conference.

Certificate of Attendance

A Certificate of Attendance will be sent to all attendees electronically after the conference. Please note certification requires full attendance to the conference. For more information please liaise with our DIA Contact Centre on basel@diaglobal.org or call +41 61 225 51 51.

Evaluation

We value your feedback on the content and organisation of this conference. To collect your mug, please complete the electronic survey through the following link: https://bit.ly/2MhfDjT

REGISTRATION FORM | ID# 18112

CMC Workshop
20-21 June 2018 | Basel, Switzerland

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CMC Short Course | 19 June 2018		
Industry	€ 900.00 ❑	€ 1'055.00 ❑
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Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA in Basel.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or online by clicking **here.**

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- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00
- Tutorial cancellation: € 50.00

For cancellations after this date, or if the delegate fails to attend the meeting, no refund of fees will be given and be responsible for the full registration fee. DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

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