

Speakers



Dr Reinhard Adam
BIPSO



Stefanie Hermanns
Merck



Dr Afshin Hosseiny
ECA & Former Director QA at GSK



Dr Hiltrud Horn
Horn Pharmaceutical Consulting



Dr Eva Keller
Ferring



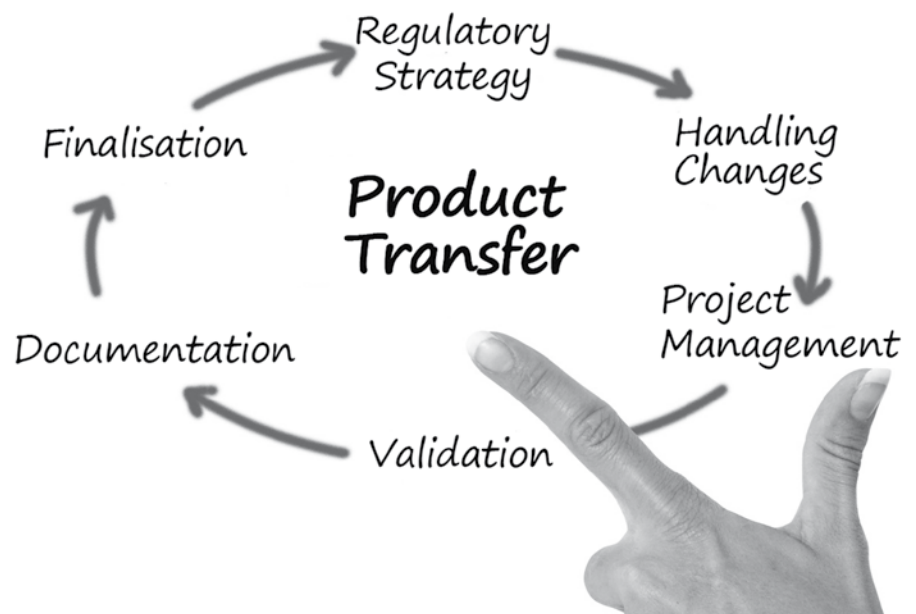
Dr Jean-Denis Mallet
Former Head of the Pharmaceutical
Inspection Dpt. AFSSAPS

Product Transfer

Organisation of a GMP-compliant Site Change



Live Online Training on 20/21 October 2020



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

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 steps 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 this:

- 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 to 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

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

Transfer to a CMO

- 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?

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 this unplanned changes?
- Classification of changes
- How do this changes alter the overall strategy?

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

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

Project Management

- Setting up the project and the Transfer team
- Project Plan and Transfer Mater 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



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 Hoffmann-La Roche in Basel and Knoll (Abbott) with global responsibility within QC / QA / Regulatory Affairs / Project Management / Medical Writing.



Dr Afshin Hosseiny
Tabriz Consulting Limited, UK

Dr Afshin Hosseiny is Managing Director of Tabriz Consulting Ltd. Before working as a consultant, he was Director of Quality Assurance for the Global Supply Network of GlaxoSmithKline. He was involved with transfer of 23000 products after the GSK merger, and wrote the GSK guidance document on technology transfer.



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.



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.



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

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Reservation Form (Please complete in full)



Product Transfer Live Online Training on 20/21 October 2020

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Date of Live Online Training

Tuesday, 20 October,
09.00 to approx. 17.30 h CEST
Wednesday, 21 October 2020,
09.00 to approx. 17.00 h 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
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.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.
CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Dr Robert Eicher (Operations Director) at
+49(0)62 21/84 44 12, or per e-mail at
eicher@concept-heidelberg.de

For questions regarding organisation please contact:
Mr Niklaus Thiel (Organisation Manager) at
+49(0)62 21/84 44 43, or at
thiel@concept-heidelberg.de.