

Speakers



Dr Michael Aigner
University Erlangen



Cheryl Chia
Lotus Phoenix Consulting



Dr Martin Egger
Pharmaserv Logistics



Prof René Geyeregger
St. Anna Children's Cancer
Research Institute



Dr Christian Grote-
Westrick
B. Braun Avitum AG



Jochen Heinzel
F. Hoffmann-La Roche



Dr Afshin Hosseiny
European GDP
Association



Saddam Huq
GlaxoSmithKline



Saskia Killer
Oncotec Pharma
Produktion



Sue Mann
Sue Mann Consultancy



Axel Radke
Trust Expertenservice



Dr Laura Ribeiro
OCP Portugal



Dr Torsten
Schmidt-Bader
moveproTEC



Emil Schwan
Swedish Medical Products
Agency



Maria Sekamwa
Surgipharm



Gundula Warnecke
Oncotec Pharma
Produktion

GDP Forum

A GDP Conference designed by the
European GDP Association

24/25 June 2020 | Barcelona, Spain



Highlights

- KPIs and Benchmarking
- Brexit Implications
- Risk Management
- Failure Investigation
- Challenges in local Markets
- Sea Freight
- Customer Master Data
- Insourcing of Logistics
- Distribution of ATMPs
- With five parallel Workshops

Every participant will get a free copy
of the ECA/PQG GDP Guidance Document!

Objectives

The aim of this conference is to inform about recent experiences made in the implementation of the EU-GDP Guidelines. Challenges and possible solutions will be discussed and examples will demonstrate how the requirements can be put into practice.

Background

It is of key importance that medicinal products are not only made to a high quality in accordance with Good Manufacturing Practice (GMP), but that the quality and integrity of these products are maintained through the entire supply chain to the patient. This is where Good Distribution Practice (GDP) comes into play.

In the last few years the world of GDP has changed in scope and complexity and continues to evolve to meet new challenges with the continued aim of safeguarding public health. The Falsified Medicines Directive (2011/62/EU) was transposed into the laws and regulations of the EU Member States alongside the introduction of revised EU guidelines on Good Distribution Practice. Many other countries followed adopting these Guidelines or implementing very similar approaches.

Target Audience

All personnel involved in pharmaceutical storage, transportation, cold chain and distribution activities and the control of those activities.

Moderator

Dr Afshin Hosseiny

About the GDP Association:

The European GDP Association aims to support Pharmaceutical Industry, Authorities and Logistic Providers with regard to the implementation of Good Distribution Practice.

It represents all stakeholders e.g. from Pharmaceutical Industry, Authorities and Logistic Providers and supports all members and stakeholders by providing them information and support in the implementation of GDP.

The Association is a not for profit organisation under the umbrella of the ECA Foundation. Membership is free to all individuals involved in Good Distribution Practice (currently more than 2.000 members).

www.good-distribution-practice-group.org

Programme

Performance beyond Compliance

- Benchmarks with sense
- When is a system or process robust?
- Easily understandable key figures
- Case studies

Brexit Implications

- Import/ export issues
- Drug shortage challenges
- Falsification
- Serialisation
- Co-operation of the agencies

GDP Challenges in Africa

- Background
- Evolution of GDP over the years
- Problems involved
- Steps taken to improve

Customer Master Data

- Definitions
- Parties involved
- Responsibilities and RP oversight
- Managing Customer Master Data
- Lifecycle Management



3 parallel Workshops:

1. Risk Management in GDP Warehousing
 - Challenges and possible solutions
 - Examples
2. When things go wrong – what can happen in the real World
 - Experiences made in examining problems in the supply chain – and what to learn from them.
3. How to deal with suspected and confirmed falsified Medicines
 - What is a suspected falsified medicine
 - How to identify falsified medicine in your workplace
 - How to approach the investigation of a suspected pack
 - What should the end user do with the pack – who should manage communication with the end users

You will be able to attend TWO of these workshops. Please choose the ones you like to attend when you register.

Case Studies:

The Roche Quality Governance Model for Distribution to Direct Markets

- Selection, implementation, operation and decommissioning of partners
- Key Performance Indicators (KPIs)
- Compliance score card

The Switch from Air-freight to Sea-Freight

- Challenges and Benefits
- Examples

From external to internal Solutions - Insourcing of Warehousing and Logistics

- Implementation of own storage areas for minimum supply at the site
- Container and transport vehicle purchasing (refrigerated, warm, hazardous)

2 parallel Workshops:

1. Master Data and Serialisation

- Master Data for Serialisation
- Alerts Handling
- Exercises

2. Distribution of ATMPs

- Challenges when dealing with ATMP
- What information is needed to help service providers
- Examples

You will be able to attend ONE of these workshops. Please choose the one you like to attend when you register.

Question and Answers Session

You will be able to send in GDP related questions before the conference. Additionally, questions can be posted on question cards during the conference.

Answers will be given by the expert speakers in a dedicated session and published in the members area of the GDP Association's website (www.good-distribution-practice-group.org).

Speakers

Dr Michael Aigner, University Hospital Erlangen, Germany
Michael Aigner is Head of Production and Qualified Person for cellular ATMP/ATIMPs.

Cheryl Chia, Lotus Phoenix Consulting, Netherlands
Cheryl Chia is Consultant for GMP and GDP compliance in the pharmaceutical supply chain.

Dr Martin Egger, Pharmaserv, Germany
Dr Martin Egger is Managing Director of Pharmaserv and responsible for the brand Pharmaserv Logistics.

Prof René Geyeregger, St. Anna Children's Cancer Research Institute, Austria
Prof René Geyeregger is associated Professor and principal investigator at the Clinical Cell Biology and FACS Core Unit.

Dr Christian Grote-Westrick, B. Braun Avitum AG, Germany
Dr Grote-Westrick is Head of Quality Assurance and lead auditor with responsibilities in GMP / GDP compliance.

Jochen Heinzl, F. Hoffmann-La Roche, Switzerland
Jochen Heinzl is Global Quality Manager Supply Chain & Affiliate Quality EEMEA Region.

Afshin Hosseiny, Ph.D., Tabriz Consulting Ltd., U.K.
Dr Afshin Hosseiny is Managing Director of Tabriz Consulting Ltd. and Chairman of ECA's GDP Association.

Saddam Huq, GlaxoSmithKline, U.K.
Saddam Huq is Senior Manager Quality for Distribution & Cold Chain Management Vaccines, Quality Assurance Shared Services.

Saskia Killer, Oncotec Pharma Produktion, Germany
Saskia Killer is head of production and responsible for the aseptic processing of cytotoxic drugs. She is a Pharmaceutical Engineer and at Oncotec since 2014.

Sue Mann, Sue Mann Consultancy, U.K.
Sue Mann is GMP/GDP consultant with more than 35 years experience in the Pharmaceutical Industry, mainly in Quality Assurance, Clinical Trials supply and production support.

Axel Radke, Trust Expertenservice, Germany
Axel Radke is Responsible Person and technical expert for investigations of issues in the storage and transport of pharmaceuticals.

Dr Laura Ribeiro, OCP Portugal
Laura Ribeiro is Director Quality and Regulatory Affairs, managing a team of Responsible Persons.

Dr Torsten Schmidt-Bader, moveproTEC Compliance & Innovation Advisory, Germany
Dr Torsten Schmidt-Bader is Managing Director at moveproTEC and a GMP/GDP lead auditor and compliance advisor.

Emil Schwan, Medical Products Agency, Sweden
Emil Schwan is Pharmaceutical Inspector at the Drug Inspectorate of the MPA and a member of the PIC/S Working Group on GDP.

Maria Sekamwa, Surgipharm, Uganda
Maria Sekamwa is Assistant Warehouse Manager and Qualified Person for Pharmacovigilance.

Gundula Warnecke, Oncotec Pharma Produktion, Germany
Gundula Warnecke is a project manager for Oncotec and was responsible for the installation of a GDP-compliant warehouse at Oncotec.



Every participant will get a free copy of the GDP Guidance on interpretation and implementation, a joint publication of the ECA Foundation and the Pharmaceutical Quality Group of the Chartered Quality Institute.

Reservation Form (Please complete in full)

GDP Forum, 24/25 June 2020, Barcelona, Spain

Please choose TWO workshops:

- Risk Management in GDP Warehousing
- When things go wrong – what can happen in the real World
- How to deal with suspected and confirmed falsified Medicines

- Please choose ONE workshop:
- Master Data and Serialisation
- Distribution of ATMPs

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

City

Country

Phone / Fax

ZIP Code

E-Mail (Please fill in)

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D-69007 Heidelberg
 GERMANY

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

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%.
 - Cancellation until 1 week prior to the conference 50%.
 - Cancellation 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 can-

cellation 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).

German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at <https://www.gmp-compliance.org/privacy-policy>). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date

Wednesday, 24 June 2020, 9.00h – 18.00h
(Registration and coffee 8.30h – 9.00h)
Thursday, 25 June 2020, 8.30h – 15.00h

Venue

Barcelo Sants Hotel
Pl. Paisos Catalans, s/n
08014 Barcelona, Spain
Phone +34 93 503 53 00
Email sants@barcelo.com

Fees (per delegate, plus VAT)

ECA Members € 1,590
GDP Association Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days 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/POG when you have registered for the course. 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.

Important Information!



The presentations of the GDP Conference will be available for download and your print-out one week before and after the conference. **Note: there will be no print-outs available during the conference.**

Conference language

The official conference language will be English.

Social Event

In the evening of the first conference day, 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.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.
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For questions regarding content:

Dr Markus Funk (Director Operations) at +49(0)62 21/84 44 40, or per e-mail at funk@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:

Ms Nicole Bach (Organisation Manager) at +49(0) 62 21/84 44 22, or per e-mail at bach@concept-heidelberg.de