

# ECA Data Integrity Workshop to comment PIC/S PI 041-1 "Good Practices for Data Management and Data Integrity in regulated GMP/GDP Environments" draft 3

Berlin, Germany, 19-20 February 2019

## Rapporteurs/Speakers



FRANK BEHNISCH  
*CSL Behring GmbH, Germany*



DR MARKUS DATHE  
*F. Hoffmann-La Roche AG,  
Switzerland*



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DR. BOB MCDOWALL  
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EBERHARD KWIATKOWSKI  
*PharmAdvantageIT, Germany*



KARL-HEINZ MENGES  
*Regional Authority Germany*



MARGARITA SABATER  
*Dako Denmark A/S, an Agilent  
Technologies Company*



YVES SAMSON  
*Kereon AG, Switzerland*



DR WOLFGANG SCHUMACHER  
*formerly F. Hoffmann-La Roche Ltd.,  
Switzerland*



DR. ROBERT STEPHENSON  
*Rob Stephenson Consultancy, UK*



## HIGHLIGHTS:

- You may comment PI 041-1 in different round-table sessions
- Your comments will be consolidated by rapporteurs and sent to PIC/S
- PIC/S will take your comments to finalise the document PI 041-1

# ECA Data Integrity Workshop to comment PIC/S PI 041-1 "Good Practices for Data Management and Data Integrity in regulated GMP/GDP Environments" draft 3

19-20 February 2019, Berlin, Germany

## Objectives & Background

Pharmaceutical inspectors from more than 50 countries have joined the Pharmaceutical Inspection Co-operation Scheme (PIC/S) now. One of the main objectives of PIC/S is developing harmonised GMP/GDP guidelines. The PIC/S provides guidelines – PI-xxx- for its inspectors which are aimed to support them in the course of inspections. These documents are publicly available and contain questions that could be asked during authority inspections.

The PIC/S is currently working on the revision of elaboration of draft guidance PI 041-1 "Good Practices for Data Management and Data Integrity in regulated GMP/GDP Environments". The second draft of the document was originally published on 10 August 2016 and released for discussion. The extensive internal comments have been consolidated by the PIC/S and resulted in a revised third draft. This third draft was published on 30 November 2018. ECA has been invited to comment this new draft.

## Target Audience

This workshop is designed for managers and staff from health care industries as well for auditors who are responsible for Data Integrity in their companies. Participants are invited to give their comments to draft 3 of the PIC/S document PI 041-1.

## Prerequisite

All attendees should read PIC/S 041 before joining the workshop. The document can be downloaded from the PIC/S webpage [www.picscheme.org](http://www.picscheme.org):

(<https://www.picscheme.org/layout/document.php?id=1567>)

## Rapporteurs

Each round table will have two rapporteurs who will be responsible for collecting the review comments during each round table discussion. At the end of a session, all comments from all round tables will be collected by two rapporteurs who will merge and collate all the review comments into a single report.

## Moderators

Bob McDowall / Yves Samson

## Social Event



On 19 February 2019, 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.

## Rapporteurs / Speakers



**Frank Behnisch,**  
**CSL Behring GmbH, Germany**

Frank is Senior Manager Project Engineering at CSL Behring GmbH in Marburg, Germany



**Dr Markus Dathe,**  
**F. Hoffmann-La Roche AG, Switzerland**

GMP Coordinator in the Small Molecules Technical Development of Roche since 2011.



**Dalia Elwakil, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany**

Head of Quality Assurance Validation Qualification / MSO (Management System Owner) Data Integrity Production Germany.



**Svend Martin Fransen,**  
**Biogen Manufacturing ApS, Denmark**

Svend is Business Analysis Manager for PO&T IT at Biogen in Denmark. Currently involved in Biogen Data Integrity projects.



**Eberhard Kwiatkowski,**  
**PharmAdvantageIT, Germany**

Member of the GAMP D-A-CH Forum



**Dr. Bob McDowall,**  
**R.D.McDowall Limited, Bromley, UK**

He is a core member of the GAMP Data Integrity SIG and member of the ECA DI IT interest group.



**Karl-Heinz Menges,**  
**Regional Authority Germany**

Head of the German Inspectors Working Group and the German delegate of the PIC/S Expert Circle for computerised systems.



**Margarita Sabater,**  
**Dako Denmark A/S, an Agilent Technologies Company**

Member of the ECA QC Group.



**Yves Samson,**  
**Kereon AG, Switzerland**

Yves is founder of Kereon AG, Basel. He is member of GAMP Europe Steering Committees and member of the ECA DI IT interest group.



**Dr Wolfgang Schumacher,**  
**formerly F. Hoffmann-La Roche Ltd., Switzerland**

Wolfgang is chairman of the ECA DI IT interest group and member of the ECA Advisory Board.



**Dr. Robert Stephenson,**  
**Rob Stephenson Consultancy, UK**

Long-standing member of the GAMP Europe Steering Committee.

## Programme

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### The PIC/S document PI 041-1 draft 3 from a regulator's point of view

#### Karl-Heinz Menges

- Why does PIC/S create a document on Data integrity?
- Relevance of the document for inspectors and industry
- Structure of the document

### The PIC/S document PI 041-1 draft 3 from an industry's point of view

#### Bob McDowall

- Comparison of PI-041 and other data integrity guidance from regulatory authorities
- Harmonisation and inconsistencies of approach
- Is anything missing from the PIC/S guidance?



In different round table sessions attendees will have the opportunity to comment the PIC/S PI 041-1.

All attendees will comment on the complete document.

#### Round Table session 1:

Chapter 5: Data governance system

Chapter 6: Organisational influences on successful data integrity management

Chapter 7: General data integrity principles and enablers

#### Round Table session 2:

Chapter 8: Specific data integrity considerations for paper-based systems

#### Round Table session 3:

Chapter 9 Part 1: Specific data integrity considerations for computerised systems (subchapter 9.1 to 9.3)

#### Round Table session 4:

Chapter 9 Part 2: Specific data integrity considerations for computerised systems (subchapter 9.4 to 9.8)

#### Round Table session 5:


Chapter 10: Data integrity considerations for outsourced activities

Chapter 11: Regulatory actions in response to data integrity findings


Chapter 12: Remediation of data integrity issues

Additional comments to Role of suppliers

## 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, 19 February 2019, 09.00 h – 18.00 h  
(Registration and coffee 08.30 h - 09.00 h)  
Wednesday, 20 February 2019, 08.30 h - 17.00 h

### Venue

Steigenberger Hotel Berlin  
Los-Angeles-Platz 1  
10789 Berlin, Germany  
Phone +49(0)30 2127 0  
berlin@steigenberger.de

### Fees (per delegate plus VAT)

ECA Members EUR 790  
APIC Members EUR 840  
Non-ECA Members EUR 890  
EU GMP Inspectorates EUR 445

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.validation-analytical.com](http://www.validation-analytical.com).

### Conference language

The official conference language will be English.

### Organisation and Contact


ECA has entrusted Concept Heidelberg with the organisation of this event

CONCEPT HEIDELBERG  
P.O. Box 10 17 64  
D-69007 Heidelberg, Germany  
Phone +49 (0) 62 21/84 44-0  
Fax +49 (0) 62 21/84 44 34  
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For questions regarding content please contact:  
Dr Andreas Mangel (Operations Director)  
at +49-62 21/84 44 41, or per e-mail at [mangel@concept-heidelberg.de](mailto:mangel@concept-heidelberg.de).

For questions regarding reservation, hotel, organisation etc. please contact:  
Ms Marion Grimm (Organisation Manager)  
at +49-62 21/84 44 18,  
or per e-mail at [grimm@concept-heidelberg.de](mailto:grimm@concept-heidelberg.de).



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Reservation Form (Please complete in full)

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Mr  Ms

Title, first name, surname

Company

Department

**Important: Please indicate your company's VAT ID Number**

**Purchase Order Number, if applicable**

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

Street / P.O. Box

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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.
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 %

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.

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