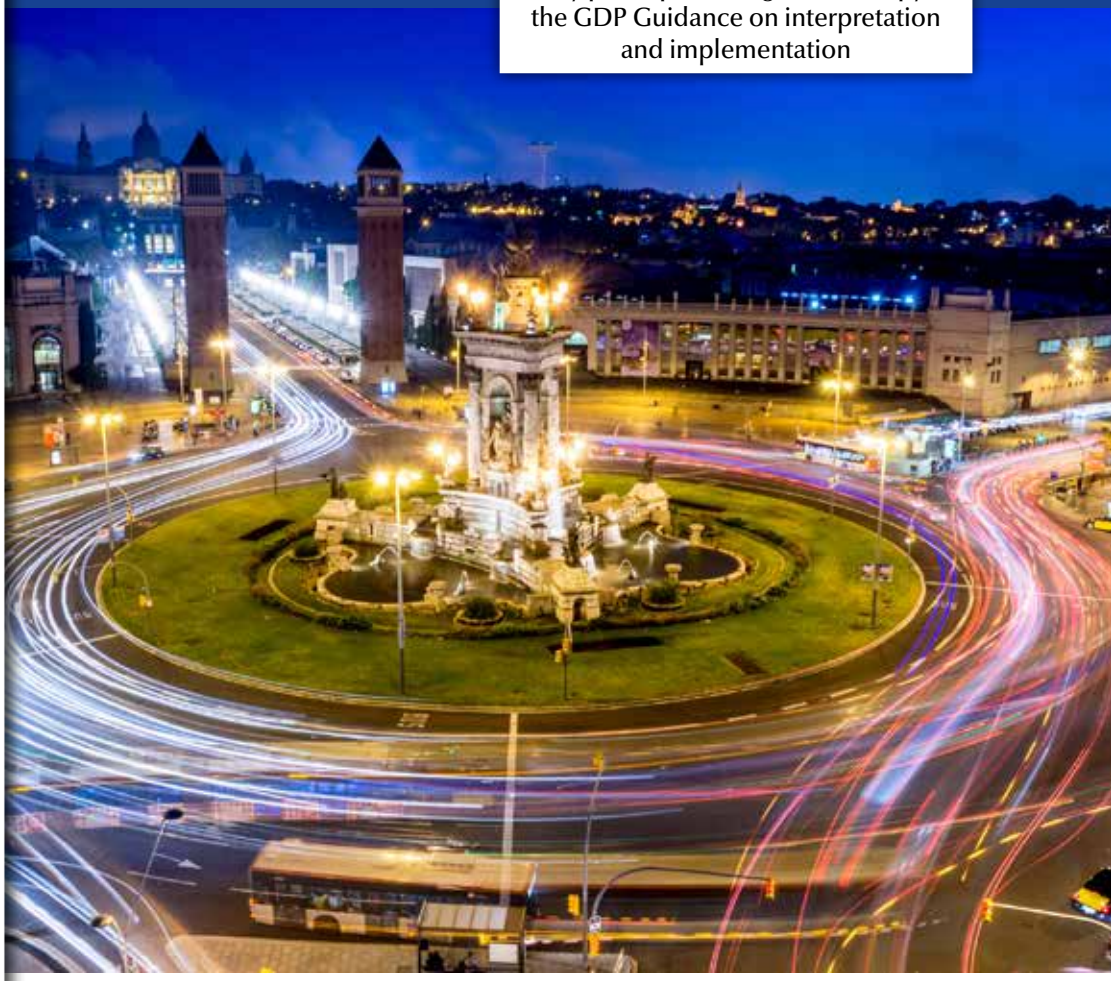
ECA Academy
Your GMP/GDP Information Source

GDP Conference

GDP and the real World

Every participant will get a free copy of the GDP Guidance on interpretation and implementation



Speakers:


Kane Edgeworth
Biomap


Dr Martin Egger
Pharmaserv Logistics


Michael Fleischer
World Courier


Dr Christian Grote-Westrick
B. Braun Avitum AG


Dr Afshin Hosseiny
European GDP Association


Saddam Huq
GlaxoSmithKline


Johanna Linnolahti
Finnish Medicines Agency Fimea


Federico Lupp
DHL Global Forwarding


Aidan Madden
FivePharma, Ireland


Dr Zvonimir Majic
Teva Pharmaceutical Industries Ltd


Sue Mann
Sue Mann Consultancy


Dr Laura Ribeiro
OCP Portugal


Emil Schwan
Swedish Medical Products Agency


Dr Rob Sleat
Minton Treharne & Davies Ltd (MTD)

5 - 6 June 2018, Barcelona, Spain

Highlights

- The GMP/GDP Interface
- Serialisation and the Consequences
- Data Integrity
- Design and Integrity of Supply Chains
- Import/ Export
- GDP GAP Analysis
- Qualification and Validation
- Failure Investigation
- Lean GDP
- Distribution of IMPs
- With five parallel Workshops

GDP Conference - GDP and the real World

5-6 June 2018, Barcelona, Spain

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

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.

Programme

Key Note: The X-Factor

Human Behaviours and Errors and what the Responsible Person needs to know about these

Import/Export Activities and their Link to GDP

- Import/export activities and their link to GDP (and what an inspector would expect regarding the GDP quality oversight)

Data Integrity in the Supply Chain

- The flow of data and how to control it
- Data Governance- what's it all about?
- The paper – IT interface
- How to reduce risks
- How to handle data and document from partners in the supply chain

Lean GDP – a risk-based Approach for Compliance

- How lean is lean?
- Efficiency without compromising Quality
- How do we deal with guidelines that allow alternative approaches?
- Risk management and other tools

Qualification in Transportation of Medicinal Products

- Regulatory background
- Main drivers for qualifications in transportation of medicinal products
- From API to medicinal samples for HCPs
- Qualification subject and applicable methodology for each transport mode
- In-house and outsourced activities interactions with highlights on 3PL and 4PL roles and responsibilities

Three parallel Workshops:

1) Supply Chain Mapping and Qualification
- End to End Supply Chain – where does it start and where does it end?
- How to map the supply chain process and who are involved?
- Control and Qualification Process of Supply Chain

2) The GMP/GDP Interface
- Where does responsibility of the manufacturer end and when does it come back?
- QP and RP co-operation
- Deviations in the supply chain: reporting and handling

3) How to perform a GAP Analysis
- Pre-requisites for an effective GDP implementation

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

Case Studies

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.

GxP in multi-centre Clinical Trial Logistics
Challenges and solutions

Two parallel Workshops:

1) Distribution of marketed Products: The 2D data matrix code implementation and what it means for distributers
- The Delegated Act for the Safety Features: the impact for the different parties in the supply chain
- Challenges and possible solutions

2) Distribution of Investigational Medicinal Products (IMPs)
- Challenges when dealing with IMPs
- What information is needed to help service providers
- Examples

You will be able to attend **ONE** of these workshops. Please choose the ones 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

Kane Edgeworth, Biomap, U.K.
Kane Edgeworth is Director at Biomap, providing temperature monitoring solutions for the Life Sciences industry. Before that, he was Operations Manager at Sensitech UK Ltd.

Dr Martin Egger, Pharmaserv Logistics, Germany
Dr Martin Egger is in charge of Pharmaserv Logistics, a Biotech Distribution Platform including GMP warehousing and temperature-controlled transport management (road, air and sea).

Michael Fleischer, World Courier
Michael Fleischer is Director and Global Head of Quality of the World Courier Transport Division. He is responsible for the compliance of the World Courier sites worldwide. Before that he was amongst others Customer Service Trainer and Temperature Control Specialist.

Dr Christian Grote-Westrick, B. Braun Avitum AG, Germany
Dr Grote-Westrick is Head of Quality Assurance and lead auditor for active pharmaceutical ingredients. He is a biochemist graduated at universities in Bochum, Harvard and Yale. After several positions in the medical device/ pharmaceutical industry he joined B. Braun in 2013 with responsibilities in GMP / GDP compliance.

Afshin Hosseiny, Ph.D., Tabriz Consulting Ltd., U.K.
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 is 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 at GSK.

Johanna Linnolahti, Finnish Medicines Agency Fimea, Finland
Johanna Linnolahti is a Senior Pharmaceutical Inspector at Fimea specialised in GDP. She is also a member of the Authority Advisory Board of the European GDP Association.

Federico Lupp, DHL Global Forwarding, Germany
Federico Lupp is Head of Business Development EMEA, Asia Pacific and Latin America at LifeConEx and DHL Global Forwarding.

Aidan Madden, FivePharma, Ireland
Aidan Madden is CEO of FivePharma, a Quality Services Company founded in 2003. Prior to setting up FivePharma Aidan held senior quality positions in Wyeth Pharmaceuticals, Baxter Healthcare and Fort Dodge Laboratories.

Dr Zvonimir Majic, Teva Pharmaceutical Industries Ltd, Croatia
Dr Zvonimir Majic is Director Global Quality Logistics. He has Ph.D. in Transportation and Logistics and is a member of IATA's Time and Temperature Task Force working group and IATA consultant for Center of Excellence for Independent Validators certification program.

Sue Mann, Sue Mann Consultancy, U.K.
Sue Mann has more than 35 years experience in the Pharmaceutical Industry, mainly in Quality Assurance, Clinical Trials supply and production support. In her last position, Sue was Vice President of International Quality Assurance at Shire Pharmaceuticals.

Dr Laura Ribeiro, OCP Portugal
Laura Ribeiro is Director Quality and Regulatory Affairs, managing a team of Responsible Persons and being responsible for the quality management system and continuous improvement of the company. Before that she was Responsible Person at ID Logistics (formerly Logiters), R&D and Regulatory Affairs Manager in the pharmaceutical industry and invited Professor at Escola Superior de Tecnologias da Saúde de Coimbra. Laura Ribeiro is also a member of the Board of Directors of the European GDP Association.

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. He is also a member of the Authority Advisory Board of the European GDP Association.

Dr Robert Sleat, Minton Treharne & Davies Limited (MTD)
Dr Robert (Rob) Sleat is a Consultant Chemist & Biotechnologist at MTD, one of the world's foremost specialists in undertaking technical investigations into large insurance claims resulting from issues arising from the movement of commodities and products through the supply chain. He has over 20 years experience in undertaking technical investigations into insurance claims arising from both pharmaceutical manufacturing and the distribution of both APIs and finished products.

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.

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

What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website http://www.gmp-compliance.org

What Are the Benefits of ECA?

During the membership, you enjoy a € 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.

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

Date
Tuesday, 05 June 2018, 9.00h – 18.00h
(Registration and coffee 8.30h – 9.00h)
Wednesday, 06 June 2018, 8.30h – 15.00h

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

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.

Conference fees (per delegate plus VAT)
ECA Members € 1,590
GDP Association Members € 1,590.-
APIC Members € 1,690
Non-ECA/GDPA 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

Registration
Via attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Mr Wolfgang Schmitt
(Director Operations) at
+49-62 21/84 44 39, or per e-mail at
w.schmitt@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Nicole Bach (Organisation Manager) at
+49-62 21/84 44 22, or per e-mail at
bach@concept-heidelberg.de.

Conference language
The official conference language will be English.

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.

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

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CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

Registration form (please complete in full)

+49 6221 84 44 34

GDP Conference - GDP and the real World
5-6 June 2018, Barcelona, Spain

Please choose TWO Workshops:
- ☐ Supply Chain Mapping and Qualification
- ☐ The GMP/GDP Interface
- ☐ How to perform a GAP Analysis

Please choose ONE workshop:
- ☐ Distribution of marketed Product
- ☐ Distribution of Investigational Medicinal Products (IMPs)

☐ Mr ☐ Ms Title _____

First name, surname

Company

Department

Important: Please indicate your company's VAT ID Number **Purchase Order No. (if applicable)**

Street / P.O. Box

City Zip Code Country

Phone / Fax

E-mail (please fill in)

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).

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 http://www.gmp-compliance.org/eca_privacy.html). 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.