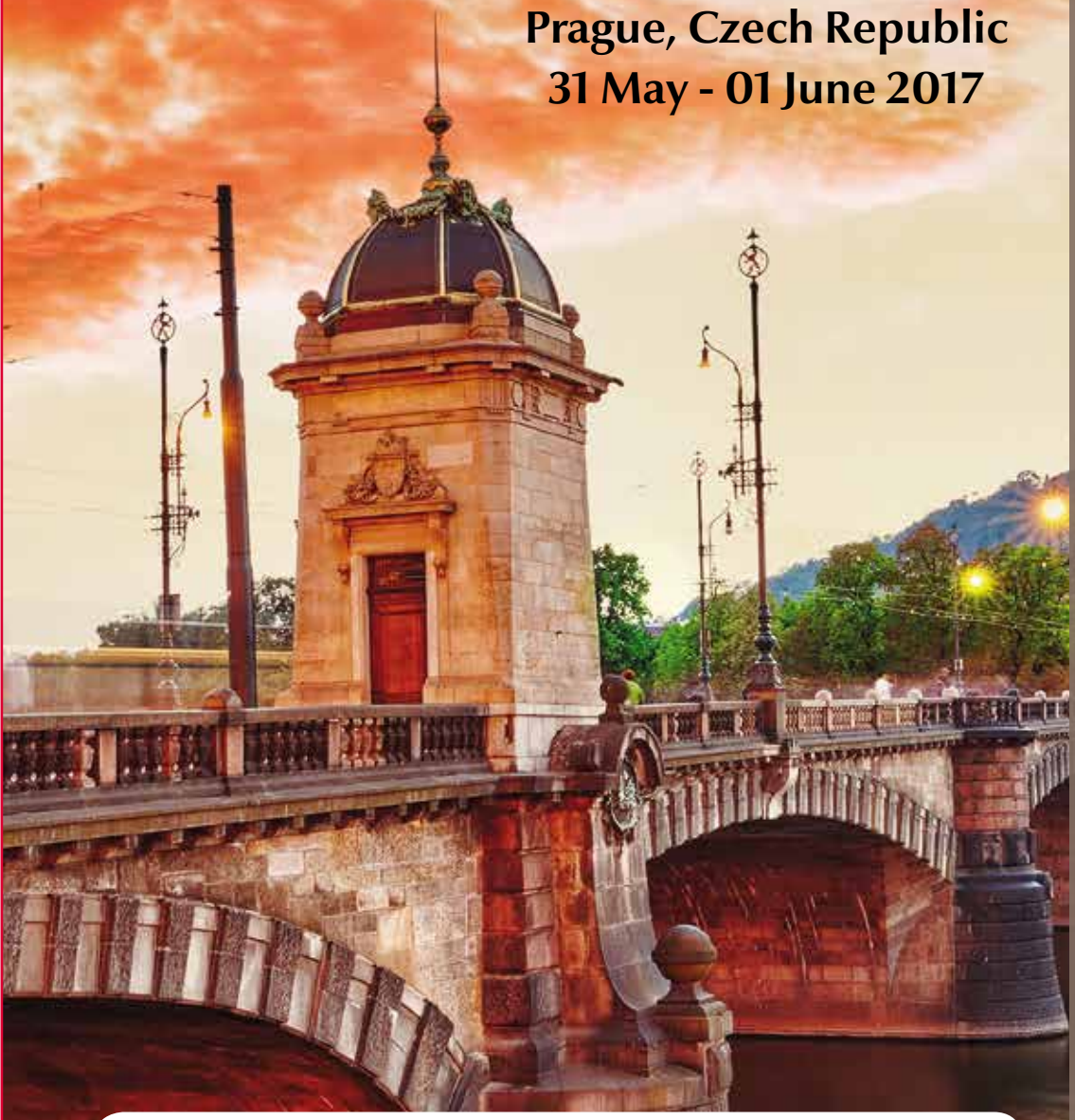
7th European GMP Conference

The biennial No. 1 Event in Europe

Prague, Czech Republic
31 May - 01 June 2017



Free of charge NEW ECA Guidance Documents

Each participant will receive a set of documents developed by ECA working and interest groups such as:

- Data Governance and Data Integrity for GMP Regulated Facilities
- Out of Expectation (OOE and Out of Trend (OOT) Guidance Management Document
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- Latest version of the GMP Matrix (comparison of EU GMP, FDA cGMP and ISO 9001)

The ECA Foundation Groups

QP Association – Analytical Quality Control Group, An ECA Foundation Working Group

ECA – Good Distribution Practices Group, An ECA Foundation Interest Group

ECA – 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 Academy
Your GMP/GDP Information Source

Speakers and Moderators:

MARIA-JESUS ALCARAZ
EMA, UK

RICHARD BONNER
Qualified Person and Chairman ECA, UK

DR CHRISTOPHER BURGESS
Qualified Person and Chairman of ECA's Quality Control Working Group, UK

KLAUS EICHMÜLLER
Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany

DR MATTHIAS HEUERMANN
NRW Centre for Health (LZG.NRW), Münster, Germany

DR AFSHIN HOSSEINY
Qualified Person and Chairman of ECA's GDP Interest Group, UK

DR ANDREAS KÖNIG
Quality König GmbH, Germany

OLIVER KÜTTNER
Shire, Austria

JOHANNA LINNOLAHTI
Finnish Medicines Agency FIMEA, Finland

GERT MØLGAARD
Chair of ECA's Working Group on Validation, Denmark

TRACY MOORE
Medicines and Healthcare Products Regulatory Agency, UK

AMELIA MUTERE
F. Hoffmann La Roche, Switzerland

DR BERND RENGER
Qualified Person and Immediate Past Chair of the EQPA, Germany

DR FRANZ SCHÖNFELD
GMP Inspectorate Germany

DR WOLFGANG SCHUMACHER
Chairman ECA´s IT Compliance Group, Switzerland

LANCE SMALLSHAW
ECA Executive Board Member, Belgium

ALEX VIEHMANN
FDA, USA

7th European GMP Conference – Industry meets inspectorates

Objectives

The EU GMP Conference is only offered every two years. This unique conference will discuss current and planned changes to the GMP regulation. All experts and managers involved in GMP compliance activities will have the opportunity to get a comprehensive GMP update and to talk to the leading experts from industry and authority.

Although EU GMP is in the center of attention, a harmonized approach with cGMP from FDA will also be an important aspect of the agenda. For international operating companies both EU GMP and FDA compliance is important and the corporate quality systems need to cover the regulation of both regions.

The agenda will therefore focus on key GMP compliance developments. Attention will be paid on the implementation of these requirements into pharmaceutical quality systems. The ECA Foundation's objective is to support industry, and therefore current activities as well as guidance documents and SOPs are presented during this conference.

Each Session will have speakers from industry and inspectorates to discuss both expectations and implementation aspects.

We wish you a successful and interesting conference.

Yours sincerely,

Richard M. Bonner
Chairman of the ECA Advisory Board

Target Group

The conference is of particular interest for GMP experts of pharmaceutical companies (e.g. QA, QC, production, distribution, regulatory affairs, validation), of GMP inspectorates and Regulatory Authorities.

Programme

WELCOME
Introduction – Update ECA
Richard Bonner, Chairman ECA

Session I Current Initiatives in EU and FDA

Moderator: Richard Bonner

This session will discuss the latest changes and current initiatives in EU GMP and FDA GMP regulation

Update from recent EU GMP changes

- Latest Changes in EU Regulations
- Latest Revisions of the EU GMP Guide and its Annexes
- New EMA Guidelines with impact to GMPs
- Look over the Pond - Important GMP developments in the US

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

The new EU/US Mutual Recognition Agreement

- Details of the new agreement
- Consequences for EU and FDA Inspections
- Transitory Provisions

Maria-Jesus Alcaraz, EMA UK

Doing business with companies that operate outside of the EU/FDA zones

- How do I know if the company is producing using equivalent GMPs
- Do cultural differences matter?
- How will I know if anything goes wrong?
- What if I am purchasing through a broker?
- What is my QP responsible for?

Richard Bonner, Chairman ECA

Session II Data Integrity of GMP Data

Moderator: Dr Wolfgang Schumacher

Data Integrity is one of the top topics since some years. Data Integrity is not very detailed described in the EU GMP Guide. So some national authorities (e.g. MHRA) published interpretations about Data Integrity. Also the FDA has published a Guideline on it. The current status regarding Data Integrity is discussed in this session.

MHRA's view about Data Integrity, Typical problem areas and findings, MHRA Guidance document on Data Integrity

- Data Integrity Governance
- Are we seeing changes in the perception of Data Integrity?
- The good, the bad, the ugly and the shining stars
- Guidance and where next?

Tracy Moore, GMP Inspectorate

Implementation of a company wide data integrity program

- Elements to be covered
- How to identify GAPs in QC Labs and Production
- Communication and Training of employees

Amelia Mutere, F. Hoffmann-La Roche

ECA's Data Integrity Guideline

- Overview of Data Integrity Interest Group
- Generation process of this guidance document
- Structure and content
- Current status and next steps

Dr Wolfgang Schumacher, Head ECA's IT Group

Session III Quality Oversight

Moderator: Dr Afshin Hosseiny

Recent FDA Warning Letters often mention 'lack of Quality Oversight'. What is the European perspective on this subject? Could the FDA requirement on 'Quality Metrics' also be used as indicator for quality oversight? These questions will be discussed in this session.

Update on FDA´s new Quality Metrics Guideline

- Explore the specific details that are new and different in the revised draft guidance, including metrics, definitions and reporting strategies.
- Overview of the FDA's plans for compiling and analyzing the metrics data from pharmaceutical companies.
- Summary of short and long-term plans for quality metrics.

Alex Viehmann, FDA

Measuring and Monitoring of Quality Assurance: Regulatory Expectations

- Legal requirements – EU and international
- Links to ICH Q8, Q9 and Q 10 - Quality oversight
- Authority requirements
- Examples

Dr Franz Schönfeld, GMP inspectorate

Quality Oversight – how to make it successful?

- Building Quality Culture
- Use of existing Systems
- Benefits from using KPI Implementation in a pharmaceutical company
- Regulatory expectations
- Case Study

Dr Andreas König, Quality König GmbH

Session IV Statistical/reduced Sampling

Moderator: Lance Smallshaw

Recent developments in GMP have focussed on statistics which involves taking large samples to assist with understanding of the processes. On the other hand Pharma industry is keen to reduce the number of samples due to costs. An EU inspector will give an overview on (statistical) GMP sampling requirements where an Industry representative will provide practical solutions for reduced sampling.

Sampling – View of an EU GMP Inspector

- API and finished goods sampling und testing
- EU GMP Guide sampling requirements
  - Part 1, Chapters 4, 5, 6
  - Part 2, Chapter 7
  - Annexes
- Other regulations
  - US / FDA Requirements
- Supplier qualification and audits
  - Reduced testing
  - Statistical sampling
- Findings

Dr Matthias Heuermann, GMP inspectorate

Sampling strategies for raw materials and packaging materials in pharmaceutical

- Sampling plans
- How to define sample size for
  - APIs
  - Excipients
  - Primary Packaging Material
  - Secondary Packaging Material
- When can sampling be reduced?
- How to deal with deviations?

Oliver Küttner, Shire

Session V Interest Group Meetings – Be involved in the next steps

Moderators:
Dr Afshin Hosseiny/ Johanna Linnolahti
Gert Mølgaard/Klaus Eichmüller
Dr Christopher Burgess/ Dr Matthias Heuermann

Get involved in the ECA Working Groups. Each delegate will be invited to discuss the upcoming developments with the Chair/Co-Chairs of the working groups.

Agenda

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

Parallel-Sessions:

Working Group GDP	**Working Group Validation**	~~**Working Group Quality Control**~~ (fully booked)

Parallel-Sessions

Good Distribution Practice – Implementation Challenges

Moderator: Dr Afshin Hosseiny, / Johanna Linnolahti

This interactive session will offer opportunity for the participants to discuss some of the key challenges they face for implementation of the EU GDP requirements, for example:

- What is expected for product segregation in a warehouse – is electronic segregation sufficient? If so what are the expectations?
- What level of computer validation is appropriate for the wholesalers?
- How to qualify distribution of the medicines, whilst demonstrating compliance?
- Is maintaining product label claim conditions during transportation necessary? What evidence is expected from the regulators to demonstrate compliance?
- What level of training and education required for the RPs, if an RP is not a pharmacists, does he/she need to have additional training? Why?

Next generation Qualification and Validation – Implementation of the new EU GMP Annex 15

Moderators: Gert Mølgaard, Klaus Eichmüller

This interactive session will offer opportunity for the participants to discuss some of the key challenges and opportunities for implementation of the new EU GMP Annex 15, for example:

- What is expected for qualification documentation from FAT, SAT, IQ, OQ, PQ etc.?
- What documentation can involve equipment suppliers, engineering services etc. in the future?
- How do you link the qualification documentation with the Process Validation?
- How do you establish a solid program for Ongoing Process Verification?
- What is the impact for the future of Product Quality Review

Are you in control? Trend analysis as part of the Quality Management System

Moderators: Dr Matthias Heuermann, Dr Christopher Burgess

This interactive session will offer participants to discuss some of the key compliance challenges from both a regulatory and technical perspective in a workshop following two presentations by a GMP inspector and the chairman of the ECA Analytical Quality Control Interest Group.

- Presentation; The importance of trend analysis in a QMS and what a regulatory inspector looks for
  Dr Matthias Heuermann LZG.NRW, Germany
- Presentation; Practical approaches to and tools for trend analysis; an overview of the new ECA AQCWG OOT &OOE guideline [Copy provided]
  Dr Christopher Burgess Chairman ECA AQCIG
- This facilitated ‚How much do we need to do' workshop session will allow participants to share and discuss their approaches and issues with Product Quality Reviews particularly with regard to what to trend and how to trend it

Social Event

On 31 May, participants and speakers 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.

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 Congress 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.

Please keep in mind that the **conference materials will not be available as print outs** in a folder and there will be no on site opportunity to get presentations printed.

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Speakers and Moderators

Richard Bonner
Qualified Person, Chairman ECA, UK
Dick has been working with Eli Lilly and Company, UK, for many years and is currently Chairman ECA and Member of ECA's Executive Board.

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

Klaus Eichmüller
Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany
Since 1996 he is working in the afield of GMP Inspections of manufacturer of medicinal products and importers. He is Head of the Inspectorate for Drug Products, APIs, Blood Products and Tissues in Hesse.

Dr Matthias Heuermann
NRW Centre for Health (LZG.NRW), Münster, Germany
Since 1995 Dr Heuermann is involved in national and international GMP inspections with a focus on QC laboratories and QA systems. He is head of the Official Medicines Control Laboratory (OMCL) within the NRW Centre for Health of the federal state North Rhine-Westphalia.

Dr Afshin Hosseiny
Qualified Person, Chairman ECA GDP Interest Group, UK
Afshin looks back to many years with Glaxo Smith Kline in the UK and is Chairman of ECA's GDP Interest Group.

Dr Andreas König
Quality König GmbH, Germany
Andreas König is owner of Quality König GmbH and has practical experiences as Senior Vice President Corporate Quality & HSE at Director Manufacturing & Quality at Aenova Holding GmbH, Vice President Global Quality Operations Animal Health at Schering Plough, Global Quality Director at Intervet and Head of QC and QA at Fresenius Kabi.

Oliver Küttner
Shire, Vienna, Austria
During the past years, he's been working for Baxter and Baxalta in local and global Quality Management positions. Currently he is in charge of the Material Life Cycle Management for raw-, starting- and packaging materials in EU and Asia at Shire.

Johanna Linnolahti
Finnish Medicines Agency FIMEA, Finland
Johanna Linnolahti is a Senior Pharmaceutical Inspector at Fimea specialised in GDP. She is also Member of the ECA Authority Advisory Board which supports the GDP Group.

Gert Moelgaard
Chairman ECA´s Working Group on Validation, Denmark
Gert Moelgaard has more than 25 years experience in the pharmaceutical and biotech industry, including several years of experience in process control, automation, computer systems validation and process validation as well as process engineering and consulting. Gert is Chairman of the ECA´s Working Group on Validation and member of ECA´s Extended Board.

Tracy Moore
Medicines and Healthcare Products Regulatory Agency, UK
Tracy is a GMDP Operations manager and Senior Inspector at the MHRA, joining in 2011 after 23 years in Industry. Tracy manages a team of GMDP inspectors and is part of the Agency's Data Integrity strategy and guidance drafting group.

Amelia Mutere
F. Hoffmann-La Roche, Basel Switzerland
Ms Mutere is head of Global Quality Inspection Management. She is responsible for Health Authority Inspections in the Roche Sites and CMOs. She also leads the Data Integrity Assurance Initiative Project at Pharma Technical.

Dr Bernd Renger
Qualified Person, Immediate Past Chairman of the 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 Franz Schönfeld
Regional GMP Inspectorate, Germany
Since 2007 he works for the centralised inspectorate for medicinal products of the government of upper Bavaria. He is head of the experts working group 7 for API's and deputy head of the Radiopharmaceutical expert working group at ZLG.

Dr Wolfgang Schumacher
Chairman ECA´s 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 ECA´s IT Compliance Group, member of ECA´s Extended Board and member of ECA´s Task Force on Data Integrity.

Lance Smallshaw
UCB Biopharma sprl, Belgium
Lance Smallshaw is Global Director of Analytical Strategy for NBEs at UCB in Belgium and Member of ECA's Executive Board.

Alex Viehmann
FDA, USA
Alex Viehman is currently Chief (acting) – Quality Intelligence Branch at FDA/CDER/OPQ/OS

Special offer with Lufthansa – discounted travel for 7th European GMP Conference attendees

Lufthansa Mobility Partner

As an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions. This is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. This link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.
We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – otherwise the booking platform window will not open.

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-conference.org

7th European GMP Conference

Date
Wednesday, 31 May 2017, 9.00 – appr. 17.15 h
(Registration and coffee 8.30 – 9.00 h)
Thursday, 01 June 2017, 9.00 – appr. 13.00 h

Venue
Corinthia Hotel Prague
Kongresova 1
14069 Prague 4, Czech Republic
Phone +420 (0)420 261 191 111
Fax +420 (0)420 261 225 011

Fees
ECA/EQPA 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 when you have registered for the event. Reservation should be made directly with the hotel. Early reservation is recommended.

Conference Language
The official conference language will be English.

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.

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
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For questions regarding content:
Mr Sven Pommeranz (Operations Director) at +49-62 21 / 84 44 47, or per e-mail at pommeranz@concept-heidelberg.de.
Mr Oliver Schmidt (Operations Director) at +49-62 21 / 84 44 23, or per e-mail at schmidt@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.

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Germany

Reservation Form (Please complete in full) +49 6221 84 44 34

◊ **7th European GMP Conference – Industry meets inspectorates**
31 May - 01 June 2017, Prague, Czech Republic

◊ I want to take part in the Social Event on 31 May:

☐ Yes ☐ No

I want to take part in the following **Working Group Session** (please tick only one)

◊ GDP
(The Validation and Quality Control Sessions are fully booked)

☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **Purchase Order Number, 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 HEIDELBERGwill 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).

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.

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