ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Technical Operations Manager

Speakers

Dr Reinhard Adam
BIPSO

Stefanie Hermanns
Merck

Dr Hiltrud Horn
Horn Pharmaceutical Consulting

Dr Eva Keller
Ferring

Christof Langer
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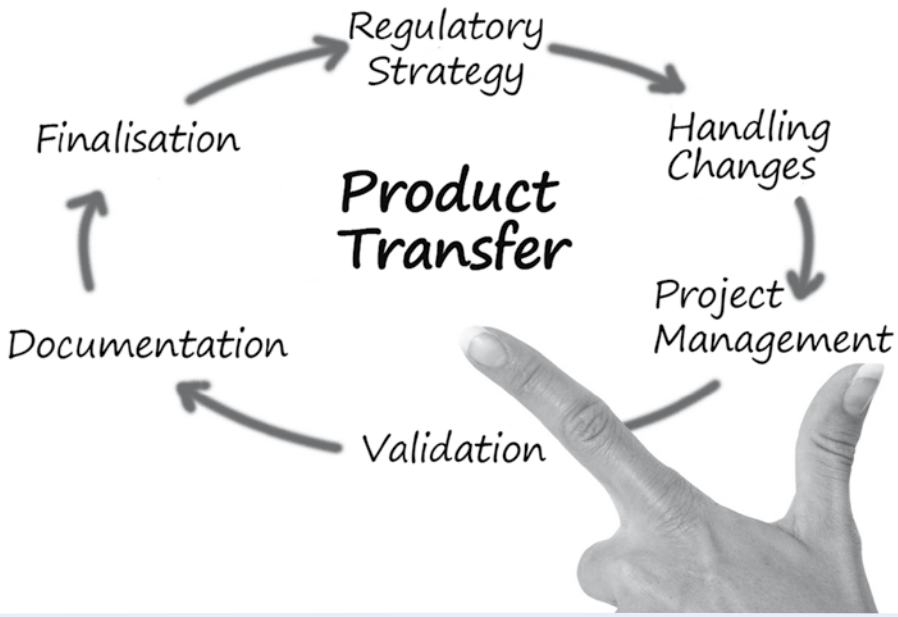
Dr Jean-Denis Mallet
Former Head of the Pharmaceutical Inspection Dpt. AFSSAPS

Product Transfer

Organisation of a GMP-compliant Site Change

Live Online Training on 28/29 September 2021



Highlights

- Development of a regulatory transfer strategy
- Handling of process changes during the transfer
- Handling of GMP and Regulatory gaps at the donor site
- Critical Quality Attributes to consider in transfers of sterile and solid dosage forms
- Organisation of the Analytic Transfer
- Project Management
  - Timelines, key milestones and structure of different transfer projects
  - Monitoring of the transfer activities
- GMP-compliant documentation of the transfer
  - Transfer SOP, Transfer Master Plan, Proof of Equivalence
- Finalisation of the transfer

Receive electronic copies of a Transfer SOP and a Transfer Master Plan

Programme

Objective

Learn how a successful and GMP-compliant process transfer should be conducted.
The key issues are the main topics of this course: development of a **regulatory strategy, project management** as well as **documentation of the transfer activities**.

Background

The changing nature of the business strategies of pharmaceutical companies necessitates intra- and intercompany transfers of technology to create additional capacity for a new product, relocations of operations, site closures, and consolidations and mergers. Transfer of processes to an alternative site can occur at any stage in the product life-cycle, from development, scale-up, manufacturing, production and launch, to the post-approval phase.

The expertise from development, manufacturing, analytics, regulatory affairs, supply chain and engineering is necessary at least. This means that a transfer cannot be handled by a single person. Therefore it is essential to build cross-functional transfer teams as a first step in the transfer project. As interests and expertise are quite different within the team, it is further essential to understand the project in its entirety and the tasks and deliveries of the single sub-teams. This is especially true for the transfer project leader.

The team is confronted with manifold issues. The process being transferred must be understood and sufficiently described – which can be a problem, especially for products from development or older products. But without this understanding the proof of equivalence after the transfer will never be successful.
In most of the cases the project is determined by the regulatory strategy. But Regulatory Affairs often finds that the filed process descriptions and the actual process in the donor site differ from each other. So transfer projects are very often also product maintenance projects. This costs time and money which both commonly were not budgeted.

The planned approach, the documentation of the transfer activities as well as written procedures are part of the EU GMP rules, as you can see, e.g., in chapter 4 of the EU GMP Guide. But also without these demands from authorities: planning and documentation are the key factors for a successful transfer.

We want to give answers to questions like these:

- What do agencies expect?
- How is the regulatory strategy developed?
- What are the milestones? How can the project be structured?
- What are the critical quality attributes in transfers of sterile or oral solid dosage form?
- How are process changes handled that are occurring during the transfer?
- What can a GMP-compliant documentation look like?

Target Audience

This course addresses staff from production, engineering, quality assurance, regulatory affairs and project management in charge of transfer projects. This involves project leaders and project team members, from receiving sites as well as from donor sites.

Programme

Fundamentals of Technology Transfer

- Various types of transfer
- Regulation and GMP challenges for Technology Transfer
- Identifying key elements of Technology Transfer
- What to consider when planning a Technology Transfer
- How to set acceptance criteria for a successful transfer

Product Transfer from a CMO Management Perspective

- Why to conduct tech transfers to a CMO?
- Facts and Figures
- Dos and Don'ts – What to consider when working with a CMO?
- How to apply the "One Face to the Customer"-Concept in complex tech transfer situations?

Technological Aspects: Non-Sterile Transfers

- Identifying materials involved
- Defining the process, equipment and facility requirements
- Defining validation requirements
- Product hand over and completion of oral dose transfer

Sterile Manufacturing Site Change – Process Characteristics

- Comparison of equipment and clean rooms / barrier systems of sending and receiving unit
- Critical quality parameters of product and process
- How to establish comparability criteria
- What is fixed and what can be changed: packaging material, process parameters, equipment, ... (?)
- Frequent failures & trouble shooting

Case Study Ferring: Transfer of an (aseptic lyophilized) US product between European sites

- Scope of the Site Change
- Project Plan, Project Phases and Timelines
- Documentation of the transfer
- Regulatory Strategy (US)
- Unforeseen gaps
- Project Reporting

Speakers

Developing a regulatory strategy for a site change

- Regulatory Guidance documents
- Differences EU, US, RoW
- Classification of transfers from a regulatory point of view
- Data & documents needed
- Timelines & costs

Handling changes during a process transfer

After having set up a regulatory strategy for a site change, most often further process and technology changes occur and become necessary for continuing with the transfer project.

- How to deal with these unplanned changes?
- Classification of changes
- How do these changes alter the overall strategy?

Project Management

- Setting up the project and the Transfer team
- Project Plan and Transfer Master Plan: how to document the transfer activities
- Monitoring of the transfer activities
- Definition of milestones and time management
- Pre-evaluation and feasibility phase, preparatory phase, project completion phase

GMP-compliant Documentation & Finalisation

- Defining documentation required pre & post transfer
- Roles and responsibilities of parties in preparation, review and approval of documentation
- Reporting of transfer findings and change control
- How to manage the transition period (e.g. first few batches!)
- Document check list

Participants' comments:
"It was a very helpful training overall. Brought great discussion. This was a helpful exercise."
Sonya Meheux, Cytonet LLC

"Good Seminar with excellent organization and venue."
Konstantinos Skopelitis, Pharmathen SA, Greece

Your Benefit

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

Dr Reinhard Adam
BIPSO GmbH, Germany

Dr Adam is a pharmacist and has been working for almost 20 years for Sanofi-Aventis (Hoechst) and Berlin Chemie as Head of Production. He has been responsible for the transfers of development products to routine production and for site changes of marketed products. Since 2017 he is General Manager of the Bracco site of BIPSO in Singen.

Stefanie Hermanns
Merck, Germany

Stefanie Hermanns is a pharmacist and works as QA Manager for Merck Healthcare KGaA. Her main focus is on process and product monitoring. She has also been working for Boehringer Ingelheim in the position of a Product Quality Manger, being responsible for CMOs with regards to QA/QC/Regulatory Affairs, Project Management and Product Transfers.

Dr Hiltrud Horn
Horn Pharmaceutical Consulting, Germany

Dr Hiltrud Horn is managing director of HORN PHARMACEUTICAL CONSULTING with focus on CMC, GMP and Regulatory Affairs. She started in pharma industry in 1990 and held several managerial positions within F.Hoffmann-La Roche in Basel and Knoll (Abbott) with global responsibility within QC / QA / Regulatory Affairs / Project Management / Medical Writing.

Dr Eva Keller
Ferring GmbH, Germany

Eva Keller is Senior Manager at Ferring GmbH in Kiel, where she is responsible for validation and product transfer to and from the Kiel site.

Christof Langer
OSConsulting

Christof Langer studied Biotechnology and is certified Risk Manager as well as a Lean Six Sigma Black Belt. He has been working as Managing Director at Baxter BioScience, responsible for Operations. Since 2009 he runs his own consultancy business.

Dr Jean-Denis Mallet
ECA; former head of the French Inspection Department AFSSAPS; NNE Pharmaplan, France

Jean-Denis Mallet was the Head of the Pharmaceutical and Cosmetics Inspection Department at the French Health Products Regulatory Agency (Afssaps). He also used to work in or with the pharmaceutical industry during many years at various positions including Quality Assurance, Production Management, Engineering and GMP Consulting. Now he is member of the ECA advisory board and works for NNE Pharmaplan.

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Reservation Form (Please complete in full)

Live Online Training: Product Transfer, 28/29 September 2021

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training

Tuesday, 28 September 2021,
09.00 to approx. 17.30 h
Wednesday, 29 September 2021,
09.00 to approx. 17.00 h
Times mentioned are CEST.

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and e-mail address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members EUR 1,590
APIC Members EUR 1,690
(does not include ECA Membership)
Non-ECA Members EUR 1,790
EU GMP Inspectorates EUR 895
The conference fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Ordering Recordings

Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at https://www.gmp-compliance.org/on-demand-online-training/recorded-on-line-training-webinars. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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