ECA Academy
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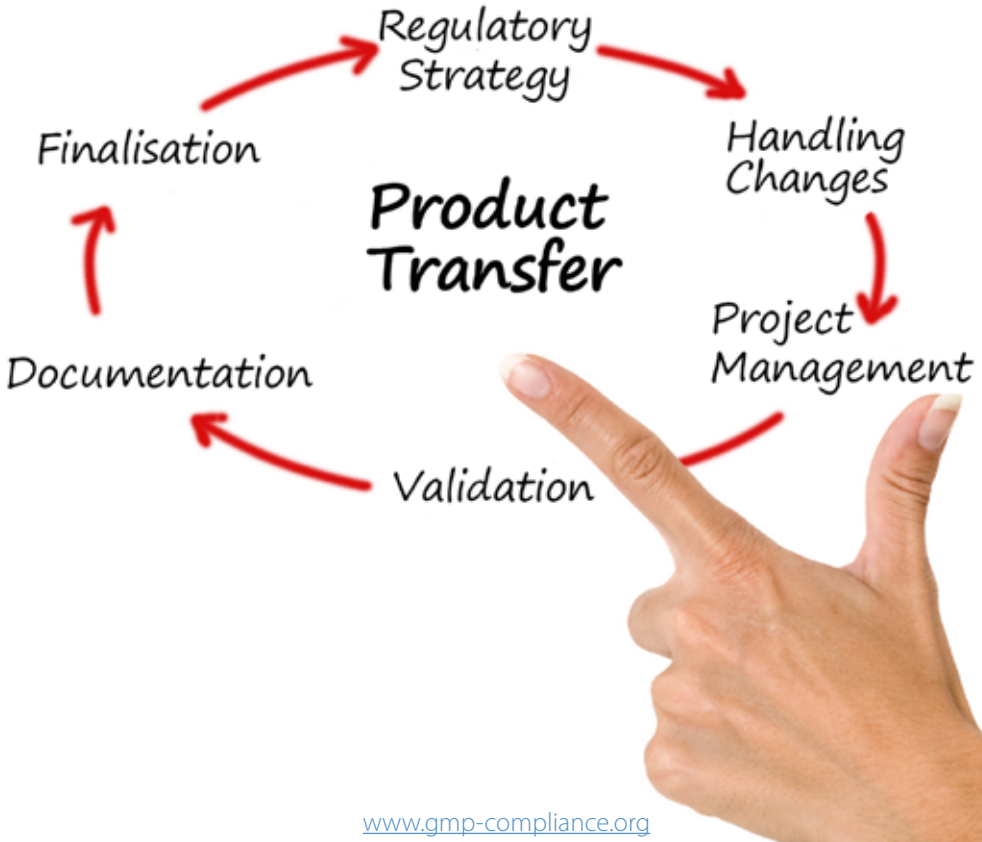
GMP Webinar
Fundamentals of Product Transfer

Date:
Wednesday, 1 July 2020, 10.00 – 11.30 h CEST

Speaker:
Dr Afshin Hosseiny
ECA & Former Director QA at GSK



ECA has entrusted
CONCEPT HEIDELBERG with the
organisation of this webinar.

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Background

The changing nature of the business strategies of pharmaceutical companies necessitates intra- and intercompany product transfers. This can happen at any stage in the product life-cycle. A transfer project has to make sure, that the receiving site manufactures product with the same quality as the donor site. But this is only one aspect of the interdisciplinary requirements of a product transfer. For an approval of the receiving site, the regulatory strategy has to be defined and the required documents have to be submitted. Maybe new equipment has to be set up and qualified. The transfer of the analytical methods, stability studies, raw materials & packaging components and logistics have to be considered as well.

This means that a transfer cannot be handled by a single-person and a cross-functional transfer teams has be installed as a first step in a 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.

Educational Objectives

In this webinar you will learn what the important steps in a product transfer are, how a transfer project is structured and what the GMP relevant deliverables are:

- Product transfer – what is it and why would you do it
- Different types of transfer
- Key steps in product transfer:
  - Transfer team & plan
  - Project management
  - Regulatory compliance – variations and dossier changes
  - Process transfer
  - Analytical method transfer
  - Validation – what we need to do
  - Stability studies
  - Finalisation and launch from the new site.
- Documentation: useful documents and 'must have' GMP documents

Target Audience

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

Speaker

Dr Afshin Hosseiny, ECA & Former Director QA at GSK

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 23,000 products after the GSK merger, and wrote the GSK guidance document on technology transfer. He is chairman of the executive advisory board of the European Compliance Academy (ECA).

Fees (plus VAT)

Single participation: € 199.- for ECA Members
Single participation: € 249,- for non-ECA Members
(This fee does not include the ECA Membership. You will find more about the ECA Membership at https://www.gmp-compliance.org/about-the-academy).

Participation of a Group

You have colleagues who also want to participate in the webinar? Then register yourself and your colleagues as a GROUP! You can view the webinar either together (e.g. in a conference room, etc.) or also each individually on your own PC.

Group Participation (fee per person):

3-10 Persons EUR 211,15
11-20 Persons EUR 186,75
more than 20 Persons EUR 161,85

Registration

By mail, fax, e-mail or online on the Internet at www.gmp-compliance.com. In order to avoid misunderstandings, please indicate the exact address and the full name of the participant. You will receive your access data by e-mail in due time prior to the event.

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 email 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.

Presentation/Certificate

The presentation will be made available to you prior to the Webinar as a PDF file. After the Webinar, we will automatically send you a certificate of participation.

Organisation/Contact

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Do you have any questions?

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Registration for the GMP Webinar "Fundamentals of Product Transfer"
on Wednesday, 1 July 2020, 10.00 – 11.30 h CEST, Speaker: Dr Afshin Hosseiny
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you
register online at www.gmp-compliance.org.

Please tick:
☐ **Single Participation**
☐ **Group Participation**
  ☐ 3-10 Persons
  ☐ 11-20 Persons
  ☐ more than 20 Persons

Important:
Deadline is 12 noon on
30 June 2020

Title, First Name, Last Name

Company | Department | VAT ID No. (mandatory)

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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 week prior to the conference 50 %, within 1 week prior to the conference 100 %.
CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.

If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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German law shall apply. Court of jurisdiction is Heidelberg.