ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Technical Operations Manager

Speakers

Dr Reinhard Adam
BIPSO

Dr Eva Keller
Ferring

Christof Langer
OSConsulting

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

Dr Lisa Matzen
Boehrimger Ingelheim

Dr Harald Stahl
GEA

NEWS

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Product Transfer

Organisation of a GMP-compliant Site Change

Live Online Training on 29/30 October 2024

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
- 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

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?

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.

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

- Basic Requirements
- Identification of critical quality attributes
- Risk assessment and risk mitigation
- Scale up strategies for granulation and tableting
- How to deal with different types of equipment?
- Examples

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

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't from a regulatory perspective

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

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

Dr Reinhard Adam, BIPSO, 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.

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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Reservation Form (Please complete in full)

Live Online Training: Product Transfer
29/30 October 2024

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:
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2. If you have to cancel entirely we must charge the following processing fees:
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- Cancellation within 2 weeks prior to the conference 100 %.

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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 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 of the Live Online Training

Tuesday, 29 October 2024,
09.00 to approx. 17.15 h CET
Wednesday, 30 October 2024,
09.00 to approx. 16.45 h CET

Technical Requirements

We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT 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 1690
APIC Members EUR 1790
Non-ECA Members EUR 1890
EU GMP Inspectorates EUR 945
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.
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