ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Technical Operations Manager

Speakers

Dr Reinhard Adam
Formerly BIPSO

Dr Eva Keller
Ferring

Christof Langer
OSConsulting

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

Dr Lisa Matzen
Boehringer Ingelheim

Dr Harald Stahl
GEA

NEWS

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Product Transfer

Organisation of a GMP-compliant Site Change

16-18 September 2025 | Barcelona, Spain

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 as Download

Workshop: Development of a Transfer 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 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?

GMP Transfer Templates

All participants will receive helpful documents and templates via download, e.g. Transfer SOP, Transfer Checklist and Transfer Master Plan.

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.

Moderator

Christof Langer

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

Regulatory Affairs for Production Transfers

- Regulatory planning and strategy for production site transfers (development projects and approved products)
- Complex global regulatory environment (country specific requirements, approval timelines, change categories and transition rules) in the context of production site transfers
- Particulars for NCEs and NBEs in the context of production site transfers
- Success factors for efficient regulatory management and execution of production site transfers

Technological Aspects: Transfer of Oral Solid Dosage Forms

- 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

Production Transfers – Case studies including do's and don'ts from a regulatory perspective

- Case study: production transfer during development (from development to commercial launch sites)
- Case study: production transfer for an approved product
- Typical health authority questions including do's & don'ts from a regulatory perspective

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 ?

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

Workshop: Development of a Transfer Plan

In the workshop you will apply what you have learned. You will develop a plan for a transfer project. This will include sourcing of the materials, the validation plan, training at the new site, and risk assessment and action planning.

Participants' comments:

"Knowledgeable and expertise of speakers helps a lot."
Venkata Ramaiah Pantulu Tholeti, Carlton Pharmaceuticals & Chemicals PVT LTD, India

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

Dr Reinhard Adam, formerly BIPSO, Germany

As General Manager of BIPSO GmbH, Dr Adam managed the BRACCO production site in Singen. In previous positions at Hoechst and Berlin Chemie, he was primarily responsible for the transfer of numerous pharmaceuticals.

Dr Eva Keller, Ferring, 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, Austria

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.

Dr Lisa Matzen, Boehringer Ingelheim, Germany

Lisa has held several positions within Boehringer including CMA RA Manager, Office Head CMC RA and Head of Cardiovascular Office (Global Regulatory Affairs). Currently she is Head of the Global CMC RA Group, (Global Regulatory Affairs) at Boehringer.

Dr Harald Stahl, GEA, Germany

Dr Harald Stahl worked in the Pharmaceutical Development of Schering AG in Germany. Since 1995 he served within GEA Process Technology in various positions. Presently he owns the position of a Group Director Application & Strategy Management of GEA. He has published more than 20 papers on various aspects of pharmaceutical production.

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.

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GERMANY

Reservation Form (Please complete in full)

Product Transfer, 16-18 September 2025, Barcelona, Spain

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)

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If you cannot attend the conference you have two options:
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2. If you have to cancel entirely we must charge the following processing fees:
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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 July 2022).
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 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, 16 September 2025, 09.00 to approx. 17.30 h
(Registration and coffee 08.30 – 09.00 h
Wednesday, 17 September 2025, 09.00 to approx. 17.00 h
Thursday, 18 September 2025, 08.30 to approx. 15.30 h

Venue
Barceló Sants Hotel
Plaça dels Països Catalans, s/n
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sants@barcelo.com

Fees (per delegate, plus VAT)
ECA Members EUR 2290
APIC Members EUR 2390
(does not include ECA Membership)
Non-ECA Members EUR 2490
EU GMP Inspectorates EUR 1245
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.

Registration
Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21609. To avoid incorrect information, please give us the exact address and full name of the participant.

Presentations/Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. 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.
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