ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Technical Operations Manager

## Speakers

Dr Reinhard Adam
BIPSO

Stefanie Hermans
Merck

Dr Afshin Hosseiny
ECA & Former Director QA at GSK

Dr Hiltrud Horn
Horn Pharmaceutical Consulting

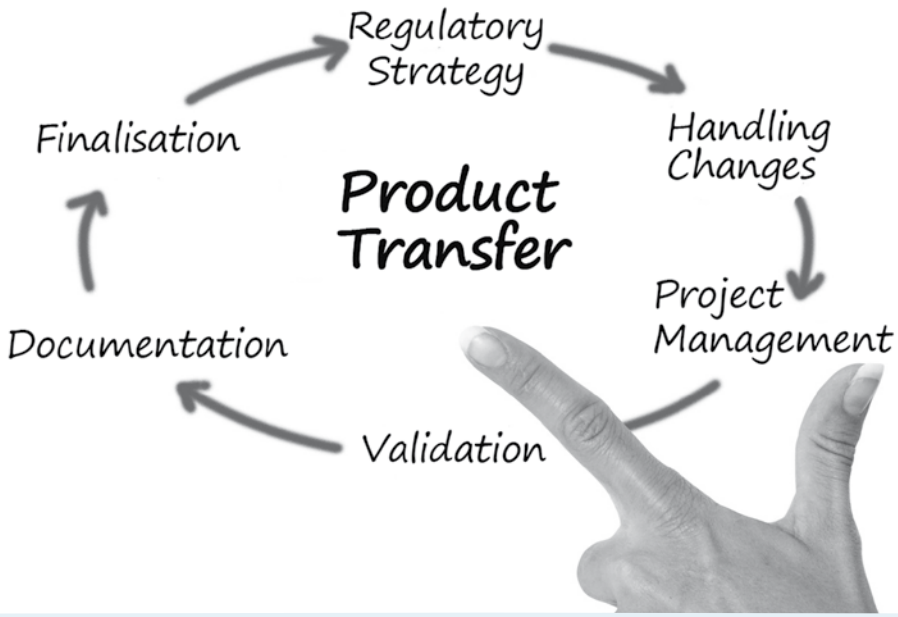
Dr Eva Keller
Ferring

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

# Product Transfer

## Organisation of a GMP-compliant Site Change

## 20-22 October 2020 | Berlin, Germany




### 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

Including:
- Workshop: Development of a Transfer Plan
- Electronic copies of a Transfer SOP and a Transfer Master Plan on USB-Stick

# 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 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

### 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?

### 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

## Analytic Transfer – Organisation & Scheduling

- Pre-requisites when considering an analytical method transfer
- Dealing with non-validated methods
- Why analytical methods should be transferred first ?
- Is training of "receiving" analysts to be performed at "sending" site ?
- Using ICH Q2 as a support for the transfer of an analytical method
- Comparison of results : what are acceptable criteria ?

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

## 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

### Workshop: Development of a Transfer Plan

In the workshop you will apply what you have learned. You can choose between a sterile or a non-sterile product and develop a Transfer Plan according to the information and requirements you will get. This will include sourcing of the materials, the validation plan, training at the new site, and risk assessment and action planning.

# Speakers

### 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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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49(0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

## Product Transfer, 20-22 October 2020, Berlin, Germany

Workshop (please select ONE workshop)

☐ *Transfer of a sterile process*

☐ *Transfer of a non-sterile dosage form*

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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If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

Terms of payment: Payable without deductions within 10 days after receipt of invoice.

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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

Tuesday, 20 October, 09.00 to approx. 17.50 h
(Registration and coffee 08.30 – 09.00 h
Wednesday, 21 October 2020, 08.30 to approx. 18.00 h
Thursday, 22 October 2020, 08.30 to approx. 15.30 h

## Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 212 7 - 0
Email berlin@steigenberger.de

## Fees (per delegate, plus VAT)

ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on all three days and all refreshments. VAT is reclaimable.

## Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

## Social Event

On the evening of the first course day you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

## Registration

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

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