Highlight Speakers:

Dr. Martin Becker
Manager Technical Operations
hameln pharmaceuticals

Dr. Frank Boettger
Head of Process Development
Vetter Pharma-Fertigung

Gerald Bürkle
Vice President Production
Vetter Pharma-Fertigung

James Drinkwater
Chairmann of PHSS (Pharmaceutical and Healthcare Sciences and Society)

Dr Tiago Bruno Ferreira
Business Development Manager
GenIbet Biopharmaceuticals

Dr Friedrich Haefele
Vice President BP Fill & Finish Germany
Boehringer Ingelheim Pharma

Dr Jean-Denis Mallet
Former Head of the Pharmaceutical Inspection Dpt. AFSSAPS

Gert Moelgaard
Vice President Strategic Development
NNE Pharmaplan

Dr Daniel Müller,
GMP Inspektor
Regierungspräsidium Tübingen

Dr Marjo Peters
Director Manufacturing Science & Technology
Astra Zeneca Operations

Dr Tobias Posset
Head of Production Support
Roche Diagnostics

Dr Lars Sukowski
Head Lyophilization PKau & KAD Transfer Lead
F.Hoffmann-La Roche

Patrick Vanhecke
Senior Manager
GlaxoSmithKline Biologicals

... and many others

- **ECA – Control of Parenterals**
- **ECA – Aseptic Processing**
- **ECA – Barrier Systems**

2015 PHARMA CONGRESS

Production & Technology

DÜSSELDORF, 24 - 25 MARCH 2015

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The Pharma Congress Overview

Users report for users has been the Pharma Congress' guiding theme since years. And this idea also guided the Steering Committee in putting together the 2015 Congress and in choosing the appropriate presentations from the wealth of submitted proposals. The result is a programme with six conferences in three subject areas in which speakers talk about the challenges in their day-to-day business and about the solution approaches. Therefore, benefit from the experience of your colleagues as well as from the direct information exchange.

Pharma Congress – Overview

Congress Key Note

Key Note 24 March

Towards a renewed or a brand new Annex 1
Dr Jean-Denis Mallet, NNE Pharmaplan & ECA Foundation Advisory Board Member

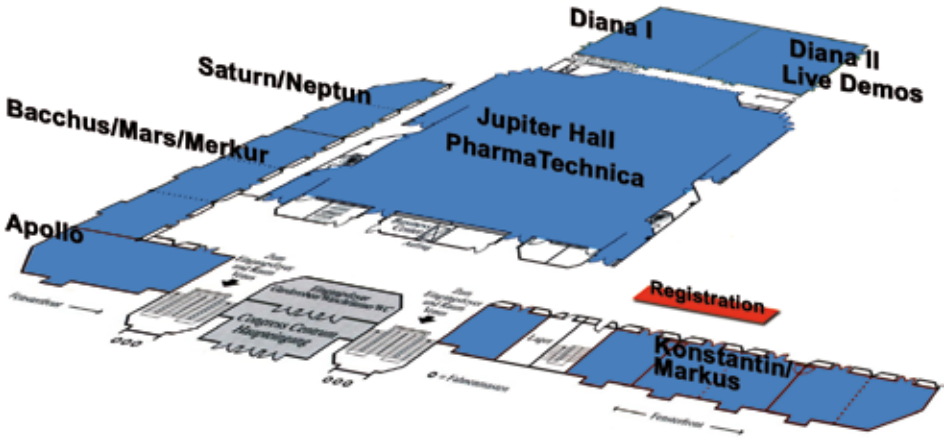
Key Note 25 March

The future of pharmaceutical production – Global developments in OSD manufacture
Dr Harald Stahl, GEA Pharma System

Conferences (One Day Ticket 690,- EUR)	24 March 9:00–17.45 h	25 March 8:30–16:45 h
ECA - Control of Parenterals		
Visual Inspection Systems	✓	
Container / Closure Integrity Testing		✓
ECA - Aseptic Processing		
Current Aseptic Technologies	✓	
Single-Use Disposables		✓
ECA - Barrier Systems		
Barrier Systems – Regulations/Technology/New Developments	✓	
Barrier Systems – Case Studies		✓
Fachmesse PharmaTechnica	✓	✓

The exact times for the single conferences as well as updates will be available on the Congress website at www.pharma-kongress.com at a later point in time.

The Room Plan



The Steering Committee

Dr Friedrich Haefele, Boehringer Ingelheim
Vice President BP Fill & Finish Germany

Roland Szymoniak, Sanofi
Manager Industrial Engineering & Transfer

Dr Rainer Schmidt, F.Hoffmann-La Roche
Site Manager Kaiseraugst

Dr Tobias Lücke, M+W Process Industrie
General Manager

Jörg Zimmermann, Vetter Pharma-Fertigung
Director Process Development and Implementation

Gert Moelgaard, NNE Pharmaplan
Vice President Strategy Development

Dr Johannes Krämer, CSL Behring
Manager Engineering

Frank Studt, Chemgineering Business Design
General Manager

Prof. Franz Maier
Former Manager Technology, Nycomed

Günter Körblein
Senior Consultant, Pharmaceutical Technology

The Exhibition

2015 PHARMA CONGRESS PharmaTechnica DÜSSELDORF, 24 - 25 MARCH 2015

Parallel to the conferences on 24 and 25 March there will be the large exhibition PharmaTechnica. Take advantage of this opportunity to get to know new technologies, products and services at the stands of the exhibitors. For that purpose there will be Live Demos integrated in some of the conferences again. These Live Demos will be conducted in the exhibition area. That way you will not only be introduced to technology in the conferences, but you will be able to touch and experience it. Get to know new concepts and technology – directly from leading companies. You will find the Live Demos in this programme under the respective conferences as well as on the Congress Website at www.pharma-kongress.com. There you will also find the daily updated exhibitor list – in addition to the list at the end of this programme.

The Fees

Charges for the one day tickets are € 690,- plus VAT (due to the special fees for the congress, ECA membership discounts are not applicable). These tickets allow you to attend any conference offered that day (you can also switch between the conferences any time). They include a lunch and beverages during the conferences and in breaks as well as the social event on the evening of the first congress day (one day ticket for the 24 March). Charges are payable after receipt of invoice. *(Please also see the information below)*

The Location

Swissôtel Congress Centrum Düsseldorf / Neuss
Rheinallee 1
41460 Neuss
Tel.: +49 (0) 2131 77 - 00
Fax: +49 (0) 2131 77 - 1367
Emailus@swissotel-duesseldorf.de

The 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 24 March 2015, 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.

Contacts

For questions regarding content:
ECA Conferences Visual Inspection Systems / Container/Closure Integrity Testing:
Dr Robert Eicher (Operations Director), Phone +49 (0)6221 84 44 12,
E-Mail: eicher@concept-heidelberg.de.

ECA Conferences Current Aseptic Technologies / Single-Use Disposables / Barrier Systems:
Dr Andreas Mangel (Operations Director), Phone +49 (0)6221 84 44 41,
E-Mail: mangel@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation, exhibition etc.:
Detlef Benesch (Organisaton Manager), Phone +49 (0)6221 84 44 45,
E-Mail: benesch@concept-heidelberg.de.

The Organiser

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ECA ACADEMY

PLEASE NOTE !

Exhibition Visit: The exhibition will also be open to visitors on both days who are not attending the Congress. Please be aware, though, that you will need to register in advance of the free of charge visit. The visitor registration will most likely be available on the website starting in December 2014. The visit of the exhibition does not entitle you to also attend any of the conferences.

Congress Materials: Please note that there will not be any print-outs at the Congress. Instead you will receive all presentations prior to the Congress as Downloads. All Congress delegates (excluding exhibition visitors) will also receive the presentations on a USB stick at the registration center.

Room Reservations: There will be no room reservations via Concept Heidelberg. Please book your hotel room directly with the reservation form which you will receive together with your confirmation/invoice! Charges are payable after receipt of the invoice.

The following exhibitors are already booked for the PharmaTechnica. For a daily updated exhibitor list please visit the Congress website at www. pharma-kongress.com.

Company	Stand
ABB Automation	18
Alfons Markert	23
Aseptic Technologies	61
Asys Group	45
Bausch & Ströbel	1
Belimed	34
Bilfinger Industrietechnik	14
Borer Chemie	22
Briem Steuerungstechnik	13
Chemgineering	67
Chemische Fabrik Dr. Weigert	73
COMECER GROUP	12
Concept	49
DEC Deutschland	19
Dockweiler	26
Ellab	17
ELPRO	60
Fette Compacting	5
Franz Ziel	41
Freudenberg Sealing Technologies – Process Seals	55
GEA Lyophil	16
GEMÜ	69
Gerflor	42
GETINGE	46
Glatt	4
Groninger	40
Hamo/Amsonic	77
Harro Höfliger	2
Harter	44
Heino Ilsemann	20
HENKEL Beiz- und Elektropolietechnik	66
Heuft Systemtechnik	33
Eurotherm by Schneider Electric	63
io-consultants	43
Jung Gummitechnik	10
Kinectis Germany	57
Lechleiter Filter- und Siebtechnik	54
Letzner	24
Levitronix	82
Lighthouse Instruments	50

Premium Sponsor

Company	Stand
Mankenberg	25
Marchesini	32
Mediseal	11
MERCK MILLIPORE	70
MK Versuchsanlagen	83
MMM Group	36
Müller Cleaning Solutions	76
multivac Sepp Haggenmüller	39
M+W Process Industries	31
NNE Pharmaplan	29
OPTIMA pharma	52
Pall	68
Particle Measuring Systems	9
pharmaserv	53
PMT Partikel-Messtechnik	30
rap.ID Particle Systems	58
Robert Bosch	38
Flecotec	27
Rota Verpackungstechnik	47
rotan	56
SCHOTT	15
SIEMENS	35
Skan	62
SPC Group	8
Steriline	28
STERISYS Industrial Sterilisation TechSpray	48
Stavanato Group	6
Telstar Life Sciences	37
Testo Industrial Services	79
Uhlmann	3
VITRONIC	65
Volkmann	59
VTU Holding	7
West	51
WILCO	21

Speakers from authorities, industry organisations and from industry (as of February 2015)

Patrizia Ascani	**Doctors without Borders** In the last 15 years she has been involved in the field as pharmacist in the framework of the of UN, International Red Cross) and MSF (doctors without borders).
Dr Martin Becker	**hameln pharmaceuticals GmbH** Head of Technical Operations and Head of Production Sterile Operations.
Dr Frank Boettger	**Vetter Pharma-Fertigung GmbH & Co. KG** Head of process development at Vetter Development Services.
Gerald Bürkle	**Vetter Pharma-Fertigung GmbH & Co. KG** Vice President Production.
Martin Dearden	**PaxVax Berna GmbH** Vice President of Quality.
James Drinkwater	**Chairman of PHSS, UK** Head of Aseptic processing technologies and GMP Compliance at F. Ziel, Germany. In addition Chairman of PHSS – Pharmaceutical and Healthcare sciences society and leader of the PHSS Bio-contamination and RABS special interest groups.
Dr Tiago Bruno Ferreira	**GenIbet Biopharmaceuticals, Oeiras, Portugal** Business Development Manager.
Dr Roland Guinet	**RGmp Compliance, Chevinay, France** From 2002-2011 GMP Inspector at AFSSaPS (French Authority). Since 2012 Consultant.
Dr Friedrich Haefele	**Boehringer Ingelheim Pharma GmbH & C. KG** Vice President Biopharma Fill & Finish Germany.
Markus Keller	**Fraunhofer IPA, Stuttgart Germany** Scientific assistant, responsible for material outgassing studies.
Alan Kelly	**Genzyme Ireland Ltd, Ireland** Mechanical engineer currently working in the Technical Development Department at Genzyme.
Saskia Killer	**Oncotec Pharma Produktions GmbH, Dessau, Germany** Since 2014 responsible person for aseptic syringe filling.
Terri Love	**Merck Millipore Ireland Ltd, Ireland** BioManufacturing Engineer, responsible for customer technical support at all scales for downstream processing.
Dr Jean-Denis Mallet	**NNE Pharmaplan & ECA Foundation Advisory Board Member** Former Head of the French Pharmaceutical Inspection Dpt. AFSSAPS.
Gert Moelgaard	**NNE Pharmaplan A/S, Denmark** Vice President for Strategic Development.
Sade Mokuolu	**Representative BPSA (Bio-Process Systems Alliance** European technical lead for Pall's Extractables and Leachables programs.
Dr Daniel Müller	**Regierungspräsidium Tübingen** GMP-Inspector with focus on biotechnological and sterile drug products.
Hansjörg Nortmeyer	**Sanofi-Aventis Deutschland GmbH, Frankfurt, Germany** Quality Manager supporting the parenteral unit within R&D in Frankfurt.
Dr Marjo Peters	**Medimmune / AstraZeneca Supply Biologics, Nijmegen, Netherlands** Previously responsible for running a small CMO business, working with customers for the manufacture of clinical Drug product (mainly biologicals).
Dr Tobias Posset	**Roche Diagnostics GmbH** Head of the Production Support Unit.
Dr Ingo Presser	**Boehringer Ingelheim Pharma GmbH & Co. KG** Responsible for the clinical trial supply and process transfer unit with the Process Science Department.
Dr Heino Prinz	**rommelag AG** Director Inspection Devices.
Lionel Quinton	**Aspen, Notre Dame de Bondeville, France** Aseptic processes technologies expert and project stromboli equipment lead.
Dr Bernd Renger	**Immediate Past Chair of the European QP Association** Member of the ECA Foundation Advisory Board and Immediate Past Chair, European QP Association. Since 2011 he is running his own consultancy business.
Mehtap Saydam	**Sanovel Pharmaceuticals, Istanbul, Turkey** R&D Specialist with focus on new combinations as parenteral and PAT, DoE and QbD.
Dr Martin Schwab	**Vetter Pharma-Fertigung GmbH & Co. KG** Project manager - customer project management department.
Dr Harald Stahl	**GEA Pharma Systems** Senior Pharmaceutical Technologist.
Dr Lars Sukowski	**F.Hoffmann-La Roche AG, Kaiseraugst, Switzerland** Head Lyophilization PKau & KAD Transfer Lead.
Patrick Vanhecke	**GlaxoSmithKline Biologicals SA, Belgium** In charge of Isolator and Aseptic Filling Technologies projects .
Dr Andrea Weiland-Waibel	**Explicat Pharma GmbH, Hohenbrunn, Germany** CMC / Technical project management.

Visual Inspection Systems

24 March 2015

Objectives

This event aims at giving an overview of optical inspection systems for the required 100% testing of parenterals. Apart from technical aspects, quality assurance topics as well as the practical operation of these systems are examined, and guidance on putting them into operation is provided.

Background

Medicinal products for parenteral application are subject to a large number of tests. An essential aspect is testing for particulate matter and primary packaging deficiencies. Here, the regulations require a 100% inspection. The question of how it is performed is left to the manufacturer's discretion. Next to manual and semi-automatic inspection, fully automatic systems become more and more important. With the help of suitable technologies, qualification and validation, they can ensure an optimum level of safety in an economical way. In this context it is crucial to set the right inspection parameters in order to run the system GMP-compliance AND economically that is to avoid a high level of rejects. But also during routine process there are new questions arising like the permission of re-testing and the usage of test-sets and setting AQL-Levels.

We will address those topics during the conference and discuss and answer questions like:

- The compendial requirements concerning particles
- QA aspects of visual inspection, statistics and AQL testing
- Selection of the appropriate inspection system
- The qualification, validation and operation of an automated inspection system

Moderator

Dr. Bernd Renger, *Immediate Past Chair of the European QP Association*

Target Audience

This conference is directed at specialists and executives from the areas engineering and production and QA dealing with the implementation and operation of visual inspection systems for in-process testing of sterile medicinal products.

Programme

Dr. Jean-Denis Mallet *NNE Pharmaplan & ECA Board Member* 09:00–10:00 h

Towards a renewed or a brand new Annex 1

Dr. Daniel Müller *GMP-Inspector, Germany* 10:30–11:15 h

Current GMP's for visual inspection of parenterals: a GMP inspector's view

- Regulatory framework: EU-GMP-Guide, European Pharmacopoeia
- Manual and semi-automated inspection: personnel, premises and equipment
- GMP requirements for qualification, validation and routine operation of automated systems
- Typical discussion topics: defect classes, warning limits, ejects & rejects handling
- Inspector's experience: recommendations, observations

Martin Dearden *PaxVax Berna* 11:15–12:00 h

From the product requirements to the appropriate inspection system: the URS as key to identify the right inspection system

- Compiling product requirements in an URS
- Comparison of products demands and machine properties
- Conduction of pre-evaluation tests
- Finding the right machine and machine supplier

Dr. Tobias Posset *Roche Diagnostics* 13:30–14:15 h

Qualification & validation of an automated inspection system

- Sample sets for qualification purposes
- Generation and Classification of defects and defect libraries
- Performance comparison with the manual inspection
- Definition and handling of ejects and rejects
- Re-qualification & re-validation

Dr. Tobias Posset *Roche Diagnostics* 14:15–15:00 h

Routine operation of an automated visual inspection system

- Usage of test kits before and after batch inspection (performance kits)
- Classification of defects / defect library
- Handling of ejects and rejects
- Re-inspection? When and how?
- Possibilities of reducing the false reject rate

Dr. Bernd Renger *Immediate Past Chair, European QP Association* 15:45–16:30 h

AQL testing of visual inspection

- 100% inspection versus AQL testing
- "Essentially free" and AQL limits
- Warning limits, Action limits and Is AQL testing mandatory?
- News from USP and chapter <790>

Patrizia Ascani *Doctors without Borders* 16:30–17:15 h

Visual Inspection from the Border of the World

- Medicines sans Frontieres' (MSF; Doctors without Borders) profile
- MSF's policy regarding parenteral: visual inspection and training for staff at end user level
- Constrains in the MSF's field: transport, storage, packaging
- Requirements in third world countries, inspired by BP, USP, EU plus WHO guidelines and the real world

Container / Closure Integrity Testing

25 March 2015

Objectives

Different products and different container types will require different testing methods: this event aims at giving an overview of the different container closure integrity (CCI) testing systems which are applied during production and as part of the quality control system. Apart from technical aspects the regulatory requirements on CCI testing will be highlighted.

Background

An intact container closure system, which is the sum of packaging components that protect the dosage form, is the pre-requisite for a safe and sterile drug product. The CC system protects the product from microbial contamination and also from exposure to gases or water vapor or the loss of solvent. Container Closure integrity testing is therefore a regulatory requirement and it is part of the whole life cycle of a sterile drug product.

Initially this testing was performed as part of the initial development of the packaging system and the system's suitability verified in stability studies including on-going stability. Over the years, the expectation was raised to perform batch by batch verification with latest trends to 100% inline or offline testing wherever possible.

We will discuss and answer questions like:

- What are the GMP- and compendial requirements?
- Will container closure integrity testing change to 100% inline testing?
- Which testing technologies are available and suitable?
- CCI testing of prefilled syringes, vials and ampoules

Moderator

Dr. Bernd Renger, *Immediate Past Chair of the European QP Association*

Target Audience

This conference is directed at specialists and executives from the areas engineering and production and QA dealing with the implementation and operation of systems for the container/closure-integrity testing of sterile medicinal products.

Programme

Congress Key Note

Dr Harald Stahl
GEA Pharma Systems
08:30–09:30 h

The future of pharmaceutical production – Global developments in OSD manufacture

Dr Bernd Renger
Immediate Past Chair, European QP Association
10:00–10:45 h

Container Closure Integrity testing of sterile drug products – requirements, expectations and exaggerations

- Container Closure Integrity during Development, Qualification and Stability Testing
- Regulatory, Pharmacopoeial and GMP requirements
- System integrity versus container damages
- Patient risks – do we need batch by batch testing? Industrial best practices

Heino Prinz
Rommelag
10:45–11:30 h

Oversight of container/closure integrity testing technologies

- Physical fundamentals of the different testing methods
- Selection matrix for products including primary container type, product properties (liquid, lyo, etc.)
- Inline versus sample testing
- Limits and false acceptance traps
- Leak sizes and leak rates (false friends and measurable properties?)

Dr Tobias Posset
Roche Diagnostics
13:00–13:45 h

Integrity testing of Prefilled Syringes

- Sampling plan
- He-leak testing
- Limitations of the He-leakage test
- Cross Validation with mCCI

Dr Martin Becker
hameln pharmaceuticals
13:45–14:30 h

100% inline CCI testing of ampoules

- High Voltage inline testing: method description
- Integration in the production process
- Limits of the system
- Qualification of the system
- Routine Operation

Dr Tobias Posset
Roche Diagnostics
15:00–15:45 h

100% Container Closure Integrity Testing of lyophilized Products in Vials

- Different CCI methods for lyo products - pros and cons
- Application of the laser-based (lyophilized DP) and conductive (liquid DP)test method
- Qualification Strategies for inline testing
- Experience from routine processing

Dr Ingo Presser
Boehringer Ingelheim Pharma
15:45–16:30 h

Inline Container Closure Integrity Testing of liquid Products in Vials

- Ensurance of container/closure tightness for defined stopper-vial combination
  - Oxygen detection with Frequency Modulated Spectroscopy (FMS)
  - Helium leakage test
- 100% control of stopper position of each vial
- Establishment of a Stopper-Position-Control Unit
- Stopper position correlation to vial tightness

Current Aseptic Technologies

24 March 2015

Objectives

Reasons to attend this conference:

- You will be informed on new regulatory and technological developments and case studies from pharmaceutical companies will show how current GMP and production requirements have to be implemented technologically in sterile manufacture.
- Live Demos will show you how technologies perform

Background

GMP regulations only define general requirements for equipment – it has to be suitable for the intended work process, easy to clean and without any negative influence on the product quality. Questions like how these general requirements have to be fulfilled concretely in sterile manufacture, which points call for special attention and which new technologies will be used in the future are in this conference's focus. Experienced speakers deal with pivotal developments in the field of sterile manufacture.

Moderator

Gert Moelgaard, *NNE Pharmaplan*

Target Audience

The event is directed at specialists from the pharmaceutical industry as well as at engineers and planners who have to deal with current aseptic technologies in clean areas in their daily practice. It particularly addresses the departments Production, QA and Engineering.

Programme

Congress Key Note

Dr. Jean-Denis Mallet Towards a renewed or a brand new Annex 1
NNE Pharmaplan &
ECA Board Member
09:00–10:00 h

Gert Moelgaard
NNE Pharmaplan
10:30–11:15 h

Aseptic Processing from orphan to blockbuster

- The challenge that most of today's "blockbusters" are injectables
- Cost-effective manufacturing of high value pharmaceutical products and specialty drugs
- Manufacturing flexibility today – and tomorrow
- Pharmaceutical equipment suppliers' flexibility challenge
- Combining flexibility and cost-efficient manufacturing
- Next step: the future of aseptic processing

Dr. Roland Guinet
RGmp Compliance
11:15–12:00 h

Technological modifications proposed by the CIG A3P for a new Annex 1

- Specific dispositions for barrier technologies and closed systems
- Microbiological qualification and detailed microbiological monitoring
- Requirement for implementation of rapid microbiological methods
- Maintenance of sterility verified at the point use for RTU components
- Introduction of new technologies for 100% controls: CGI, maintenance of vacuum, residual humidity
- Specific requirements for aseptic process simulations and interpretation
- Points to discard to better explain

Mehtap Saydam
Sanovel Pharmaceuticals
13:30–14:15 h

Case Study: Developing and Production of Sterile Dosage Forms According to QbD Approach

- Definitions of QbD terminology for Sterile Dosage Forms
- Risk Assessment on Sterile Dosage Forms
- Current Aseptic Technologies Sterile Filtration Validation according to QbD Design Space concept
- Control strategy and PAT Technologies on sterile parenteral dosage forms inspections
- Statistical Process Control of parenteral preparations according to QbD
- Comparison of Traditional and QbD Development Approach on Sterile parenteral dosage forms

Live Demos
14:15–15:00 h

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

- **Using laser-based headspace inspection to determine sterility**
  Lighthouse Instruments
- **Inspection of non-transparent products with x-ray technology in a pulsed operation mode**
  Heuft Systemtechnik
- **Schott adaptiQ™, Schott sterile vials – added customer value through forward integration**
  SCHOTT
- **OMPI EZ-FILL™ Vials: Flexible Fill&Finish of presterilized nested Objects based on a Standard Platform**
  Ompi

Dr. Andrea Weiland-Waibel
Explicat Pharma
15:45–16:30 h

Case Study: The Use of PAT tool TEMPRIS® in Aseptic and Sterilisation Processes: 2 Cases of Improved Production Scale Real-Time Testing

- Practical and technical aspects during instrumentation with TEMPRIS® as PAT tool
- Hot & Cold Spot (HCS) determination in lyophilisers and sterilizers
- Critical Process Parameter: Improvements from lab scale to production scale and improvements in process design all the way towards continuous process verification and for parametric/real time release
- Impacts on modern approaches in process validation: Assurance of sterility and stability of the drug product

Dr. Lars Sukowski
F.Hoffmann-La Roche
16:30–17:15 h

Case study: Antibody Drug Conjugate (ADC) Manufacturing at PKau – A cytotoxic product in a shared facility

- Brief introduction to antibody drug conjugates
- Regulatory directives & Guidelines
- Building setup and process flow
- People safety measures

Single-Use Disposables

25 March 2015

Objectives

Reasons to visit this conference:

- You will get an overview on the current state of single use technologies and a prospect on new developments
- You will get first hand information on how to design and implement a robust and efficient single use technology
- You will get case studies from pharmaceutical companies about the use of single use technology in development and production
- You will benefit from Live Demos on how to use single use technology.

Background

The use of single use technology increases in many biotechnological processes as well as in sterile filling processes. There are different reasons for this development, i.e. avoiding cleaning and cleaning validation, reducing time to market by omitted construction activities and simplified scale-up procedures. On the other side – especially in comparison to stainless steel – new questions arise like "How to qualify and validate the technology?", "What is the relevance of extractables and leachables?" or "What are the consequences for approval activities?". These questions will be discussed by experts from pharmaceutical companies and leading suppliers.

Moderator

Dr Frank Boettger, *Vetter Pharma-Fertigung*

Target Audience

The event is directed at decision-makers from pharmaceutical industry and suppliers from production, research & development, quality assurance/control, engineering who need to be well informed about current developments in the field of Single use technology.

Programme

Dr Harald Stahl
GEA Pharma Systems
08:30–09:30 h

The future of pharmaceutical production – Global developments in OSD manufacture

Dr Marjo Peters
Medimmune / AstraZeneca Supply Biologics
10:00–10:45 h

Case Study: Single-Use Disposables in a Multi-Product Facility

- Pro's and con's of single-use disposables – the Medimmune perspective
- Maintaining flexibility / Impact on Tech transfer
- Quality and importance of supplier relationship
- Qualification and routine use

Sade Mokuolu
Representative BPSA (Bio-Process Systems Alliance)
10:45–11:30 h

An Approach to the Qualification of Single-use components for Biopharmaceutical Manufacturing

- Utilization of polymeric materials in biopharmaceutical manufacturing
- Concerns about the nature of extractables and how to demonstrate safety of their biopharmaceutical products
- A manageable and cost-effective approach to meeting regulatory requirements for extractables safety
- Explain how supplier data can be used in a risk assignment exercise to provide information on the impact of the single-use process equipment component on the final drug product
- Latest trends and changes to USP & ICH guidance

Terri Love
Merck Millipore Ireland
13:00–13:45 h

Case Study: The Retrofit of an Existing Filling Line to Accommodate Single Use Filling Assemblies

- Accommodation of single use filling assemblies on an existing filling line
- Critical considerations for successful completion of the project
  - Timing (timelines and key milestones will be reviewed)
  - Design of SU assembly to ensure operation on existing filling line
  - Operation of filtration assembly

Live Demos
13:45–14:30 h

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

- **Single-Use Mixers: What type is best for my process application?**
  Pall
- **Final Filling: Process Flexibility through Single-Use Technology**
  Merck Millipore

Hansjörg Nortmeyer
Sanofi-Aventis Deutschland
15:00–15:45 h

Case study: Evaluation of a modular Single Use System for R&D purpose

- What was the key driver to look for a single use system?
- Evaluation strategy to find the right system and the right supplier
- Risk-Benefit-Evaluation for the implementation of a single-use System
- Proper Risk Assessment in order to implement a modular Single use System

Dr Martin Schwab
Vetter Pharma-Fertigung
15:45–16:30 h

Case Study: Use of disposables in clinical manufacturing operations – opportunities and challenges

- Commercial vs. clinical
- Needs of clinical processes
- Design of equipment

Regulations/Technology/New Developments 24 March 2015

Objectives

This is why you will benefit from attending this conference:

- Case studies from various pharmaceutical companies deal with the implementation, qualification and operation of isolator and RABS systems.
- You will get to know the regulatory expectations as well as the current state of the art and new technological developments in Barrier Systems technology.
- Experts from pharmaceutical companies will share their experience regarding weak points and operational experience.
- You will be able to share your point of view - discuss which points have not yet been managed satisfactorily or need to be improved.

Background

The protection against microbial contamination is the most important point for drugs produced by aseptic processes. The classical clean-room cannot be considered as state of the art any longer, though – especially with regard to new facilities for sterile manufacturing. Today the supervisory authorities require a more strict separation between operators and product in the form of an access barrier.

Two systems are on the market – RABS (Restricted Access Barrier System) and Isolators. But only isolators are referred to by the US FDA as advanced aseptic technology. This conference will therefore focus on the current questions of barrier systems with regard to isolators in detail, and it will specifically address the subject from the perspectives of pharmaceutical operators, planners and engineers.

Moderator

Dr. Friedrich Haefele, *Boehringer Ingelheim Pharma*

Target Audience

This event is directed at decision-makers from pharmaceutical production, development and quality assurance/control. It also addresses engineers and planners who need to be well informed about current developments in the field of barrier systems.

Programme 24 March 2015

Congress Key Note

Dr Jean-Denis Mallet **Towards a renewed or a brand new Annex 1**
NNE Pharmaplan & ECA Board Member
09:00–10:00 h

Dr Friedrich Haefele
Boehringer Ingelheim Pharma
10:30–11:15 h

Standardized Isolators for Clinical Trial supply and small products

- The specific demands of Biotech
- Concept and design studies
- B+S – Variosys + Skan PSI-L: the solution from machine manufacturers
- Case Study: BI Flexible Isolator Plant, Fremont, CA
- Summary & outlook

Live Demos
11:15–12:00 h

In the practical part of the conference on 24th March 2014, suppliers will show you different components and solutions in relation to Barrier Systems. You will come in contact with the equipment and you have the chance to discuss your questions immediately with technology experts.

- **Introduction of Filling Systems into the Isolator**
  Ziel
- **PSI-L: an aseptic isolator for all processes like compounding and automated filling of various packaging materials**
  Skan
- **TBN**
  MK Versuchsanlagen und Laborbedarf
- **Enhanced safety and compliance with Mobile Glove Testing System GTS for automatic glove integrity testing**
  Metall + Plastic

James Drinkwater
Chairman of PHSS
13:30–14:15 h

Key operational aspects in using Isolator Barrier Technology

- Understanding the contamination control attributes of Isolators for different processing applications – strengths and limitations
- Isolator and Glove leak integrity – how this relates to operations, associated risk in deviations and what actions to be taken in failed leak tests
- Key operational aspects of Gaseous disinfection (GD-VHP) of Isolator barriers and transfer load surface decontamination – including GMP non-conformance issues to avoid
- Operators completing environment monitoring of critical Isolator zones – key points to consider

Dr Daniel Müller
GMP-Inspector, Germany
14:15–15:00 h

Barriers in pharmaceutical industry

- Regulatory framework: guidelines and recent developments
- GMP-inspector's view on pharmaceutical barrier applications (aseptic filling)
  - definitions & impact on facility layout / production mode
  - decontamination techniques
  - material transfer
  - interventions during production
- Inspection experience: discussion points & observations

Case Studies

25 March 2015

Markus Keller
Fraunhofer IPA
15:45–16:30 h

Ad- and desorption of Vaporized Hydrogen Peroxide (VPHP) from Materials
- Current knowledge regarding ad- and desorption of VPHP from materials
- Prolonged aeration phase of isolators due to VPHP desorption from materials (after the sterilization process)
- Standardized material test: how do different materials behave? (regarding VPHP ad- and desorption?)
- Catalytic effect of selected materials to VPHP
- New VDI guideline for a standardized material assessment

Gerald Bürkle
Vetter Pharma-Fertigung
16:30–17:15 h

Case study: Improved RABS-Concept - the combination of Quality- and OEE-advantages between Isolator and RABS
- Actual requirements for a CDMO in the aseptic filling world
- Design of the "Improved RABS-Concept"
- Quality Aspects
- Business/OEE-Aspects

Programme

25 March 2015

Dr Harald Stahl
GEA Pharma Systems
08:30–09:30 h

The future of pharmaceutical production – Global developments in OSD manufacture

Dr Friedrich Haefele
Boehringer Ingelheim Pharma
10:00–10:45 h

RTU-Components in RABS and Isolators
- RTU-Components: Overview
- Transfer Systems
- Deco-Procedures
- Cost impact on isolator technology
- Summary

Dr Tiago Bruno Ferreira
GenIbet Biopharmaceuticals
10:45–11:30 h

Case study: Use of Isolator Technology on Aseptic Filling of final products for clinical trials
- Small Introduction to GenIbet
- Aspects to consider for the acquisition of an Isolator –A GenIbet perspective?
- Qualification of the Isolator
- Fumigation procedure
- Qualification of the Fumigation
- Aseptic Filling validation
- Example of an Aseptic Filling performed on Isolator: Adenovirus to be used in clinical trials

Lionel Quinton
Aspen
13:00–13:45 h

Case study: Design of a production isolator – from user need to realization
- Description of the key item of decision to achieve an optimal solution for future production
- Design decision based on experience with existing equipment and actual state of the art equipment

Saskia Killer
Oncotec
13:45–14:30 h

Case Study: Isolators in sterile production – zoning concepts versus GMP requirements
- GMP requirements for class "A" isolator concepts
- Requirements for the surrounding clean room
- Design of in- and outlets of isolators for continuous processes covering EU and FDA requirements
- Worst case & monitoring – how to minimise the risks
- Experiences from several years of working with isolators

Alan Kelly
Genzyme Ireland
15:00–15:45 h

Case Study: Set-up of two aseptic filling lines
- Comparing functionality and operation of both lines, including VHP cycle, glove testing, Isolator leak test, and microbial monitoring
- VHP trends over the last few years
- Integrated design between Isolators and Freeze Dryers / High stopper detection and capper in RABs
- Philosophy for clean room class
- Current challenges / How the lines maybe set up to run bigger batches in the future

Patrick Vanhecke
GlaxoSmithKline Biologicals
15:45–16:30 h

Case study: Biosafety Containment and Isolator Technology
- Biosafety regulations
- Manufacturing process
- Isolator design
- Decontamination process

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24 March 2015

Time	ECA – Control of Parenterals Visual Inspection Systems	ECA – Aseptic Processing Current Aseptic Technologies	ECA – Barrier Systems Regulations/Technology/ New Developments	Time
9.00 Uhr 9:15 Uhr 9.30 Uhr 9:45 Uhr	Congress Key Note Towards a renewed or a brand new Annex 1 *Dr Jean-Denis Mallet, NNE Pharmaplan and ECA Foundation Advisory Board Member*			9.00 Uhr 9:15 Uhr 9.30 Uhr 9:45 Uhr
10.00 Uhr 10:15 Uhr	Break			10.00 Uhr 10:15 Uhr
10.30 Uhr 10:45 Uhr 11.00 Uhr	Current GMP's for visual inspection of parenterals: a GMP inspector's view *Dr Daniel Müller, GMP-Inspector, Germany*	Aseptic Processing from orphan to block-buster *Gert Moelgaard, NNE Pharmaplan*	Standardized Isolators for Clinical Trial supply and small products *Dr Friedrich Haefele, Boehringer Ingelheim Pharma* *Bernd Wieland, Bausch+Ströbel*	10.30 Uhr 10:45 Uhr 11.00 Uhr
11:15 Uhr 11.30 Uhr 11:45 Uhr	From the product requirements to the appropriate inspection system: the URS as key to identify the right inspection system *Martin Dearden, PaxVax Berna*	Technological modifications proposed by the CIG A3P for a new Annex 1 *Dr Roland Guinet, RGmp Compliance*	Live Demos	11:15 Uhr 11.30 Uhr 11:45 Uhr
12.00 Uhr 12:15 Uhr 12.30 Uhr 12:45 Uhr 13.00 Uhr 13:15 Uhr	Lunch Break			12.00 Uhr 12:15 Uhr 12.30 Uhr 12:45 Uhr 13.00 Uhr 13:15 Uhr
13.30 Uhr 13:45 Uhr 14.00 Uhr	Qualification & validation of an automated inspection system *Dr Tobias Posset, Roche Diagnostics*	Case study: Developing and production of sterile dosage forms according to QbD approach *Mehtap Saydam, Sanovel Pharmaceuticals*	Key operational aspects in using Isolator Barrier Technology *James Drinkwater, Chairman of PHSS*	13.30 Uhr 13:45 Uhr 14.00 Uhr
14:15 Uhr 14.30 Uhr 14:45 Uhr	Routine operation of an automated visual inspection system *Dr Tobias Posset, Roche Diagnostics*	Live Demos	Barriers in pharmaceutical industry *Dr Daniel Müller, GMP Inspector, Germany*	14:15 Uhr 14.30 Uhr 14:45 Uhr
15.00 Uhr 15:15 Uhr 15.30 Uhr	Break			15.00 Uhr 15:15 Uhr 15.30 Uhr
15:45 Uhr 16.00 Uhr 16:15 Uhr	AQL testing of visual inspection *Dr Bernd Renger, Immediate Past Chair of the European QP Association*	Case study: The use of PAT tool Tempris® in aseptic and sterilisation processes: 2 cases of improved production scale real-time testing *Dr Andrea Weiland-Waibel, Explicat Pharma*	Ad- and desorption of Vaporized Hydrogen Peroxide (VHHP) from materials *Markus Keller, Fraunhofer IPA*	15:45 Uhr 16.00 Uhr 16:15 Uhr
16.30 Uhr 16:45 Uhr 17.00 Uhr	Visual Inspection from the Border of the World *Patrizia Ascani, Doctors without Borders*	Case study: Antibody drug conjugate (ADC) manufacturing at PKau – a cytotoxic production in a shared facility *Dr Lars Sukowski, F.Hoffmann-La Roche*	Case study: "Improved RABS-Concept - the combination of Quality- and OEE-advantages between Isolator and RABS" *Gerald Bürkle, Vetter Pharma-Fertigung*	16.30 Uhr 16:45 Uhr 17.00 Uhr
17:15 Uhr 17.30 Uhr	Discussion	Discussion	Discussion	17:15 Uhr 17.30 Uhr
18.00 Uhr	Social Event for Congress Delegates, Speakers and Exhibitors			18.00 Uhr

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25 March 2015

Time	ECA – Control of Parenterals Container / Closure Integrity Testing	ECA – Aseptic Processing Single-Use Disposables	ECA – Barrier Systems Case Studies	Time
8.30 Uhr 8.45 Uhr 9.00 Uhr 9:15 Uhr	Congress Key Note The future of pharmaceutical production – Global developments in OSD manufacture *Dr Harald Stahl, GEA Pharma Systems*			8.30 Uhr 8.45 Uhr 9.00 Uhr 9:15 Uhr
9.30 Uhr 9:45 Uhr	Break			9.30 Uhr 9:45 Uhr
10.00 Uhr 10:15 Uhr 10.30 Uhr	Container Closure Integrity testing of sterile drug products – requirements, expectations and exaggerations *Dr Bernd Renger, Immediate Past Chair of the European QP Association*	Case study: Single-use disposables in a MultiProduct Facility *Dr Marjo Peters, Medimmune/AstraZeneca Supply Biologics*	RTU-Components in RABS and Isolator *Dr Friedrich Haefele, Boehringer Ingelheim Pharma*	10.00 Uhr 10:15 Uhr 10.30 Uhr
10:45 Uhr 11.00 Uhr 11:15 Uhr	Oversight of container/closure integrity testing technologies *Heino Prinz, Rommelag*	An Approach to the qualification of Single-Use components for biopharmaceuti-cal manufacturing *Sade Mokuolu, Representative BPSA*	Case study: Use of Isolator Technology on Aseptic Filling of final products for clinical trials *Dr Bruno Ferreira, GenIbet*	10:45 Uhr 11.00 Uhr 11:15 Uhr
11.30 Uhr 11:45 Uhr 12.00 Uhr 12:15 Uhr 12.30 Uhr 12:45 Uhr	Lunch Break			11.30 Uhr 11:45 Uhr 12.00 Uhr 12:15 Uhr 12.30 Uhr 12:45 Uhr
13.00 Uhr 13:15 Uhr 13.30 Uhr	Integrity testing of Prefilled Syringes *Dr Tobias Posset, Roche Diagnostics*	Case study: The retrofit of an existing filling line to accommodate Single-Use Filling Assemblies *Terry Love, Merck Millipore*	Case study: Design of a production isolator – from user need to realization *Lionel Quinton, Aspen*	13.00 Uhr 13:15 Uhr 13.30 Uhr
13:45 Uhr 14.00 Uhr 14:15 Uhr	100% inline CCI testing of ampoules *Dr Martin Becker, hameln pharmaceuticals*	 Live Demo	Case study: Isolators in sterile production - zoning concepts versus GMP requirements *Saskia Killer, Oncotec*	13:45 Uhr 14.00 Uhr 14:15 Uhr
14.30 Uhr 14:45 Uhr	Break			14.30 Uhr 14:45 Uhr
15.00 Uhr 15:15 Uhr 15.30 Uhr	100% Container Closure Integrity Testing of lyophilized Products in Vials *Dr Tobias Posset, Roche Diagnostics*	Case study: Evaluation of a modular Single-Use System for R&D purpose *Hansjörg Nortmeyer, Sanofi-Aventis Deutschland*	Case study: Set-up oft wo aseptic filling lines *Alan Kelly, Genzyme Ireland*	15.00 Uhr 15:15 Uhr 15.30 Uhr
15:45 Uhr 16.00 Uhr 16:15 Uhr	Inline Container Closure Integrity Testing of liquid Products in Vials *Dr Ingo Presser, Boehringer Ingelheim Pharma*	Case study: Use of disposables in clinical manufacturing operations – opportunities and challenges *Dr Martin Schwab, Vetter Pharma-Fertigung*	Case study: Biosafety Containment and Isolator Technology *Patrick Vanhecke, GlaxoSmithKline Biologicals*	15:45 Uhr 16.00 Uhr 16:15 Uhr
16.30 Uhr 16:45 Uhr	Discussion	Discussion	Discussion	16.30 Uhr 16:45 Uhr
17.00 Uhr				17.00 Uhr

Easy Registration

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With a one day ticket you can attend any conference offered that day. To be able to prepare the conference rooms, though, we would appreciate it if you marked the conference you are interested in addition to marking the day you plan on attending the Congress. Please mark only one conference per day.

☐ **Day 1 (24 March 2015)**: I would like to attend the Congress on day 1. I'm primarily interested in the conference:

- ☐ ECA – Visual Inspection Systems
- ☐ ECA – Current Aseptic Technologies
- ☐ ECA – Barrier Systems: Regulations / Technology / New Developments

☐ I would also like to take part in the Social Event on the evening of 24 March 2015.

☐ **Day 2 (25 March 2015):** I would like to attend the Congress on day 2. I'm primarily interested in the conference:

- ☐ ECA – Container / Closure Integrity Testing
- ☐ ECA – Single-Use Technology
- ☐ ECA – Barrier Systems: Case Studies

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- Please note that there will **not be any print-outs** at the Congress. Instead you will receive all presentations prior to the Congress as Downloads. All Congress delegates (excluding exhibition visitors) will also receive the presentations on a USB stick at the registration center.
- There will be no room reservations via Concept Heidelberg. Please book your hotel room directly with the reservation form which you will receive together with your confirmation/invoice! Charges are payable after receipt of the invoice.

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