



With three Case Studies
and one Workshop

SOPs: Efficient Design, Management and Training

3-4 November 2011, Berlin, Germany

SPEAKERS:

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LEARNING OBJECTIVES:

- Regulatory Requirements and Expectations
- Management
 - Creation
 - Authorisation
 - Integration
 - Distribution
 - Revision
- Training
 - When to train
 - How to train
 - Assessment of Effectiveness
- Case Studies:
 - Implementation of an electronic SOP Management System
 - How to assign and train SOPs efficiently
 - How to reduce the Number of SOPs while remaining in Compliance

SOPs: Efficient Design, Management and Training

3-4 November 2011, Berlin, Germany

Learning Objectives

During this Education Course **you will learn how you can design, manage and train your SOPs efficiently.** Experts will show you possibilities to improve your system and how to run it lean and (c)GMP-compliant.

Background

A Standard Operating Procedure (SOP) is a written document or instruction detailing all steps and activities of a process or procedure. SOPs give directions for performing any process that could affect the quality of the product like for example cleaning, sampling, testing, equipment operation and environmental control.

Many staff members are involved in writing, checking and managing SOPs. And all relevant personnel needs to be trained in the respective SOPs. However during the last years SOPs and the systems to manage and train them have been becoming more and more complex resulting in problems like:

- SOPs are too long
- SOPs are complicated and not easy to understand
- SOPs are not routinely checked
- Training is inefficient
- Old SOP versions are used

But SOPs are an essential part of every pharmaceutical Quality Management System (QMS) and are necessary for the daily work. And to benefit from the system, SOPs must be designed, written, managed and trained in the most efficient way.

Target Audience

This Education Course is designed for all persons in pharmaceutical, biopharmaceutical and API industry who write, manage or train Standard Operating Procedures.

Moderator

Wolfgang Schmitt

Programme

Overview of Regulatory Requirements and Expectations

- Applicable rules and regulations
- Which SOPs are required
- Regulatory expectations on SOP management

SOPs as Part of the Documentation Management System

- How to integrate in the overall QMA and DMS
- Difference to other GMP-regulated documents
- Document flow

SOP Life Cycle

- Coming into effect and duration of effectiveness
- Distribution and change control
- Revisions
- Translations

SOP Design Part 1:

Basics

- Who should write
- What is needed
- Master SOP
- Checking and approval

SOP Design Part 2:

Creating concise and unambiguous documents

- Format
- Templates
- Annexes

Workshop on SOP Design

Understanding of technical instructions and SOPs is the prerequisite for the applicability and acceptance of these documents. In this workshop delegates will learn to describe and structure written procedures to facilitate understanding and express what is really meant.



Benefits and Drawbacks of electronic SOP systems

- Overview of various systems on the market
- How to identify the best system
- Benefits, efforts, challenges and possible pitfalls

Case Studies:

- Implementation of an electronic SOP-Management System in a mid-size Company
- How to assign and train SOPs efficiently in a global Company
- How to reduce the Number of SOPs while remaining in Compliance

Efficient SOP Training

- What does training actually mean to a person working in the industry and the trainee's ability to learn
- When to train
- Different possibilities of SOP training (e.g. read and understand, interactive electronic systems, classroom training etc.) and the pros and cons and viability of each approach for various SOPs
- Assessment and ongoing monitoring to ensure compliance
- Using internal trained trainers or external experts
- Documentation

Speakers

Dr Susanne Dommasch, *Nextpharma*

Dr. Susanne Dommasch is Head of Quality Assurance at the allphamed Pharbil Arzneimittel GmbH and PenCef Pharma GmbH, Göttingen (Subsidiary of Nextpharma Technologies Holding Ltd). She has been responsible establishing a computerised training system and an electronic SOP management system

Dr Afshin Hosseiny, *Tabriz Consulting, form. GSK*

Afshin Hosseiny is Managing Director of Tabriz Consulting, U.K.. Before working as a consultant, he was Director of Quality Assurance for the Global Supply Network of GlaxoSmithKline.

Dr Gerald Kindermann, *F. Hoffmann-La Roche AG*

Dr Gerald Kindermann is Product Quality Manager at the the Global Quality Group at Roche working on quality systems. Before that he was Group Leader Quality control and Quality Manager for the Supply Center.

Wolfgang Schmitt, *Concept Heidelberg, Germany*

Before Wolfgang Schmitt started as Director Operations at Concept Heidelberg in 2006, he worked for Abbott (the former Knoll AG, Germany). Wolfgang Schmitt was Head of Quality Management at SOLIQS (Abbott's global Drug Delivery Business Unit) and later an Associate Director and Qualified Person at Abbott's Global Pharmaceutical Research and Development QA, where he was responsible for GMP and GLP Compliance.

Social Event

On 3 November, 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.



GMP Certification Programme

This seminar is recognised within the GMP Certification Programme Module "Certified QA Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification modules:

- ECA Certified Validation Manager
- ECA Certified QA Manager
- ECA Certified API Production Manager
- ECA Certified Quality Control Manager
- ECA Certified Technical Operations Manager
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- ECA Certified Microbiological Laboratory Manager
- ECA Certified Sterile Production Manager
- ECA Certified Biotech Manager
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