SPEAKERS

DANIEL O. BLACKWOOD
Pfizer

JAMES DRINKWATER
Chairman of PHSS

DR FRIEDRICH HAEFELE
Boehringer Ingelheim Pharma

ROB HANRATHS
Grünenhhal

DR PHILIP HÖRSCH
Vetter Pharma-Fertigung

DR BOB MCDOWALL
Board Member of the ECA IT Compliance Interest Group

GERT MOELGAARD
Chair ECA Validation Interest Group

DR DANIEL MÜLLER
GMP-Inspektor, Regierungspräsidium Tübingen

YVES SAMSON
Kereon AG; Board Member of ECA IT Compliance Interest Group

DR WOLFGANG SCHUMACHER
former E. Hoffmann-La Roche; Chairman ECA IT Compliance Interest Group

ALEXANDRA STÄRK
Novartis Pharma

DR ARNO TERHECHTE
Bezirksregierung Münster, Germany

JÖRG ZIMMERMANN
Vetter Pharma-Fertigung

HIGHLIGHTS:

- Manufacturing Data Integrity
  - Manufacturing Data Integrity from the inspector’s point of view
  - Integrity of manufacturing data
  - Handling of data integrity requirements for legacy systems and new acquisition as well as consideration within corporate’s policy
  - What can (Software) Suppliers do to help regulated customers ensure Data Integrity?
  - How to solve Data Integrity problems in manufacturing

- Revision of EU Annex 1
  - New Technologies – an inspector’s point of view
  - Current Status of Annex 1 – an Update
  - Pharma Industry / PHSS members perspective on the revision of EU GMP Annex
  - Discussion / Workshop: The needs for an Annex 1 revision
  - Live Demos: Bausch + Ströbel / Metall + Plastic / Franz Ziel / MK Versuchsanlagen
Objectives

Reasons to attend this conference:
- Understand the current regulatory requirements from FDA, EU, WHO and PIC/S on data integrity
- Learn what is required for a data governance systems from senior management to staff in manufacturing
- Understand the data life cycle in manufacturing and how it is linked to business processes

Background

At the moment Data Integrity is one of the hottest topics in the regulatory world. Besides patient safety and quality the integrity of data is another important criterion for drug quality. A lot of findings by inspectors on data integrity issues during the last years make the regulators aware of the importance of a GMP compliant Data Life cycle.

Target Audience

Managers and staff from Manufacturing and QA from pharmaceutical companies and suppliers who need to understand the current regulatory requirements on Data Integrity.

Moderator

DR WOLFGANG SCHUMACHER, formerly F. Hoffmann-La Roche; Chair ECA IT Compliance Interest Group

Programme

The future of Pharmaceutical manufacturing: Flexibility and sustainability through small footprint, modular equipment trains
- Current and emerging technologies in primary and secondary manufacturing (focus on non-biologic / small molecules)
- Continuous and semi-continuous (hybrid) operations
- Enhancing process robustness, higher quality and lower cost potential especially at the development/clinical manufacturing/commercial manufacturing interfaces

MANUFACTURING DATA INTEGRITY from the inspector’s point of view
- Regulatory Update
- Paper Based Systems in Manufacturing
- Manufacturing Instruction / - Record
- Packaging Instruction / - Record
- Computerized Systems in Manufacturing
- SPS / Process Control Systems / MES
- Data Flow in Production / Hybrid Systems
- Remote Access to Production Equipment
- Data Integrity during Inspection / Inspection Findings

DR ARNO TERHECHTE, Bezirksregierung Münster

What can (Software) Suppliers do to help regulated customers ensure Data Integrity?
- Technical and procedural controls for software in regulated environments
- Focus on technical controls for software to ensure data integrity
- Database vs. operating systems directories
- Networked vs. standalone system
- Security and access control
- Audit trails and their reviews

BOB MCDOWALL, R.D. McDowall

Handling of data integrity requirements for legacy systems and new acquisition as well as consideration within corporate’s policy
- Which requirements on data integrity topics are new and how should they be considered in corporate’s policy and written procedures (SOPs)
- How to deal with legacy systems: execution of system analyses, identification of gaps, initiation of measures
- Implementation of additional requirements for the acquisition of new computerized systems
- Adaption of training concept
- Experience from audits and inspections

DR PHILIP HÖRSCHE, Vetter Pharma-Fertigung

Integrity of manufacturing data
- Reality of the manufacturing field
- An approach to secure manufacturing data
- Taking advantage of a systematic approach

YVES SAMSON, Kereon

How to solve Data Integrity problems in manufacturing
- Training program
- Computerised equipment compliance
- Audit trail review approach
- Audit concept

DR WOLFGANG SCHUMACHER, formerly F. Hoffmann-La Roche; Chair ECA IT Compliance Interest Group

Data Integrity “Mind the GAP”
- Building a Data Integrity culture in Manufacturing
- Knowing your Manufacturing processes “MES example”
- Performing a GAP analysis “where is the meat?”
- BPM “Business Process Modell and Notation”
- Understanding current regulatory requirements
- Electronic Records, what’s in it

ROB HAHNRATHS, Grünenthal
This is why you may want to attend this conference:
- You get to know the current status of the revision of EU GMP Annex 1
- Inspectors and pharmaceutical operators discuss the consequences of the changes for the operational processes

Since the establishment of the EU-GMP Guide, the specific requirements for sterile medicinal products have been specified in Annex 1. After various smaller revisions, the pending revision will be quite comprehensive. In early 2015, the EMA (European Medicines Agency) issued a “Concept Paper on the revision of Annex 1 of EU-GMP Manufacture of sterile medicinal products EMA/INS/GMP/735037/2014” in which the authority asked the industry to provide proposals for changes and additions. Currently, an inspectors working group prepares a first draft for public discussion.

The conference is directed to senior management from the pharmaceutical industry and suppliers who have to deal with the new EU-GMP-Annex 1 revision.

JÖRG ZIMMERMANN, Vertter Pharma-Fertigung

Programme

Trends in the pharma market and sterile dosage forms
- Megatrends influencing the pharma market
- Market shares and developments in sterile dosage forms
- Strategies to support patient compliance and convenience
- PENS, Autoinjectors, Safety Devices
- Subcutaneous delivery: patch pumps etc.
- Polymer Syringes
- Needle-less systems
- Conclusions

JÖRG ZIMMERMANN, Vice President Development Services, Vetter Pharma-Fertigung

New Technologies – an inspector’s point of view
- Existing guidelines on sterile manufacture / aseptic processing
- Current guidelines vs. new developments / trends
- Updating Annex 1: challenges & options

DR DANIEL MÜLLER, Local Government Tübingen

Live Demos

In the practical part of the conference, suppliers will show you different components and solutions. You will come in contact with the equipment and you have the chance to discuss your questions immediately with technology experts.

W-LAN Glove Testing System
- Fast and easy integrity testing of gloves
- Secure with RFID-Technology (Radio Frequency Identification)
- Fully automated measurements with low documentation effort
- Flexible (stand-alone) or complete integrated solution for isolator or MTC

The permanent use, recurrent cleaning processes, e.g., with H2O2, and further work steps in pharmaceutical plants especially isolators, make enormous demands on the stability of the gloves. This produces a huge risk potential for possible leaks. Therefore, it is important to check the tightness of the gloves regularly. METALL + PLASTIC GmbH offers glove testing systems with associated documentation to measure easy, wireless, and efficient.

METALL + PLASTIC GmbH (Member of OPTIMA)

Simulation of the air flow conditions below laminar flow units by means of air flow calculation and visualization (CFD) already during the product engineering process

The presentation is about the main benefits of air flow calculations already during the product engineering process at the virtual model. It includes the theoretical connections of the basic principles and some already realized use cases and the optimizations which have already been implemented into B+S solutions are shown. In addition, the results of the air flow calculations can be shown live at the virtual model within the presentation. Furthermore, the opportunities within the Virtual Reality (VR) system are explained.

In the end, the opportunities and hazards of those air flow calculations are examined.

Bausch + Ströbel Maschinenfabrik Ilshofen GmbH + Co. KG
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<tr>
<th>Barrier Glove Management Life cycle</th>
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<tbody>
<tr>
<td>On any Barrier technology system (Isolators or RABS) Barrier gloves are the weakest link and although there has been some attention to Glove leak testing it has now become necessary to develop a Glove management strategy based on a Life cycle approach including, replacement before degrade, in-process integrity testing, response to detected leaks after production operations. This live demo will work through the elements of the Life cycle to present Glove management in operation during a simulated production operation.</td>
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<td>Franz Ziel</td>
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<tr>
<th>Glove Tester Next Generation – GITS 4</th>
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<tbody>
<tr>
<td>■ New glove tester</td>
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<td>■ New software / hardware</td>
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<td>■ New interfaces</td>
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<td>■ New features</td>
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<td>MK Versuchsanlagen</td>
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<th>Current Status of Annex 1 – an Update</th>
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<tr>
<td>■ Update with regards to the draft recently discussed at 84. GMDP Inspectors WG</td>
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<td>■ Application of pre-use integrity testing</td>
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<td>■ Container Closure Integrity Test</td>
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<td>■ Current Timeline</td>
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<td>DR ARNO TERHECHTE, Bezirksregierung Münster</td>
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<th>Pharma Industry / PHSS members perspective on the revision of EU GMP Annex</th>
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<tr>
<td>■ Overview of key considerations in Annex 1 revision and impact on the Pharma industry.</td>
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<td>■ GMP compliance for new biological product types, new technologies and new methods of aseptic processing.</td>
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<td>■ The challenge of aligning risked based initiatives including QRM with real applications.</td>
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<td>■ A few detail points to consider: EM Process monitoring, Trend Metrics, Training/Knowledge exchange.</td>
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<td>JAMES DRINKWATER, Chairman of PHSS</td>
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<th>Discussion / Workshop: The needs for an Annex 1 revision</th>
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<tr>
<td>■ Clean rooms</td>
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<td>■ Barrier Technologies</td>
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<td>■ Environmental monitoring</td>
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<td>■ Process simulation</td>
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<td>■ Filtration</td>
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<td>■ Single Use Equipment</td>
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<tr>
<td>■ Lyophilisation</td>
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<tr>
<td>■ Aseptic process Filling of pre-sterilised containers</td>
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<tr>
<td>■ Assurance of product sterility in aseptic processing via verification the process environment is under control. Process verification, Environmental conditions verification and associated batch record reporting together with trending/periodic reviews.</td>
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<tr>
<td>■ Compatibility of Hydrogen peroxide vapour and biological products and how to manage surface sterility of Stopper Feeder bowls/pathways</td>
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<td>DR FRIEDRICH HAEFELE, Boehringer Ingelheim Pharma</td>
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<td>JÖRG ZIMMERMANN, Vetter Pharma-Fertigung</td>
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<td>GERT MOELGAARD, Moelgaard Consulting</td>
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SOCIAL EVENT

The Social Event at the Pharma Congress is already a tradition, and is networking and relaxation at the same time.

On the evening of the first congress day, on 28 March 2017, all congress delegates and speakers are invited to a „Get together” in the Congress Center. Take advantage of this opportunity for an information exchange and enjoy the laid-back atmosphere and the entertainment programme.

SPEAKERS

DANIEL O. BLACKWOOD, Pfizer Inc.
Technical Program Lead, PCM&M Development and Manufacturing Initiative for OSD, Pfizer.

JAMES DRINKWATER, Chairman of PHSS, UK
Head of Aseptic processing technologies and GMP Compliance at F. Ziel, Germany. In addition James has a voluntary role as Chairman of PHSS – Pharmaceutical and Healthcare sciences society and leader of the PHSS Bio-contamination and RABS special interest groups plus a member of the UK mirror group re-writing the standard ISO 14698 on bio-contamination (surfaces and airborne).

DR FRIEDRICH HAEFELE, Boehringer Ingelheim Pharma GmbH & C. KG
Dr Haefele has been in the pharmaceutical industry for almost 20 years now. In May 2006 Dr Haefele joined Boehringer-Ingelheim Pharma where he is responsible for the department Biopharma Fill & Finish Germany.

ROB HAHNRATHS, Grünenthal GmbH, Aachen
Rob studied electronics and IT in the Netherlands and moved to Germany in the year 2000. He has more than 16 years of experience in the area of computerized system validation in the pharmaceutical industry. Since 2013 he is Global Computerized Systems Validation QA at Grünenthal. In 2005 he is joined the ISPE and currently he is a member of the GAMP Special Interest Group “Raw Data”.

DR PHILIP HÖRSCH, Vetter Pharma-Fertigung GmbH & Co. KG, Ravensburg

DR BOB MCDOWALL, R.D. McDowell Limited, Bromley, Kent, UK
Analytical chemist with over 40 years experience including 15 years working in the pharmaceutical industry and afterwards working for the industry as a consultant. Bob is an ISO 17025 assessor and he has been involved with the validation of computerised systems for over 25 years. He is a core member of the GAMP Data Integrity SIG and board member of the ECA IT Compliance Interest Group.

GERT MOELGAARD, Moelgaard Consulting, Lyngby, 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. He has previously worked in Novo Nordisk, Novo Nordisk Engineering and NNE Pharmaplan. Since 2015 he is Consultant. He is member of the ECA Validation interest group.

DR DANIEL MÜLLER, GMP Inspector, Local Government Tübingen
Currently Daniel Muller is head of GMP inspectorate (local competent authority) at Tübingen, Germany. Since 2001 he has been working as GMDP inspector, conducting national inspections as well as EMA- and overseas inspections. Before joining the authority Dr. Muller was working in pharmaceutical industry, last serving as qualified person for sterile drug products. He is member of german expert groups ‘biotechnology & tissue’ and ‘quality assurance’.

YVES SAMSON, Kereon AG, Basel, Switzerland
Yves is founder of Kereon AG, Basel. He is member of GAMP Europe Steering Committees, chairman and co-founder of GAMP Francophone and edited the French version of GAMP 4 and GAMP 5. He is board member of the ECA IT Compliance Interest Group.

DR WOLFGANG SCHUMACHER, formerly F. Hoffmann-La Roche Ltd., Switzerland
Dr Schumacher studied chemistry and pharmacy. After entering Asta Medica, he headed different positions. In 2001 he joined F. Hoffmann-La Roche, Basle, where he was Head of the department of Quality Computer Systems. He is a chairman of the ECA IT Compliance Interest Group.

ALEXANDRA STÄRK, Novartis Pharma AG, Basle, Switzerland
After studying Hygiene Technology at the Technical University of Allstadt-Signainingen, Alexandra Stärk has worked since 1995 at Novartis Pharma AG in Basel/Stein. She is currently responsible for the microbiological QA and QC. She plays a key role in rapid microbiology and in microbiology for sterile production

DR ARNO TERHECHTE, Bezirksregierung Münster, Germany
After 5 years in the pharmaceutical industry he was from 1998 – 2003 in the Bezirksregierung Düsseldorf. Since 2003 he is inspector in the Bezirksregierung Münster. Arno Terhechte is member of the German expert group II “computerised systems”.

JÖRG ZIMMERMANN, Vetter Pharma-Fertigung
Vice President Development Services.
Easy Registration

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

e-mail: info@concept-heidelberg.de
Internet: www.pharma-kongress.com

Date
Tuesday, 28 March 2017, 09.00 – 17.45 h
Wednesday, 29 March 2017, 08.30 – 17.00 h
(Registration: Monday, 27 March 2017, 19.00 – 20.30 h
Tuesday, 28 March 2017, 08.00 – 09.00 h
Wednesday, 29 March 2017, 07.30 – 08.30 h)

Venue
Swissôtel Düsseldorf / Neuss
Rheinallee 1
D-41460 Neuss, Germany
Tel.: +49 (0) 2131 77 - 00, Fax: +49 (0) 2131 77 - 1367
emailus.neu02@gchhotelgroup.com

Fee
EUR 690.- per delegate and day plus VAT (EUR 1.380.- for both days)
due to the special congress fees, ECA membership discounts are
not applicable, and participation does not entail ECA membership.
The conference fee is payable in advance after receipt of invoice
and includes lunch on that day/both days, beverages during the
event and during breaks as well as the Social Event on 28 March.
VAT is reclaimable.

Registration
Via the reservation form below, by e-mail or by fax message. Or you
register online at www.pharma-kongress.com

Regulatory Trends (28/29 March 2017)
Part of the Pharma Congress Production & Technology 2017
Düsseldorf/Neuss, Germany, 28/29 March 2017

I register for:
☐ Manufacturing Data Integrity (28 March 2017)
☐ Revision of EU Annex I (29 March 2017)
☐ Both days (28/29 March 2017 – 1.380.- €)

☐ Yes, I would also like to participate in the Social Event on 28 March
☐ Mr ☐ Ms

If the bill-to-address deviates from the specification
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after receipt of invoice.

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your message. In case you do not appear at the event without
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PLEASE NOTE: Please book your hotel room directly with
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the reservation form

For questions regarding reservation, hotel, organisation etc.: Dr.
Andreas Mangel (Operations Director) at +49-6221/84 44 41, or
per e-mail at mangel@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.: Mr.
Detlef Benesch (Organisation Manager) at +49-6221/84 44 45, or
per e-mail at benesch@concept-heidelberg.de.

Organisation & Contact
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www.concept-heidelberg.de

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the contact form on this website.