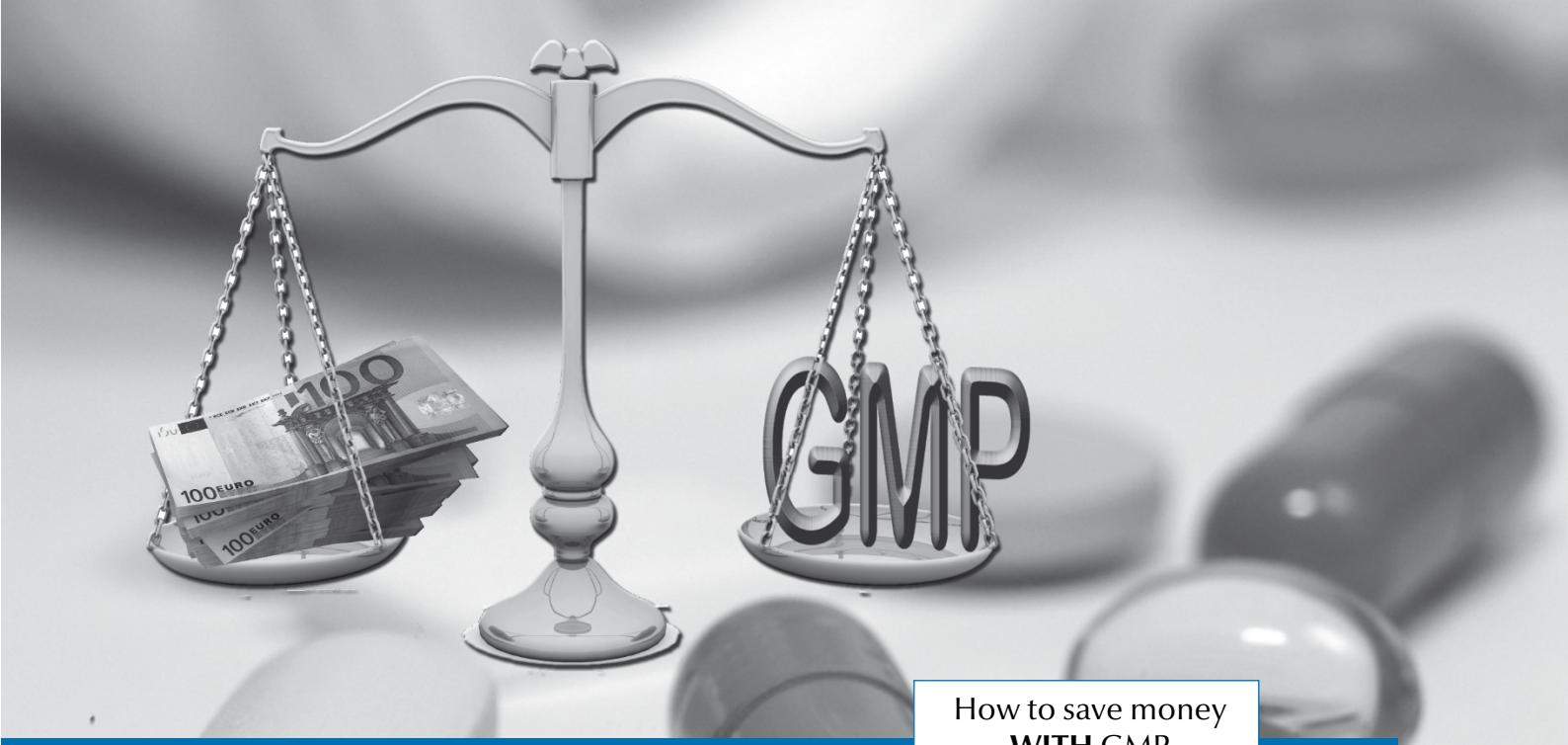


How to save money
WITH GMP

GMP & Money

Thoughts about cost savings in a GMP environment

12-13 June 2014, Munich, Germany

SPEAKERS:

Dr Heinrich Prinz
Apceth GmbH & Co. KG

Wolfgang Rudloff
gmp-experts

Rico Schulze
GMP Inspectorate

LEARNING GOALS:

- Reducing costs through more Compliance
- Thoughts on cost savings potential in the Quality Assurance environment
- Thoughts on cost savings potential in Technology

ECA
ACADEMY

GMP & Money

12-13 June 2014, Munich, Germany

Objectives

This comprehensive course aims to show that even in a GMP environment, optimising costs can be achieved without neglecting compliance. Experts from the pharmaceutical industry and the authority with long practical experience have critically examined the current implementation of cGMP requirements. In the course, they will express their opinions on identifiable trends.

Besides, practical examples focused on quality assurance and technology will be presented:

- From an authority perspective
- With regard to efficient use of GMP
- Risk management
- Modern Aspects of Process Optimisation
- Qualification
- Audits
- Deviation/Complaints/CAPA

Mini workshops will give food for thought

Background

The implementation of the EU GMP Guide at the beginning of the nineties opened the door to GMP in Europe. In the USA though, the American GMP regulations CFR 210/211 have already been applicable since the sixties. In both regions, the new Compliance requirements have led to costs for the pharmaceutical industry. This trend is continuing. New GMP requirements such as the creation of a Product Quality Review for the EU area or FDA's required "Continued Process Verification" have created new expenses.
In return, politics call for affordable medicinal products and at the same time increase cost pressures on pharmaceutical companies.

Target Audience

This course is of particular interest for persons who are responsible for the budget (heads of department, group leaders, etc.) in GMP regulated areas and interested in saving money in a GMP environments

Moderator

Wolfgang Rudloff, GMP-experts

Programme

Introduction

- Balancing between costs and compliance
- The GMP spiral retrospected
- GMP – who or what drives us?

Regulatory View – Is GxP and Efficiency a contradiction?

- What is genuinely necessary in a GxP environment? Undefined legal concepts/ Quality criteria/ Current state of the art
- Flexibility(ies): Are there any? How to use them?
- Personal responsibility vs. consultation with the authority: Are there any? How to use them?
- Higher-level evaluation criteria / supply of medicinal products / prices / availability

Efficient use of GMP

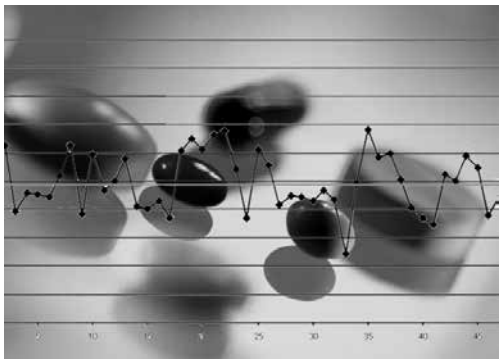
- What GMP´s?
- Optimising review periods
- Give more paper versus Give less paper
- Signatures
- Reducing procedures in GMP environments
- Optimising life cycles
- Using employees' autonomy
- Information management as element of control
- Applying regulatory flexibility
- GMP Training
- Outsourced activities
- Mini Workshop: Trending

Saving money thanks to risk management

- How to use risk management as a tool
- Risk management to save costs
- Knowledge management and transfer of know-how not only for validation phases
- Mini-Workshop: Cost savings with risk management

Modern aspects of process optimisation

- QbD
- DoE
- PAT
- Real Time Release



Modern economical qualification

- How much qualification must / should it be?
- Qualification documentation: the more, the better?
- GMP vs. GEP
- How much for qualification?
- Which material certificates are required in qualification?
- Internal/external qualification – costs versus efficiency and know-how
- Maintenance: inhouse vs. outsourcing
- Mini Workshop: Maintenance

Savings potential for audits

- Which audits are compulsory? Which aren't?
- Do joint audits really enable saving money?
- Qualification of auditor
- Mini Workshop: Costs of audits

Cost savings, how to avoid deviations and complaints

- GMP requirements regarding deviations and complaints
- What is CAPA?
- Rising costs through absurd CAPA activities
- How to use CAPA correctly?
- How to prevent deviations/complaints
- Mini Workshop: Calculating costs of deviations

Speakers

Dr Heinrich Prinz

Apceth GmbH & CoKG, Germany

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 works 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.

Wolfgang Rudloff

gmp-experts GmbH, Germany

Mechanical Engineer, legal expert in cleanroom technology and GMP management, expert in industrial engineering, safety engineer, worked in technical and process lead positions within Warner Lamber - Gödecke in Freiburg. His qualification comprises lead auditor, head of construction management, process engineering, GMP consultancy. After the position as managing director of LSMW, Switzerland he became in 2001 managing director, senior consultant and senior auditor for PCS. Today, he is a freelance consultant and specialises in technical GMP management, auditing and training for the pharmaceutical and API industry.

Rico Schulze

GMP Inspectorate, Local Authorities Dresden, Germany

Rico Schulze is a Pharmacist and holds a degree in Economics. Since 2003, he is GMP and GDP Inspector at the Local Inspectorate in Dresden. From 2008 to 2011 he was working at the Saxon State Ministry of Social affairs. He is also the Head of the German Authorities' Radiopharmaceuticals Working Group.

Social Event

On 12 June 2014, 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.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Reservation Form (Please complete in full)

GMP & Money,
12-13 June, 2014 Munich, Germany

☐ Mr ☐ Ms

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **PO Number if applicable**

Street/P.O. Box

City | Zip Code | Country

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

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

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GERMANY

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 %.

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. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
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

Thursday, 12 June 2014, 10.00 – 18.00 h
(Registration and coffee 09.30 – 10.00 h)
Friday, 13 June 2014, 08.30 – 13.15 h

Venue

Holiday Inn Munich -
City Centre
Hochstraße 3
81669 Munich, Germany
Phone +49 (0)89 - 4803 0
Fax +49 (0)89 – 448 7170

Fees

ECA Members € 1,290.- per delegate plus VAT
APIC Members € 1,390.- per delegate plus VAT
Non-ECA Members € 1,490.- per delegate plus VAT
EU GMP Inspectorates € 745.- 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 conference. Reservation should be made directly with the hotel. 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

CONCEPT HEIDELBERG
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69007 Heidelberg, Germany,
Phone ++49-62 21/84 44-0
Fax ++49-62 21/84 44 34
info@concept-heidelberg.de
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For questions regarding content:
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For questions regarding reservation, hotel, organisation etc.:
Ms Marion Grimm (Organisation Manager) at +49-62 21 / 84 44 18, or per e-mail at grimm@concept-heidelberg.de.

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