ECA Academy
Your GMP/GDP Information Source

The European GMP & GDP FORUM

22-24 JUNE 2021 | LIVE ONLINE

SPEAKERS & MODERATORS:

Ib Alstrup
GxP IT Medicines Inspector with the Danish Medicines Agency, DMA, Denmark
Dr Christopher Burgess
Qualified Person, Chaiman ECA Quality Control Group, UK
Cheryl Chia
Lotus Phoenix Consulting, Netherlands
Loretta Dougan
Jazz Pharmaceuticals, Ireland
Prabjeet Dulai
GDP & Quality Matters, UK
Dr Rainer Gnibl
GMP Inspector, District Government of Upper Bavaria, Germany
Dr Afshin Hosseiny
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Saddam Huq
GlaxoSmithKline, U.K.
Dr Ulrich Kissel
Chairman, European QP Association, Germany
Gert Moelgaard
Chairman ECA Validation Group, Denmark
Axel Radke
Trust Expertenservice, Germany
Jonathan Riley
Astellas Pharma Europe Ltd
Dr Bernd Renger
Qualified Person, Immediate Past Chairman European QP Association, Germany
Dr Jens-Uwe Rengers
JeRo Consulting, Switzerland
Maria Sekamwa
Surgipharm, Uganda
Dr Torsten Schmidt-Bader
moveproTEC Compliance & Innovation Advisory, Germany
Dr Franz Schönfeld
District Government of Upper Franconia, Germany
Dr Wolfgang Schumacher
Chairman ECA Data Integrity & IT Compliance Group, Switzerland
Lance Smallshaw
UCB Biopharma S.A., Chairman ECA Cannabis Group, Belgium
Dr Ingrid Walther
Pharma Consulting Walther, Former Head of the Business Unit iv Drugs, Fresenius

** ALL PARTICIPANTS RECEIVE AN EXCLUSIVE PACKAGE OF NEW ECA GUIDELINE DOCUMENTS | FURTHER INFORMATION INSIDE **

THE ECA FOUNDATION GROUPS

ECA QP Association — An ECA Foundation Interest Group
ECA Analytical Quality Control Group — An ECA Foundation Interest Group
ECA GDP Association — An ECA Foundation Interest Group
ECA Data Integrity & IT Compliance Group — An ECA Foundation Interest Group
ECA Pharmaceutical Microbiology Group — An ECA Foundation Working Group
ECA Validation Group — An ECA Foundation Interest Group
ECA Visual Inspection Group — An ECA Foundation Interest Group
ECA ATMP Group — An ECA Foundation Interest Group
ECA Cannabis Group — An ECA Foundation Working Group

WELCOME

Dear Colleagues,

I would like to invite you to the European GMP & GDP Forum from 22 – 24 June 2021.

Our ECA members are familiar with biennial conferences on GMP and GDP we have been running for several years. However, we have now developed this unique Forum by combining the European GMP Conference and the European GDP Forum. I believe with this new event by combining both GMP and GDP subjects, we have created a new opportunity for you to hear speakers from across the industry, and learn about the whole Pharma supply chain challenges.

Travelling and face-to-face meetings are still difficult. Therefore, we decided to offer the first GMP & GDP Forum live online.

We have dedicated day 1 to GMP, day 2 will be a combination of both GMP, and GDP and the final day will be focussed on GDP topics only. This will allow you as a participant to take advantage of the event based on your personal needs and interest in the specific subject areas, you can now choose to attend the forum just for one of the three days, two days or all three days.

We intend to host the Forum every two years which I am sure will become a major European event for GMP and GDP professionals. For our first Forum in June 2021 we have invited speakers from Regulatory Authorities and Pharmaceutical Industry to share and discuss with you the latest GMP & GDP developments.

I look forward to welcoming you to this event – live online!

Yours sincerely,
Dr Afshin Hosseiny, Chairman of the ECA Foundation Advisory Board

TARGET GROUP

The conference is of particular interest for GMP experts of pharmaceutical companies (e.g. QA, QC, production, regulatory affairs), of GMP inspectorates and Regulatory Authorities. It is also of interest for all personnel involved in GDP – pharmaceutical storage, transportation, cold chain and distribution activities and the control of these activities.

WELCOME

Introduction – Update ECA
Dr Afshin Hosseiny, Chairman ECA

PROGRAMME 22 JUNE – GMP PART

Moderated by: Lance Smallshaw

SESSION

Current GMP Initiatives Worldwide

This session will discuss the latest changes and current initiatives in GMP and GDP regulations.

GMP Update 2021 and Outlook 2022 –
Current Trends and Developments in Europe and the US

➲ Dr Bernd Renger, *QP and immediate past chair of the EQPA*

- Major GMP developments and their impact for pharmaceutical industry
- GMP Revisions – Annex 1 & 21
- GMP for Marketing Authorisation Holders
- The new EU GMP Annex 21 on Importation and its implication
- Analytical Procedure Development and Validation (ICH Q14/Q2)
- Other GMP Developments from EMA, FDA and others
- Brexit and its consequences for the European QPs

ICH Q 12: Views and Expectations of a GMP-Inspector

➲ Dr Franz Schönfeld, *GMP Inspector*

- Quality Risk Management
- Life Cycle Approach
- Views and Expectations

How to Implement ICH Q 12 into Daily Practice of Manufacturers – What QA (and QPs) needs to know?

➲ Dr. Ulrich Kissel, *Chairman European QP Association*

- What does QA (and QPs) need to consider?
- Some Quality systems become key
- Efficiency potential for Quality systems of manufacturing organizations
- ICH Q12 and key performance indicators
- Plan precisely, assess risks proactively, share transparently

SESSION

Industry Meets Inspectors

GMP Inspections from Russian Authority in Europe
To be named

Global Inspection Management: Cultural Differences to consider in hosting Competent Authorities

➲ Dr Jens-Uwe Rengers, *Zürich, Switzerland*

- General Organisation
- Roles and Responsibilities
- Preparation
- Cultural Aspects

Annex 1 Revision: Comments from the Industry

➲ Dr Ingrid Walther, *Head of ECA´s adhoc Task Force for comments to the Annex 1 revision*

- New requirements?
- New requirements!
- The role and importance of Quality Risk Management
- Contamintation Control Strategy

Inspection – readiness for new Annex 1: Comments from the Inspector

➲ Dr Rainer Gnibl, *GMP Inspector*

- What is essential?
- What do I need to change or improve?
- Is it really such serious?

Final Q&A Session (Day 1)

PROGRAMME 23 JUNE – GMP & GDP PART

Moderated by: Dr Urich Kissel

Brexit: Consequences for GMP and GDP Environment

➲ Dr Afshin Hosseiny, *Chairman ECA Foundation and European GDP Association*

- What is the impact of Brexit on Pharma Regulations?
- New GMP and GDP expectations from UK
- How Pharma Industry in EU should manage the UK business
- What impact all this has on the patients?

EU GMP Annex 21: Import of Medicinal Products

➲ Dr. Ulrich Kissel, *Chairman European QP Association*
- The meaning of importation within scope of Annex 21
- What is new in Annex 21 (draft)?
- What do we miss in Annex 21 (draft)?
- Conclusions and comments on the document

PARALLEL SESSIONS & WORKSHOPS WITH INSPECTORS

Moderatored by: Dr Afshin Hosseiny / Dr Ulrich Kissel, Gert Moelgaard / Dr Rainer Gnibl, Dr Wolfgang Schumacher / Ib Alstrup, Dr Christopher Burgess / N.N., Saddam Huq / Prabjeet Dulai

Get involved in the ECA Interest and Working Groups. Each delegate will be invited to discuss the upcoming developments with the Chairs/ members of the groups and EU inspectors.

AGENDA

You can address topics of interest and you can provide feedback on the currently planned activities. It is the aim of the Interest and Working Groups to provide a platform for discussion with both colleagues from industry and regulatory authorities.

Parallel-Sessions

Validation Group	Quality Control Group	Data Integrity & IT Compliance Group	GDP Group

Option 1 (Validation Group): Qualification & Validation: Supplier integration – how does this fit with GMP?

This interactive session will offer the opportunity for the participants to discuss some of new developments in qualification and validation activities:
- How can qualification and GEP interact?
- How can suppliers be integrated?
- Categorisation of equipment – a tool for streamlining qualification efforts
- Electronic qualification documentation

Option 2 (Quality Control Group): QC: How sure are you that your Laboratory Instrument/System is fit for its intended Purpose?

1. Introduction to the ECA AQC Group Guideline on Analytical Instruments and Systems Qualification Lifecycle
2. Overview of USP General Chapter<1058> and revision of spectroscopic General Chapters USP <85x> and <185x> and their relationship to the newly proposed analytical procedure lifecycle in USP <1220>
3. Reference standards for calibration and establishment of acceptance criteria for 'fitness for purpose'

Option 3 (Data Integrity & IT Compliance Group): Data Integrity in the GMP area

This interactive session will offer the opportunity for the participants to discuss current Data Integrity issues
- How to prepare for a Data Integrity inspection – the industry view
- Data Integrity Risk Assessment
- Data Integrity Inspection findings

Option 4 (GDP Group): How to Identify and Manage Falsified Medicines in the Supply Chain

This workshop will offer the opportunity to discuss the following aspects:
- 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?
- Routine monitoring of incoming goods
- Who should manage communication with the end users?

Option 5 (GDP Group): Risk Management in GDP Warehouse

The risk-based approach is a fundamental requirement for processes in the GDP environment. Risk management is one of the mandatory basic elements. It is applicable to a variety of activities and processes. This workshop will cover challenges and possible solutions concerning risk management in GDP warehouses. Different examples will be discussed.

SESSION

Inspections/Audits in Covid-19 Times

The corona pandemic causes unusual supplier qualification activities. Meetings face-to-face are reduced or not possible at all. This concerns supplier audits but also regulatory inspections. To fulfil GMP-requirements and to prevent travelling and meeting people personally is a balancing act. How to react?

Distant Assessments – GMP-inspector´s view
➲ Dr Rainer Gnibl, *GMP Inspector*
- Regulatory basis
- Requirements from guidelines
- Examples from inspections
- Reliability in "real life"

Supplier Management during Covid-19 Pandemic
➲ Loretta Dougan, *Jazz Pharmaeceuticals*
- What is different than "normal"
- How to qualify suppliers during the pandemic?
- How to do reaudits from established suppliers?
- Remote audits as an alternative?

Final Q&A Session (Day 2)

PROGRAMME 24 JUNE – GDP PART
Moderated by: Dr Afshin Hosseiny

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.
On day 3, challenges and possible solutions will be discussed and examples will demonstrate how the requirements can be put into practice.

GDP Update & Outlook
Dr Afshin Hosseiny, *Chairman ECA Foundation and European GDP Association*
- Major GDP developments

Case Studies: When Things go Wrong – What can Happen in the Real World?
➲ Axel Radke, *Trust Expertenservice*
- First plan, then start
- Hand in hand for safe transport
- Basis of all considerations "Worst Case Scenario"

Case Study: The Switch from Air-freight to Sea-Freight
➲ Saddam Huq, *GlaxoSmithKline*
- Challenges and Benefits
- Examples

GDP Challenges in Africa
➲ Maria Sekamwa, *Surgipharm*
- Background
- Evolution of GDP over the years
- Problems involved
- Steps taken to improve

Performance beyond Compliance
➲ Dr Torsten Schmidt-Bader, *moveproTEC Compliance & Innovation Advisory*
- Efficient GDP quality policy
- GDP-relevant quality targets
- Helpful benchmarks for auditors
- Critical review of GDP certificates

Master Data
➲ Cheryl Chia, *Lotus Phoenix Consulting*
- EU requirements
- Master Data framework for Medicines
- Impact to the Pharmaceutical Supply Chain
- QA/QP/RP oversight of the supply chain

GDP Responsibilities for Financial Trading Organisation
➲ Prabjeet Dulai, *GDP & Quality Matters* &
Jonathan Riley, *Astellas Pharma Europe*
- Involvement of Marketing Authorisation Holders in the distribution network
- The role of the Responsible Person when product handling is not involved
- Control of outsourced activities in integrated supply chains
- Processes used in financial distribution, and validation of computerised systems

Final Q&A Session (Day 3)

SPEAKERS & MODERATORS

Ib Alstrup, *GxP IT Medicines Inspector with the DMA, Denmark*
Ib Alstrup is a GxP IT Medicines Inspector with the Danish Medicines Agency. With a background as a software designer and tester, he has specific focus and large experience in inspection of validation and operation of computerised systems throughout the GxP areas. He is a co-writer of the new PIC/S guide on Data Integrity and holds a B.Sc. in Electronic Engineering.

Dr Christopher Burgess, *Qualified Person, Chairman ECA Quality Control Group, UK*
Chris has been working in the pharmaceutical industry for many years and is currently among others Chairman of the ECA Quality Control Group, member of the ECA Foundation's Extended Board and member of the ECA Task Force on Data Integrity.

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

Loretta Dougan, *Jazz Pharmaceuticals, Ireland*
Loretta Dougan is Associate Director Quality Assurance and Qualified Person for IMPs.

Prabjeet Dulai, *GDP & Quality Matters, UK*
Prabjeet Dulai is a Consultant at GDP & Quality Matters Ltd. Before working as a consultant she was the RP and Senior Supply Chain Pharmacist for the UK Ministry of Defence, and worked as a Pharmacist within the NHS/private hospital sector, retail and pharmaceutical industry.

Dr Rainer Gnibl, *GMP Inspector, District Government of Upper Bavaria, Germany*
Dr Rainer Gnibl is pharmacist and GMP Inspector for the District Government and the EMA and performs GMP inspections worldwide. Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

Dr Afshin Hosseiny, *Qualified Person, Chairman ECA Foundation and European GDP Association, UK*
Afshin looks back to many years with Glaxo Smith Kline in the UK and is Chairman of the ECA Foundation and the European GDP Association.

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

Dr Ulrich Kissel, *Chairman European QP Association*
Ulrich Kissel is Qualified Person and Chairman of the European Qualified Person Association (EQPA). Previous to his current role he held leadership positions in Quality and Supply Chain and served for many years as QP for Roche.

Gert Moelgaard, *Chairman ECA Validatop Group, Denmark*
Gert Moelgaard has more than 25 years experience in the pharmaceutical and biotech industry, with experience in process control, automation, computer systems validation and process validation as well as process engineering and consulting. Gert is Chairman of the ECA Validation Group and member of the ECA Foundation's Extended Board.

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

Jonathan Riley, *Astellas Pharma Europe Ltd*
Jonathan Riley is a QA professional with over 18 years quality management experience including GMP, GDP, GLP and GCP in contract research, pharmaceuticals, clinical trials and chemicals manufacturing.

Dr Bernd Renger, *Qualified Person, Immediate Past Chairman European QP Association, Germany*
Bernd worked for many years in the pharmaceutical industry and is Immediate Past Chairman of the European QP Association (EQPA).

Dr Jens-Uwe Rengers, *JeRo Consulting GmbH, Switzerland*
Prior to the funding of his consultancy business, Jens-Uwe Rengers acted as General Manager at Akorn AG. Before that he was Director Quality and QP and held different other roles at Byk Gulden (now Takeda), Cytos Biotechnology AG and Siegfried Ltd.

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

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. Since 2010 he has been supporting the life science industries and pharma logistic providers with GDP implementation. For SGS ICS, he certified several providers against WHO and EU GDP standards.

Dr Franz Schönfeld, *District Government of Upper Franconia, Germany*
Dr Franz Schönfeld is a GMP and GDP inspector at the local inspectorate for medicinal products and active substances of the District Government of Upper Franconia. He is head of the expert working group for APIs at the Central Authority of the Federal States for Health Protection.

Dr Wolfgang Schumacher, *Chairman ECA Data Integrity & IT Compliance Group , Switzerland*
He was til July 2017 Head of the department of Quality Computer Systems at F. Hoffmann-La Roche. He is currently Head of the ECA Data Integrity & IT Compliance Group, member of the ECA Foundation's Extended Board and member of ECA´s Task Force on Data Integrity.

Lance Smallshaw, *UCB Biopharma S.A., Chairman ECA Cannabis Group, Belgium*
Lance Smallshaw is Global Analytical and Quality Expert – Head of Compendial Affairs at UCB in Belgium and Member of ECA´s Executive Board.

Dr Ingrid Walther, *Pharma Consulting Walther, Former Head of the Business Unit iv Drugs, Fresenius*
Dr Walther was employed in various positions and has long years of experience in the fields of research and development,QA/QC and the management of strategic projects and as head of a Business Unit Validation and GMP Compliance. Since July 2009 she runs her own business as consultant. She was Head of ECA´s adhoc task force commenting the Annex 1 revision.

Date

Tuesday, 22 June 2021, 09.00 – approx. 17.30 h
Wednesday, 23 June 2021, 09.00 – approx. 17.00 h
Thursday, 24 June 2021, 09.00 – approx. 17.00 h

All times mentioned are CEST.

Technical Requirements

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Conference Fees (per day and delegate plus VAT)

ECA members and European GDP Association members receive a 200.- Euro discount.
APIC members receive a 100.- Euro discount.
EU GMP Inspectorates receive a 50% discount.

Day 1 or day 2 or day 3: EUR 990.-
Day 1 and 2: EUR 845.- (total EUR 1690.-)
Day 1 and 3: EUR 845.- (total EUR 1690.-)
Day 2 and 3: EUR 845.- (total EUR 1690.-)
Day 1-3 EUR 665.- (total EUR 1990.-)

The conference fee is payable in advance after receipt of invoice.

Registration

You can either register via the attached reservation form, by E-Mail or by fax, or you can register online at www.gmp-conference.org. Your registration will be confirmed by E-Mail.

Conference Material

Important Information!
Just prior to the conference you will get access to a download area where you will find the presentations as PDFs. Presentations will be uploaded up to the Conference as they become available. We hope for your understanding, though, if individual presentations are not available for download due to restrictions from the authors.

Conference Language

The official conference language will be English.

Organisation and Contact

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
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content (GMP Part):
Sven Pommeranz (Operations Director) at +49-62 21 / 84 44 47,
or per e-mail at pommeranz@concept-heidelberg.de.

For questions regarding content (GDP Part):
Dr Markus Funk (Operations Director) at +49-62 21 / 84 44 40,
or per e-mail at funk@concept-heidelberg.de.

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

AS A PARTICIPANT YOU WILL RECEIVE AN EXCLUSIVE PACKAGE OF NEW ECA GUIDELINE DOCUMENTS

Each participant will receive a set of PDF documents developed by ECA Working and Interest Groups such as:

- Data Governance and Data Integrity for GMP Regulated Facilities (Version 02)
- Analytical Procedure Lifecycle Management Guideline
- Out of Expectation (OOE and Out of Trend (OOT) Guidance Management Document
- Integrated Qualification and Validation – A guide to effective qualification based on Customer-Supplier Partnership (Version 1.0)
- Good Distribution (GDP) Interpretation Guide (ECA/PQG)
- Latest version of the GMP Matrix (comparison of EU GMP, FDA cGMP and ISO 9001)

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LIVE ONLINE: GMP & GDP FORUM 2021, 22-24 June 2021

Participation:
I would like to attend on the folowing days: ☐ Day 1 ☐ Day 2 ☐ Day 3

ONLY ON DAY 2: PARALLEL SESSIONS – PLEASE CHOOSE ONE
- ☐ Qualification & Validation: Supplier integration - how does this fit with GMP?
- ☐ Quality Control: How sure are you that your Laboratory Instrument/System is fit for its intended Purpose?
- ☐ Data Integrity: Data Integrity in the GMP area
- ☐ GDP: How to Identify and Manage Falsified Medicines in the Supply Chain
- ☐ GDP: Risk Management in GDP Warehouse

☐ Mr ☐ Ms

Title, first name, surname

Company Department

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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.
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- Cancellation until 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
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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.
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