ECA
European Compliance Academy

GMP-Webinar

How to handle the new EU Site Master File (Part III EU GMP Guide)?

Date:
Monday, 03 June 2013, 14.00 – 16.00 h (CEST)

Speaker:
Dr Heinrich Prinz, Apceth GmbH & Co. KG, Munich

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

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Background
A company description (SMF - Site Master File) is requested from inspecting authorities before performing any GMP inspection. Recently, the creation of a Site Master File has also become part of the EU GMP Guide in Part III. **In so far, the preparation of a Site Mater File concerns each single pharmaceutical company which is expecting a GMP inspection**. For years now, a document from the Pharmaceutical Inspection Convention Scheme (PIC/S) under the current name PE 008 has been state of the art for questions regarding the development of an SMF. Version -3 of the PIC/S document provided companies very tight details on writing an SMF. The document - divided in requirements and "guidance" on how to interpret the requirements - was very helpful for many SMF writers.

The content of both documents (EU Site Master File and PIC/S document PE 008 in its current Version -4) are almost identical. Both documents have been definitely brought up to the current state of the art.

The **changes** made to the initial PIC/S document **are considerable**. They have affected all current SMFs created since then. Many detailed regulations have disappeared. "**Guidance**" as support **doesn't exist any longer**. At the latest, during the next GMP inspection, authorities will expect an up-to-date Site Master File.

Educational Objectives
The Webinar aims to enable a comparison between the current PIC/S document (PE 008-4) and the requirements as laid down in Part III of the EU GMP Guide and the older version of the PIC/S document (PE 008-3), as well as to critically examine the changes made.

Site Master File Matrix/Template of imaginary company „Example"
To support you updating your existing Site Master File according to the new structure you will receive an extensive matrix with a step-by-step comparison between older and current version of the PIC/S document. You can see at a glance the changes made to the chapters and which detailed regulations have disappeared. This tool is very helpful to quickly identify significant changes and to transfer them into a new document. In addition, all participants will receive the template of a Site Master File of „imaginary company example" from the German Medicines Manufacturers´ Association. The template is bilingual: English and German.

Target Audience
The Webinar addresses staff members of pharmaceutical companies which are directly or indirectly involved in the creation of a Site Master Files and who would like to be informed about the latest changes. Staff members of API manufacturers, blood and blood component processing companies may also be interested by the topic.

Fee
€ 149.- plus VAT for ECA members
€ 199.- plus VAT for non-ECA Members (This fee does not include the ECA Membership. You will find more about the ECA Membership at www.gmp-compliance.org/eca_about.html.)

Speaker


Dr Heinrich Prinz, Apceth GmbH & Co KG
Dr Prinz worked with Boehringer Mannheim before he joined Biotest. Until recently, he was Head of Quality Assurance, responsible for both the pharmaceutical and the medical device division of Biotest AG. Since 2003 he has been working as a freelance consultant and, part of his time, he is the Senior Supervisor of Quality Control and Quality Assurance System of Apceth GmbH & Co KG.

Participation of a Group
The registration fee only authorises an individual to take part in the Webinar. Therefore, we do not issue more than one certificate per registration. With the registration fee being paid only once, it would infringe the copyright of CONCEPT HEIDELBERG as well as that of the speaker if the transmission was followed by several persons.
If you wish to register a group, please send an e-mail to info@concept-heidelberg.de or contact us by phone (+49 (0)62 21 / 84 44 51 Mr Strohwald). Prior to the Webinar date, we will help you to establish and test the Internet access.

Technical Requirements
To be able to take part in a Webinar, you need a computer with high-speed Internet access (i.e. DSL) and speakers.
Your Internet browser must have following features to use the GMP Webinar system:
1. Adobe Flash-Player must be installed.
2. Javascript must be allowed.
3. Port 1935 must be released.

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.

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

Do you have any questions?
Questions regarding content: Mr Sven Pommeranz,
phone +49 62 21 - 84 44 47, pommeranz@concept-heidelberg.de.
Questions regarding technical aspects: Mr Matthias Zimmermann,
phone +49 62 21 - 84 44 59, zimmermann@concept-heidelberg.de.

Registration for the GMP-Webinar: How to handle the new EU Site Master File (Part III EU GMP Guide)?
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Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

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