GMP-compliant Process Transfer

Regulatory Affairs, Project Management, Technology

12-13 September 2012, Prague, Czech Republic

SPEAKERS:

Dr Reinhard Adam
Berlin-Chemie

Dr Afshin Hosseiny
Tabriz Consulting Limited

Dr Hiltrud Horn
Horn Pharmaceutical Consulting

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

ECA
EUROPEAN COMPLIANCE ACADEMY

LEARNING OBJECTIVES:

- Authorities' expectations on product transfers
- Development of a regulatory transfer strategy
- Handling of process changes during the transfer
- Handling of GMP and Regulatory gaps in the donor site
- Critical Quality Attributes to consider in transfers of sterile and solid dosage forms
- Project Management
  - Implementation of the transfer team
  - 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 and stumbling blocks

This education course is recognised for the ECA GMP Certification Programme „Certified Technical Operations Manager". Please find details at www.gmp-certification.eu

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Learning Goals

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 and monitoring** as well as **documentation of the transfer activities**.

Background

A transfer of a medicinal product from A to B is always a cross-functional project. This is true for transfers from development to a launch plant as well as for marketed products being transferred to another site or to a contractor.
At least the expertise from development, manufacturing, analytics, regulatory affairs, supply chain and engineering is necessary. 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 7.4. Since 2010 Chapter 4 of the EU GMP guide has continuously been supplemented with new requirements on the documentation of a transfer and the requirements on written procedures for the execution of a transfer. 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?
- How can the transfer activities be monitored?
- How can psychological problems in the transfer team be handled?
- What can go wrong?

Target Group

This course addresses to staff from Development, Production, Engineering, Quality Assurance, Regulatory Affairs and Project Management in charge of Transfer Projects. This involves Project Leaders and project team members, from receiving site as well as from donor site.

Moderator

Afshin Hosseiny

Programme

Fundamentals of Technology Transfer
- Pharmaceutical product life cycle and Technology Transfer
- Various types of transfer
- Regulation and GMP challenges for Technology Transfer
- Setting up the transfer team
- Identifying key elements of Technology Transfer
- What to consider when planning Technology Transfer

Technological Aspects: Oral Dosage Form Transfers
- Defining the transfer scope
- Identifying materials involved
- Defining the process, equipment and facility requirements
- Defining validation requirements
- Product hand over and completion of oral dose transfer

Transfer of sterile processes: technological aspects
- 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

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?
- Examples

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
- Project Examples

GMP Compliant Documentation

- Defining documentation required pre transfer
- Defining documentation required during the transfer
- Documentation required post transfer
- Roles and responsibilities of parties in preparation, review and approval of documentation
- Sign off and completion of transfer

Finalisation of transfer

- Reporting of transfer findings and change control
- How to manage the transition period (e.g. first few batches!)
- Roles and responsibilities of both parties
- Key challenges during the transfer (people and cultural aspects)
- What can go wrong?

Social Event

On 12 September 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.

Speakers

Dr Reinhard Adam
Berlin-Chemie AG, Germany
Dr Adam is a pharmacist and has been working for almost 20 years for sanofi-aventis and predecessor companies such as Hoechst and Aventis before he joined Berlin Chemie in 2010. At Aventis he used to work as Head of Lead Technology & Engineering Centre Sterile Products and has held various positions in Italy, France, UK and Germany where he has been responsible for the transfers of development products to routine production and for site changes of marketed products. Since 2010 he is Head of Production at Berlin-Chemie where he is responsible for manufacturing of oral solid and liquid forms, sterile products and for managing toll manufacturing.

Dr Hiltrud Horn
Horn Pharmaceutical Consulting, Germany
Dr Hiltrud Horn is managing director of HHorn Pharmaceutical Consulting. From 1990 to 1997, she was employed by Hoffmann-La Roche in Quality Control/Quality Assurance. From 1997 to 1999, she dealt with medical writing in the 'International Drug Regulatory Affaires and Project Management' department of the same company. In 1999, she joined Knoll AG as head of the departments 'Regulatory Compliance and CMC Documentation' and 'Dossier Production and Compliance' for international drug registration. In 2002, she started at Cap Gemini Ernst & Young, where she was the responsible consultant for questions concerning biotechnology and life sciences

Dr Afshin Hosseiny
Tabriz Consulting Limited, Great Britain
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 Jean-Denis Mallet
ECA, former head of the French Inspection Department AFSSAPS, SNC LAVALIN, France
Jean-Denis Mallet is a pharmacist. He was previously 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. He has also been auditor of the International Red Cross Now he is member of the ECA advisory board and works for SNC LAVALIN.

Easy Registration

Reservation Form:
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P.O. Box 10 17 64
69007 Heidelberg
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Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@gmp-compliance.org

Internet:
www.gmp-compliance.org

If the bill-to-address deviates from the specifications on the right, please fill out here:

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

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GERMANY

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

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12-13 September 2012, Prague, Czech Republic
☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **P.O. Number (if applicable)**

Street/P.O. Box

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 %
- until 1 weeks prior to the conference 50 %
- 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)

Date

Wednesday, 12 September 2012, 10.00 – 18.00 h
(Registration and coffee 09.30 – 10.00 h
Thursday, 13 September 2012, 08.30 – 13.00 h

Venue

Hotel
Corinthia Hotel Prague
Kongresova 1
14069 Prague, Czech Republic
Phone +(0) 420 261 191 111
Fax +(0) 420 261 225 011

Fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
(does not include ECA membership)
Non-ECA Members € 1,690.- per delegate plus VAT
EU GMP Inspectorates € 845.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on the first day 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 when you have registered for the event. Please use this form for your room reservation or be sure to mention "ORSO110912" to receive the specially negotiated rate (single room € 137,50 per night, incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 14 August 2012. Early reservation is recommended.

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

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