2013 PHARMA CONGRESS

Production & Technology

DÜSSELDORF, 19 - 20 MARCH 2013

network. experience. benefit.

Image: Takeda

- ECA Conference
  Sterile Fill & Finish
- ECA Conference
  Current Aseptic Technologies
- ECA Conference
  Glass – Glass Breakage – Delamination
- ECA Conference
  Barrier Systems (Isolators/RABS)

With:

Udo J. Vetter
Head of the Control Board
of Vetter Companies

Gert Moelgaard
VP Innovation & Business Dev.
NNE Pharmaplan

Jörg Zimmermann
Dir. Process Dev. & Implementation, Vetter Pharma-Fertigung

Dr Daniel Müller
GMP Inspector
Regierungspräs. Tübingen

James Drinkwater
Process & Compliance Dir.
Bioquell

CONCEPT HEIDELBERG

Pharmaceutical Quality
Training. Conferences. Services.

Media Partner:

PMPS

Greeting

Dear Colleagues,

on 19/20 March 2013 the 15th Pharma Congress will take place in Düsseldorf. It has already become a tradition that the industry comes together to this event.

During this Congress many international projects will be introduced that are characterised through current developments and innovations. The various conferences will also be accompanied again by the large trade show PharmaTechnica showcasing more than 80 exhibitors.

It is the goal of this international event to present lectures as technical applications "from users for users", thus primarily concentrating on the practical benefit. The current technical state of the art will be demonstrated through presentations in the areas sterile technology, packaging, manufacture of solid dosage forms, automation and energy management. At the same time delegates take advantage of the Congress for an information and experience exchange, and this exchange certainly also contributes for finding a solution for the one or other problem.

Due to the globalisation we are all dependent on building and maintaining "good and productive" networks to stay on top of current developments and trends and to find out more about interesting and sustainable solutions.

I look forward to welcoming you to the Pharma Congress 2013. It will most certainly be another interesting event to be part of.

Yours sincerely
Franz Maier
Prof. Dipl. Ing. Franz Maier
Nycomed GmbH

The Pharma Congress Overview

Pharma Congress Overview		
Conference One day ticket 690 EUR	**19 March**	**20 March**
ECA Conference Sterile Fill & Finish	✓	
ECA Conference Current Aseptic Technologies	✓	✓
ECA Conference Glass – Glass Breakage – Delamination	✓	✓
ECA Conference Barrier Systems	✓	✓
Trade Show PharmaTechnica	✓	✓

The exact times for the single conferences as well as updates are available in the agenda in the back of the programme and on the Congress website at www.pharma-kongress.com.

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

PLEASE NOTE

There will be no 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 Fees

One day tickets will enable you to visit the congress either only on day 1 or only on day 2 or on both days. Charges for the one day tickets are € 690,- plus VAT, for the two days ticket € 1.190,- plus VAT (due to the special fees for the congress, ECA membership discounts are not applicable). 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. Charges are payable after receipt of invoice.

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 19 March 2013, 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.

The Contacts

For questions regarding content:
ECA Conferences Current Aseptic Technologies / Sterile Fill & Finish / Glass – Glass Breakage – Delamination / Barrier Systems:
Dr Andreas Mangel (Operations Director), Tel. +49 6221 84 44 41,
E-Mail: mangel@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Detlef Benesch (Organisation Manager), Tel. +49 6221 84 44 45,
E-Mail: benesch@concept-heidelberg.de.

The Organiser

CONCEPT HEIDELBERG – On behalf of the European Compliance Academy (ECA)
P.O. Box 10 17 64
D-69007 Heidelberg
Phone +49 62 21 84 44-0
Fax +49 62 21 84 44 34
E-Mail: info@concept-heidelberg.de
www.gmp-navigator.com

ECA
European Compliance Academy

The Media Partner

PMPS

Pharmaceutical Manufacturing and Packing Sourcer (PMPS) is a specialist magazine for the pharmaceutical manufacturing, packaging and supply chain sectors. Every quarterly edition features articles written by key opinion leaders, ranging from pharmaceutical sponsors and key services providers, to industry associations and regulatory authorities. *PMPS* combines technological, operational and corporate perspectives on this growing sector, along with industry interviews, event previews and books reviews.

PLEASE NOTE

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.

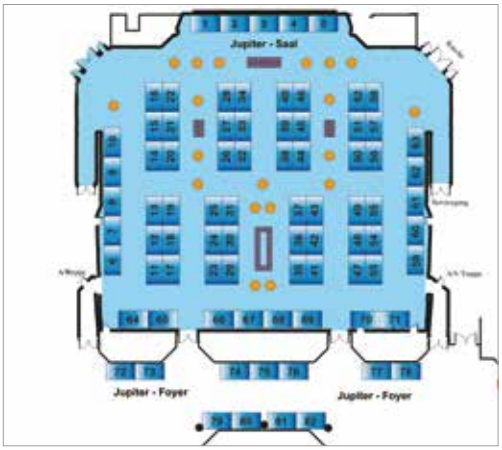
The Trade Show PharmaTechnica

Parallel to the Pharma Congress from 19 and 20 March there will also be taking place the large trade show PharmaTechnica. This show with more than 80 internationally oriented exhibitors will allow you to get to know and to discuss new technologies, products and services as well as to network. For the current exhibitor list please see below or visit the website at www.pharma-kongress.com.

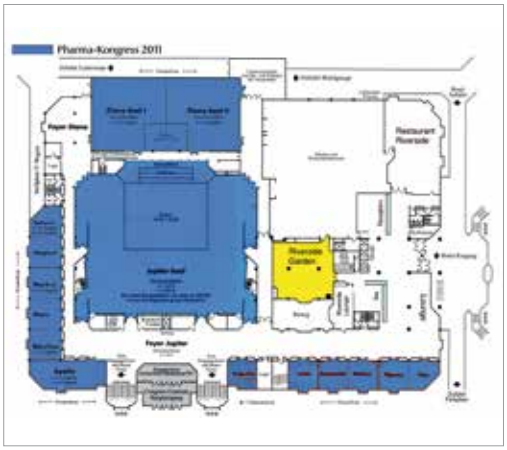
PLEASE NOTE

The PharmaTechnica is also open for visitors who do not want to participate in any of the conferences. However, please note that you will need to register for the free of charge visit of the trade show. The online registration on the website will be active in December 2012. The free visit of the PharmaTechnica does not entitle you to attend any of the conferences.

The PharmaTechnica



The Conferences



The Exhibitors (as of March 2013)

2013 PHARMA CONGRESS
PharmaTechnica
DÜSSELDORF, 19 - 20 MARCH 2013

Company	Stand
ANDERSON-NEGELE	59
ASEPTIC TECHNOLOGIES	60
basan GmbH	9
Bausch & Ströbel	1
Belimed	34
bioMérieux	15
Bioquell	56
Bilfinger Industrietechnik	27
Borer	46
Catalent	28
COMECER	64
Concept GMP Engineering	49
Datwyler	76
DEC Deutschland	19
Dockweiler	26
Ellab	24
ebro Elektronik	43
ELPRO Messtechnik	48
Esau & Hüber	36
Extract Technology	44
FEDEGARI	13
Festo	32
Fette Compacting	5
Filtrox	70
Foster Wheeler	77
Franz Ziel	41
Frigo-Trans	58
GEA Lyophil	82
GEMÜ	14
Gerresheimer	17
Getinge	61
Glatt	4
Groninger	40
Harro Höfliger	2
Harter	54
HENKEL	69
HEUFT SYSTEMTECHNIK	11
Höntzsch	74
International Packaging Systems	33
Invensys Systems >EUROTHERM<	63

Company	Stand
iQ-Mobil Solutions	16
Kiesel Steriltechnik	31
Laetus	81
Letzner	23
Levitronix	52
Lighthouse Instruments	45
Mankenberg	25
Martin Christ	42
Matthews Europe	71
Müller Cleaning Solutions	12
multivac	18
Neumo	67
NNE Pharmaplan	30
OPTIMA pharma	22
Pall	68
Particle Measuring Systems	38
Pfankuch Maschinen	80
PMT Partikel-Messtechnik	53
ProSys	78
Rapid Micro Biosystems	79
Robert Bosch	20
ROMACO	6
Rota Verpackungstechnik	37
rotan	50
scanware electronic	66
SCHOTT	35
ServoTech	21
SIEMENS	55
Skan	62
SPC Manufacturing	10
Stäubli Tec-Systems	39
Steriline	47
SWAN	29
Telstar Life Sciences	7
Uhlmann	3
VITRONIC	65
VTU Engineering	8
West	51
WILCO	57

Speakers

Edgar Bauer
Bausch + Ströbel Maschinenfabrik Ilshofen GmbH + Co. KG, Ilshofen, Germany
Has been in charge of the French market in the Sales Department since 2000.

Dr Andrea Behrenswerth
Gerresheimer Bünde GmbH, Bünde, Germany
Head of Quality Assurance within Gerresheimer Bünde.

Stefan Bernsau
Harro Höfliger Verpackungsmaschinen GmbH, Allmersbach, Germany
Division Leader Pharma Liquids

Dave Boerschel
Catalent Pharma Solutions, Woodstock, USA
Program Manager in the R&D department since 2010, leading a group of project managers.

Dr Bettine Boltres
SCHOTT AG, Mitterteich, Germany
Product Manager Pharmaceutical Tubing.

Heiko Bütehorn
GEA Diessel GmbH, Hildesheim, Germany
Four years management of F&B Division.

Bart E. Burgess
West Pharmaceuticals Services, Lionville, USA
Initiated business development for West patch injection systems in 2010.

Christian Doriath
Skan AG, Allschwill, Switzerland
Special Operation Engineer.

James Drinkwater
Bioquell UK / PHSS
Process and Compliance Director. Chairman of the Pharmaceutical and Healthcare Sciences Society – PHSS.

Leopold Gruber
SBM Schoeller Bleckmann Medizintechnik Ges.m.B., Ternitz, Austria
Active from 1974 till the end of 2010 in the area of the design and sales in leading functions.

Dr Roland Guinet	**RGmp Compliance, Chevinay, France** Consultant Regulatory Compliance Sites and Processes.
Maik Häring	**F. Hoffmann-La Roche Ltd, Kaiseraugst, Switzerland**
Kathrin Holtei	**hameln pharmaceuticals GmbH, Hameln, Germany** Assistant to Head of Manufacturing, working on optimizing the efficiency of all areas, especially Barrier systems.
Manfred Holzer	**Skan AG, Allschwil, Switzerland** Heads the business development of the Skan RABS Systems.
Sascha Karhöfer	**West Pharmaceuticals Services, Eschweiler, Germany** Manager for Injectable Container Closure Solutions Platform in Europe.
Horst Koller	**SCHOTT Schweiz AG** Head of technical and quality support syringes.
Dr Timo Krebsbach	**Labor L+S AG, Bad Bocklet, Germany** Head of the sterility testing department, responsible for sterility tests performed in a cleanroom & isolators.
Dr Thomas Jahnen	**HEUFT Systemtechnik GmbH, Burgbrohl, Germany** Sales Director Technic.
Uli Kuchenbrod	**Vetter Pharma-Fertigung GmbH & Co. KG, Ravensburg, Germany** Director Quality Control Incoming Goods.
Dr Jörg Lümkemann	**F. Hoffmann-La Roche AG, Basel, Switzerland** Heading the dptm. for implementation of new technologies and engineering support for parenteral production.
Gert Moelgaard	**NNE Pharmaplan, Søborg, Denmark** Vice President for Innovation & Business Development.
Michael de la Montaigne	**Bosch Inspection Technology Inc., Allendale/USA** Global Sales Director for the inspection machinery (Eisai Machinery).
Dr Daniel Müller	**Regierungspräsidium Tübingen, Germany** GMP-Inspector with focus on biotechnological active ingredients and sterile drug products.
Dr Wenzel Novak	**groninger & co. gmbH, Crailsheim, Germany** Responsible for pharmaceutical research and development since 2006.
Matthias Poslowski	**OPTIMA pharma gmbh, Schwäbisch Hall, Germany** Technical Sales Director.
Dr Tobias Posset	**Roche Diagnostics GmbH, Mannheim, Germany** Heading the Production Support unit in the Pharma Production in Mannheim.
Dr Ingo Presser	**Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany** Responsible for clinical trial supply and process transfer unit with the Process Science Department.
Dr Heino Prinz	**Wilco AG, Wohlen, Switzerland** In charge of research and development.
Dr Johannes Rauschnabel	**Robert Bosch GmbH, Crailsheim, Germany** Director Process Engineering Packaging Technology Pharma.
Dr Andreas Reicke	**Vetter Pharma-Fertigung GmbH & Co. KG, Ravensburg, Germany** In charge of sterility testing performed in isolators.
Dr Uwe Rothhaar	**SCHOTT AG, Mainz, Germany** Primarily focused on the chemical resistance and mechanical stability of pharmaceutical primary packing.
Ray Rugebregt	**Catalent Pharma Solutions, Woodstock, USA** Project Manager in R&D since 2011.
Hartmut Schaz	**NNE Pharmaplan GmbH, Bad Homburg, Germany** Senior Expert for Small Volume Parenteral Products and is a Director of the Board of NNE Pharmaplan India.
Dr Daniel Scherzinger	**Skan AG, Allschwil, Switzerland** Head of Scientific Laboratory.
Boris Schmid	**Stevanato Group, Piombino Dese, Italy** Quality Director focused on Glass Quality- and GMP improvements and worldwide standardization.
Robert Schwarz	**Baxter AG, Vienna, Austria** Responsible for equipment qualification, sterilisation validation and cleaning validation.
Dominique Sierakowski	**Octapharma SA, Lingolsheim** Head of Corporate Pharmaceutical Production.
Dr Dirk Sievers	**Pall Life Sciences GmbH, Dreieich, Germany** Technical Marketing Manager.
Paul Stone	**Stäubli UK Ltd., Telford, UK** General Manager of Stäubli (UK) based in Telford.
Jamie Thompson	**GE Analytical Instruments, Dublin, Irland** EMEA Applications Specialist.
Stefanie Trudel	**Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany** Head of the new isolator filling line Biopharmaceutical Manufacturing 5.
Benoît Verjans	**Aseptic Technologies S.A., Les Isnes, Belgium** Currently Commercial Director.
Udo J. Vetter	**Vetter Pharma-Fertigung GmbH & Co. KG, Ravensburg, Germany** Head of the Control Board of Vetter Companies.
Dr Christian Vogt	**Novartis Pharma Stein AG, Basle, Switzerland** Head Biological & Microbiological Services.
Dr Andrea Weiland-Waibel	**Explicat Pharma GmbH, Hohenbrunn, Germany** CMC / Technical project management.
Sokhorn Yim	**Genentech, Inc., San Francisco, USA** Currently working in Process Development Engineering.
Jörg Zimmermann	**Vetter Pharma-Fertigung GmbH & Co. KG, Ravensburg, Germany** Director Process Development and Implementation.

In Cooperation with

ECA European Compliance Academy

Conference Sterile Fill & Finish

Objectives

Why should you attend this conference?

- You will get first hand information on modern filling and finishing technologies, even for sterile fluid and sterile solid products
- Three case studies from pharmaceutical companies will show you different aspects of planning and operating sterile filling lines

Background

Bild: OPTIMA pharma

Sterile fill and finish operations, e.g. the filling of vials, the filling of sterile powders and usage of prefilled syringes, are difficult to handle. In many cases the technologies are rather simple but the requirements for sterility make the process often difficult and complex. Separation of personnel from open processes by Barrier Systems is one of the strategies to avoid microbial contamination.

On the other hand active ingredients become more and more potent / toxic. Therefore filling operations and Barrier Systems muss secure personnel from potential contamination as well.

Target Audience

This conference targets staff in the pharmaceutical industry, suppliers and engineering companies responsible for sterile fill and finish activities. Addressed will particularly the areas

- Development
- Production
- Quality Assurance
- Engineering / Technology

Moderator

Hartmut Schaz, *NNE Pharmaplan*

Programme 19 March

9:00 h — **Pharma Manufacturing 2020: Development and Investment Strategy – The View of an aseptic filling Company using Platform Technologies**

Key Note

➲ **Udo J. Vetter, Vetter Pharma-Fertigung**

- What are the trends in aseptic manufacturing
- Success factors for a growth strategy
- Extension of capacity and the practical implementation
- Technical and regulatory challenges for the upcoming years
- Expectations with regard to planning and engineering companies

9:45 h — **State of the art production facilities for small volume parenteral products – what makes the difference?**

➲ **Hartmut Schaz, NNE Pharmaplan**

- Building / Layout
- Process technology
- Building and process utilities

11:00 h — **Startup of a multiproduct isolator filling line**

➲ **Stefanie Trudel, Boehringer Ingelheim Pharma**

- Project Scope and timeline for the implementation of 2 high-speed filling lines in isolator technology including layout and product and material flow
  - Line 1 is a vial filling line for liquid and freeze dried products
  - Line 2 is a combiline for vials as well as double chamber cartridges. Both filling lines are linked to the same two freeze dryers
- Mode of operation as a flexible multiproduct line
- Lessons learnt from startup and qualification phase

11:50 h — **Case Study: Highly flexible toxic/aseptic filling of clinical trial material in Prefilled Syringes**

➲ **Dr Jörg Lümkemann, F. Hoffmann-La Roche**

- Process description and zone concept / containment philosophy
- Stopper handling approach
- Processability of syringe components
  - Divergence of tub design
  - Binded tray issues
  - Nested syringe optimization

14:05 h **Case study: Fill-finish considerations for monoclonal antibodies**

➲ **Jörg Zimmermann, Vetter Pharma-Fertigung**

- Fill-finish process within the scope of pharmaceutical development
- Typical fill-finish process
- Formulation
- Inherent challenges
- Examples of challenges
- Source of challenges
- Case studies
- Composition of excipients
- High dose application
- Susceptibility to interfaces
- Compatibility to contact material
- Selection of a medical device
- Summary

14:55 h **Inspection trends & findings in sterile fill & finish**

➲ **Dr Daniel Müller, Regierungspräsidium Tübingen**

- Important updated regulatory guidence documents, e.g.
  - Annex 1 (Rev. 2008), section on capping
- Trends in manufacture (GMP-inspector's view), e.g.
  - Pre-fillable syringes
  - RABS
  - Single-use disposables
- Current challenges (GMP-inspector's view)
  - Particles in parenterals / glass breakage / visual inspection
  - Packaging material & containers / leachables & extractables / particles
- Examples of observations (sterile manufacture)

16:15 h **Powder filling in closed containers: from myth to reality**

➲ **Benoit Verjans / Stefan Bernsau, Aseptic Technologies / Harro Höfliger**

- The closed vial technology
- products dispensed as sterile powders (e.g. Antibiotics)
- Filling closed vials with powder through the piercing needle
- Better sterility assurance level

17:05 h **Inspection of pre-filled syringes incl. methodology for preparing samples**

➲ **Michael de la Montaigne, Bosch Inspection Technology**

- Technologies used
- Type(s) of samples
- Preparing samples
- Sample verification
- Bracketing products

Bild: groninger

Bild: Bosch

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Conference Current Aseptic Te

Objectives

Three good reasons to attend this conference:

- You are informed about the latest technological developments in sterile / aseptic manufacture
- You learn how current GMP and production requirements have to be implemented technologically in sterile manufacture
- You will get the interpretation of new guidelines and regulations from the industry's point of view

Background

Bild: groninger

GMP regulations only define general requirements on equipment – it has to be suitable for the intended work process, easy to clean and without any negative influence on the product quality. The questions of 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 the focus of this event. Speakers from the pharmaceutical industry, from planning and engineering companies as well as from Inspectorates deal with pivotal developments in the field of sterile manufacture.

Target Audience

The event is directed at specialists from the pharmaceutical industry, at engineers and planners who have to deal with current aseptic technologies in clean areas in their daily practice. It particularly aims at the departments production, quality assurance and engineering / technology.

Moderator

Gert Moelgaard, *NNE Pharmaplan*

Programme 19 March

9:00 h **Pharma Manufacturing 2020: Development and Investment Strategy – The View of an aseptic filling Company using Platform Technologies**

Key Note

➲ **Udo J. Vetter, Vetter Pharma-Fertigung**

- What are the trends in aseptic manufacturing
- Success factors for a growth strategy
- Extension of capacity and the practical implementation
- Technical and regulatory challenges for the upcoming years
- Expectations with regard to planning and engineering companies

9:45 h **Aseptic Processing – preparing for the future?**

➲ **Gert Moelgaard,NNE Pharmaplan**

- Aseptic technologies with new opportunities
- Quality Risk Management and regulatory challenges
- The challenge of convenience in sterile drug delivery systems
- Main trends of the future

11:00 h **Development of a Patch Injection System for Large Volume Biotherapeutics**

➲ **Bart Burgess, West Pharmaceuticals Services**

- Describes development of a patch injection system for large volume (> 1mL) biotherapeutics
- Development of a container appropriate to these products, current fill/finish technology, and system function
- Development of a drive mechanism that allows for both speed and precision and
- Optimization of human factors starting early in development process to ease user and regulatory acceptance

11:50 h **Working with challenging tech transfers**

➲ **Dave Boerschel / Ray Rugebregt, Catalent Pharma Solutions**

- Current Aseptic processes and best practice standards
- Examples of customer processes that do not match standards & how to address
- Utilizing automation to retire risk
- Incorporating other continuous improvement activities into a tech transfer
- Results – CTQ (Critical to Quality) scorecards, and KPI's (Key Performance Indicators)

14:05 h **Environmental Monitoring requirements for A/B clean rooms and Isolators aseptic processes**

➲ **Roland Guinet, RGmp Compliance**

- Particle monitoring
- Microbiological monitoring
- Differences in EU / WHO / FDA-USP requirements
- Specific requirements for A/B clean room – aseptic processes
- Specific requirements for Isolators – aseptic processes
- Result of a 2012 survey on manufacturers' practices

14:55 h **E-Beam for presterilized tubs – Challenges in validation: Dosimetry, Killkinetic, Residuals**

➲ **Manfred Holzer, Skan**

- Basics of E-Beam Systems for presterilized tubs
- Dosimetry – practical approach & equipment needed
- Killkinetic – 25 KGy dose versus BI-kill
- Residuals O3, NOx – measurement & values of the field

16:15 h **Different Systems for Fogging and Gassing to decontaminate clean Rooms, Isolators and Lyophilizers**
➲ **Robert Schwarz, Baxter**
- Requirements for a decontamination process
- Different gassing / fogging systems on the market
- Qualification of a Dry Fog device
- Validation of a Dry Fog process
- Lyophilizer decontamination / chemical sterilization

17:05 h **Applying the H_2O_2 process in a vacuum sterilizer for alternative use in the transfer of materials and components**
➲ **Leopold Gruber, SBM Scholler-Bleckmann Medizintechnik**
- H_2O_2 as an alternative method for surface decontamination
- Vacuum sterilizer equipped with a supplementary H_2O_2 decontamination system
- Pre-conditions for the using of vacuum sterilizers
- Application examples
- Benefits

Programme 20 March

9:00 h **Trends in parenteral packaging and the application of QbD-principles to Primary Packaging development and manufacturing**
➲ **Sascha Karhöfer, West Pharmaceuticals Services**
- Current market trends of today's primary packaging requirements
- How the use of an ultra-clean and dry elastomeric material can improve operational efficiency of drug filling and packaging operations
- How Quality by Design (QbD) can be implemented into primary packaging component development and manufacturing
- Applying QbD principles to development and manufacturing of container closure systems

9:50 h **Wireless Temperature Measurement in Sterilizers and Parametric Release**
➲ **Dr Andrea Weiland-Waibel, Explicat Pharma**
- Wireless temperature measurement allows precise determination of the product temperature in sterilizer
- Hot-Cold spot mapping
- Parametric Release of terminally sterilized parenterals possible
- The application is of special interest for physically labile products (e.g. Fat Emulsion)
- Modular system can be installed into existing equipment

11:05 h **TD-NMR spectroscopy – a new technology for filling weight determination of parenteral drug solution**
➲ **Dr Tobias Posset, Roche Diagnostics**
- TD-NMR
- IPC Method
- Filling weight determination
- Non-destructive method
- Parenteral drug solution filled in pre-filled syringes

11:55 h **Challenges in Implementing On-line TOC Instruments for Real Time Testing**
➲ **Jamie Thompson, GE Analytical Instruments**
- A shift in the regulatory landscape: EMA updates mandates on RTRT
- How this impacts you're current state and desired state
- Real Time Testing has three phases that are all acceptable: Monitoring, Control, Release
- Implementation steps you need to consider to ensure success
- Summary highlighting the key "insights / guiding policies from the presentation"

14:00 h **Robotics in aseptic processing**
➲ **Paul Stone / Benoit Verjans, Stäubli / Aseptic Technologies**
- Robotics aims to eliminate the operator of the environment
- Robot system safety by product protection in aseptic processing
- Two case studies are shown in aseptic processing:
  - Clean and sterile vial manufacturing
  - Aseptic filling

15:15 h **Continuous inline blending technology under aseptic conditions with PAT inline analysis**
➲ **Heiko Bütehorn, GEA Diessel**
- General explanation of continuous inline blending technology
- Possible fields of application in the pharma industry
- Case study for a pharmaceutical product
- PAT sensors and process validation

16:05 h **Sterile air filtration in critical, high temperature and oxygen-enriched applications**
➲ **Dr Dirk Sievers, Pall**
- Problems of sterile filtration under challenging conditions
- Comparison of common and new filter materials
- Integrity testing of vent filter

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Conference Glass – Glass Break

Objectives

Why you should attend this conference:

- What are the causes of glass defects? You will learn what process steps in the production chain jeopardise the containers
- Delamination is one of the most discussed topics: You will become familiar with how to prevent delamination
- The conference will cover the problems in daily practice and will demonstrate solution approaches making processes safer
- You can discuss questions and problems with inspectors, glass manufacturers, equipment manufacturers and pharmaceutical operators

Background

Delamination and ensuring the integrity of pharmaceutical glass containers for parenterals are currently among the most discussed issues. Various incidents in the recent past led to an increased focus on the topic in authority and customer audits.

That's why in practice "0" defects are either requested or defined as goal. For that purpose the entire process chain from production of the glass tubes to the final packaging has to be carefully checked.

In many process steps there is a lot potential for improvement regarding the reduction and detection of glass defects. This requires an intensive cooperation and exchange of experience of packaging manufacturers and pharmaceutical companies.

Target Audience

This conference targets staff from glass manufacturers, equipment manufacturers and pharmaceutical operators who deal with glass as packaging material every day (development, quality assurance and quality control, production).

Moderator

Dr Wenzel Novak, *groninger*

Programme 19 March

9:00 h — **Pharma Manufacturing 2020: Development and Investment Strategy – The View of an aseptic filling Company using Platform Technologies**

Key Note

➲ **Udo J. Vetter, Vetter Pharma-Fertigung**

- What are the trends in aseptic manufacturing
- Success factors for a growth strategy
- Extension of capacity and the practical implementation
- Technical and regulatory challenges for the upcoming years
- Expectations with regard to planning and engineering companies

9:45 h — **"Glass – still an option as primary packaging material?"**

➲ **Horst Koller, SCHOTT Schweiz**

- "Actual" issues with glass – facts & figures
- Regulatory expectations – ambition and reality
- Glass – advantages & disadvantages
- Options – Chances, Opportunities, and Limitations

11:00 h — **Glass breakage – Microcracks – Delamination: Inspector's point of view**

➲ **Dr Daniel Müller, Regierungspräsidium Tübingen**

- typical genesis of a quality related recall
- glass breakage & micro cracks - a risk for drug products
- decision criteria for introducing a recall
- expectations of a GMP inspector
  - on handling recalls and associated investigations & measures
  - and on detection & mitigation of glass breakage during production process
- examples of quality issues & recalls based on glass defects

11:50 h — **Challenges for Glass Containers: Breakage and Delamination**

➲ **Dr Uwe Rothhaar, SCHOTT**

- Introduction to glass as a material for drug containers
- Characterization of glass breakage – Fractography
- Container strength – Prediction of overload tests
- Chemical attack of glass
- Delamination risk – tailored design of accelerated tests

14:05 h — **Glass Delamination – Characterization and Prevention from Design to Market**

➲ **Boris Schmid, Stevanato Group**

- Summary of glass delamination studies carried out by Stevanato Group
- Impact from parameters like glass raw material, surface treatment, forming process considering different buffer solutions
- Risk assessment and own test method for delamination prediction
- Overview how to prevent glass delamination from Design to Market

14:55 h **Not every Type I glass is the same – differences in Type I glasses and their impact**
➲ **Dr Bettine Boltres, SCHOTT**
- Definition and basics of Type I
- Mechanism of alkali release and surface reactions
- Type I glasses and differences in release
- Advantages of a low alkali value
- Tubing and molded glass production process / Inner and outer surface treatments

16:15 h **CMO Interface with Glass Suppliers**
➲ **Uli Kuchenbrod, Vetter Pharma-Fertigung**
- Vetter Supplier Management System
- Specification setting approach
- CMO challenges on managing multiple product codes
- Incoming inspection: present and future
- Examples on lessons learned

17:05 h **Panel Discussion on current Glass Issues**

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9:00 h **Final Quality Inspection of primary glass containers for pharmaceutical products**
➲ **Dr Heino Prinz, Wilco**
- Combination of various inspection technologies within one inspection device
- Detection of glass breakage under crimps and stoppers / Functional defects on syringes and vials
- Needle quality inspection in glass syringes through the needle shield
- Foreign particles in liquids, suspensions and powders
- Stopper position and container closure integrities
- Moisture measurement of product trough the glass container
- Technologies combined: Visual, Y-Ray, Laser Headspace and NIR spectroscopy

9:50 h **Minimizing glass container damage with a linear inspection machine**
➲ **Dr Thomas Jahnen, HEUFT Systemtechnik**
- Linear inspection machines for full and empty glass vials or syrup bottles avoid stress
- 100% empty glass inspection to prove the suppliers glass quality
- Automatic adjustment for different products without the need of format parts
- Production data acquisition for a complete line analysis – Revealing the weak points of the process
- Smart conveyor control for a smooth transportation of containers

11:05 h **Case Study: Safe glass handling - possibilities for risk mitigation**
➲ **Dr Ingo Presser, Boehringer Ingelheim**
- Failure types and causes during the aseptic filling process
- Risk assessment / Handling of rare events
- Specifications, tolerances and machines

11:55 h **Case study "New parenteral drug product plant at Roche": Design measures of filling machines to minimizes cosmetic defects**
➲ **Maik Häring, F. Hoffmann-La Roche**
- Introduction to a new parenteral drug product plant at Roche
- Requirements/expectations regarding cosmetic defects
- Design measures to avoid defects during filling:
  • Washing / Sterilization/Depyrogenisation / Transport Glass contact

14:00 h **Crack Prevention and process controls in pre-fillable syringe manufacturing**
➲ **Dr Andrea Behrenswerth, Gerresheimer Bünde**
- Definition of cracks
- Development of cracks and prevention, technical solutions
- Current inspection technology for glass syringes and future development
- Analysis of syringes with cracks

15:15 h **Glass Breakage! Solutions in present-day pharmaceutical machine design**
➲ **Edgar Bauer, Bausch + Ströbel**
- What is the current practice
- Further development based on the previous findings
- Case study

16:05 h **Cosmetic and critical Impacts of fill- and finish lines to glass containers (incl. a case study)**
➲ **Dr Wenzel Novak, groninger**
- Handling of primary packaging containers made from glass during the fill process
- Causes to create damage during filling
- Options to avoid damage (new design vs. existing equipment)
- Options to avoid any glass-glass-contact

In Cooperation with

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Conference Barrier Systems

Objectives

- Case studies from various pharmaceutical companies deal with the implementation and qualification of barrier systems
- You get to know the current state of the art as well as future technological developments in the field of barrier systems
- Which are the weak points of the systems – which operational experience has been gathered? Experts from pharmaceutical companies share their experience with you
- Discuss which points have not yet been managed satisfactorily or need to be improved?

Background

Bild: OPTIMA pharma

Especially in connection with sterile medicinal products produced by aseptic processing, protection against microbial contamination increases in importance. In case of new facilities for sterile manufacturing, the classical cleanroom cannot be considered as the state of the art any longer. Today the supervisory authorities require a more strict separation between staff and product in the form of an access barrier – RABS (Restricted Access Barrier System) or isolator. The level of contamination safety as well as that of personnel protection is clearly higher in both systems. This conference focuses on topical questions on barriers systems in detail from the perspective of pharmaceutical operators, planners and engineers.

Target Audience

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

Moderator

Jörg Zimmermann, *Vetter Pharma-Fertigung*

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9:00 h **Pharma Manufacturing 2020: Development and Investment Strategy – The View of an aseptic filling Company using Platform Technologies**

Key Note

➲ **Udo J. Vetter, Vetter Pharma-Fertigung**

- What are the trends in aseptic manufacturing
- Success factors for a growth strategy
- Extension of capacity and the practical implementation
- Technical and regulatory challenges for the upcoming years
- Expectations with regard to planning and engineering companies

9:45 h **Case study: How to run a RABS clean room successfully**

➲ **Jörg Zimmermann, Vetter Pharma-Fertigung**

- Aseptic Process Design
- Clean Rooms – RABS – Isolator: Advantages and Disadvantages
- Types of RABS and implications
- Mock-up studies
- Daily operations of a RABS
- Glove integrity testing / Media fills / Monitoring
- Case studies from real life

11:00 h **Pros and Cons of Isolator and Cleanroom based on 10 years of operating experience in sterility testing**

➲ **Dr Timo Krebsbach, Labor L+S**

- Practicability / Reliability / Costs
- Practical problems and solution strategies

11:50 h **Aseptic transfers across a barrier**

➲ **Benoit Verjans , Aseptic Technologies**

- Crossing a wall has been very challenging during many years
- New transfer solutions, called Rapid Transfer Ports (RTP) have been initially developed for solid transfer whereas the complex "Clean in Place – Steam in Place" (CIP-SIP) remained the leading solution for liquid transfer
- Some RTP solutions are now applied for liquid transfer
- A case study is shown with a small and rapid disposable solution, the SART connector

14:05 h **Special considerations in Aseptic processing of Biological-Toxic products in Isolators**

➲ **James Drinkwater, Bioquell / PHSS**

- Challenges of processing Aseptic – Biological and Toxic products
- Control logic to provide aseptic environment, prevent operator exposure and cross contamination
- Managing compatibility between disinfection agents and Biological products
- Reducing risk with single use disposable technologies but understanding the process challenges
- Applying environmental monitoring systems together with contamination risk management

14:55 h **A day in the life of an isolator glove: Glove testing and glove lifetime study:**

➲ **Johannes Rauschnabel, Robert Bosch**

- Manual interventions with gloves
- Glove testing / Simulation of glove use
- Particle measurement
- Lifetime study
- Exchange intervals

16:15 h **Glove management**
➲ **Kathrin Holtei, hameln pharmaceuticals**
- The journey of gloves through a sterile production area
- Key parameters for process design
- Traceability of glove life cycle
- Lifecycle management at "hameln pharmaceuticals – example for a contract manufacturing company"
- Most common questions (authorities, customer, supplier)

17:05 h **Implementation of a sterility test isolator – a case study**
➲ **Dr Andreas Reicke, Vetter Pharma-Fertigung**
- Regulatory background
- Previous considerations (design, location, utilities)
- From the planning phase to the start of operation
- Problems and solutions

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9:00 h **Production and validation concepts of an isolator filling line**
➲ **Stefanie Trudel, Boehringer Ingelheim Pharma**
- Microbiological monitoring program
- Glove procedures including discussion and frequency of physical and visual glove tests
- Glove tracking and benefit of glove tracking to glove integrity test procedures and microbiological monitoring sampling
- Media Fill in an isolator
- Validation of campaign filling
- Change over times
- Aseptic handling in an isolator

9:50 h **Production thinking by H_2O_2 decontamination in isolators; Relevance of critical parameters on the efficiency of the decontamination cycle**
➲ **Christian Doriath, Skan**
- Influence of the parameters like
  • Bio-indicators / Temperature / Relative humidity / low residual concentration
- Approach for a better process understanding and acceptation

11:05 h **Absorption and Adsorption of Vapor Phase Hydrogen Peroxide on Various Filling Components**
➲ **Sokhorn Yim, Genentech**
- Hydrogen peroxide ingress through the filling system
- Hydrogen peroxide uptake based on product height/fill volumes in the vials
- Determine the saturation point of hydrogen peroxide in different vial sizes

11:55 h **Development for Biological Indicators for Hydrogen Peroxide Decontamination**
➲ **Dr Daniel Scherzinger, Skan**
- Requirements for Biological Indicators
- Development of a Biological Indicator for H2O2 decontamination processes
- Goals of project / development / customer review / final product
- Characteristics and qualification of the Biological Indicator

14:00 h **Microbiology in Filling Isolators**
➲ **Dr Christian Vogt, Novartis Pharma Stein**
- Bringing an isolator under microbiological control
- How to achieve a state of "practically free of microorganisms"
- Control of an isolator with physical and microbiological monitoring
- Maintenance aspects and integrity checks of isolator systems
- Validation of an filling isolator with media fills
- Microbiological problems in isolators

15:15 h **Case study: Qualification of an isolator with fast airlock**
➲ **Dr Christian Vogt, Novartis Pharma Stein**
- From preparation to the realization: return of experience
- Major steps in the qualification of an isolator
- Mapping studies and performance qualification of the decontamination cycle
- Fast airlock qualification and use in routine

16:05 h **Is aseptic filling under isolator realistic in the context of multi-products, multi-formats and high flexibility?**
➲ **Matthias Poslovski / Dominique Sierakowski, OPTIMA pharma / Octapharma**
- High value product
- Wide range of formats / frequency of format changes
- Small batch sizes
- Minimize product loss, rejects, down time
- Isolator was preferred due to higher sterility assurance level
- Campaigning

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Time	ECA Conference Current Aseptic Technologies	ECA Conference Sterile Fill & Finish	ECA Conference Glass – Glass Breakage – Delamination	ECA Conference B
9.00 h 9:15 h 9.30 h	Pharma Manufacturing 2020: Development and Investment Strategy – The View of an aseptic filling Company using Platform Technologies *Udo J. Vetter, Vetter Pharma-Fertigung*			
9:45 h 10.00 h 10:15 h	Aseptic Processing – preparing for the future? *Gert Moelgaard,NNE Pharmaplan*	State of the art production facilities for small volume parenteral products – what makes the ***difference?*** *Hartmut Schaz, NNE Pharmaplan*	"Glass – still an option as primary packaging material?" *Horst Koller, SCHOTT Schweiz*	Case study: How to r room successfully *Jörg Zimmermann, Vetter*
10.30 h 10:45 h	Break	Break	Break	Break
11.00 h 11:15 h 11.30 h	Development of a Patch Injection System for Large Volume Biotherapeutics *Bart Burgess, West Pharmaceuticals Services*	Startup of a multiproduct isolator filling line *Stefanie Trudel, Boehringer Ingelheim Pharma*	Glass breakage – Microcracks – Delamination: Inspector's point of view *Dr Daniel Müller, Regierungspräsidium Tübingen*	Pros and Cons of Isol based on 10 years of in sterility testing *Dr Timo Krebsbach, Labo*
11:45 h	Break	Break	Break	Break
12.00 h 12:15 h	Working with challenging tech transfers *Dave Boerschel / Ray Rugebregt, Catalent Pharma Solution*	Case Study: Highly flexible toxic/aseptic filling of clinical trial material in Prefilled Syringes *Dr Jörg Lümkemann, F. Hoffmann-La Roche*	Challenges for Glass Containers: Breakage and Delamination *Dr Uwe Rothhaar, SCHOTT*	Aseptic transfers acro *Benoit Verjans, Aseptic Tec*
12.30 h 12:45 h 13.00 h 13:15 h 13.30 h 13:45 h	Break	Break	Break	Break
14.00 h 14:15 h 14.30 h	Environmental Monitoring requirements for A/B clean rooms and Isolators aseptic processes *Roland Guinet, RGmp Compliance*	Case study: Fill-finish considerations for monoclonal antibodies *Jörg Zimmermann, Vetter Pharma-Fertigung*	Glass Delamination – Characterization and Prevention from Design to Market *Boris Schmid, Stevanato Group*	Special consideration processing of Biologi Isolators *James Drinkwater, Bioque*
14:45 h	Break	Break	Break	Break
15.00 h 15:15 h 15.30 h	E-Beam for presterilized tubs – Challenges in validation: Dosimetry, Killkinetic, Residuals *Manfred Holzer, Skan*	Inspection trends & findings in sterile fill & finish *Dr Daniel Müller, Regierungspräsidium Tübingen*	Not every Type I glass is the same – differences in Type I glasses and their impact *Dr Bettine Boltres, SCHOTT*	A day in the life of an testing and glove lifet *Johannes Rauschnabel, R*
15:45 h 16.00 h	Break		Break	Break
16:15 h 16.30 h 16:45 h	Different Systems for Fogging and Gassing to decontaminate clean Rooms, Isolators and Lyophilizers *Robert Schwarz, Baxter*	Powder filling in closed containers: from myth to reality *Benoit Verjans / Stefan Bernsau, Aseptic Technologies / Harro Höfliger*	CMO Interface with Glass Suppliers *Uli Kuchenbrod, Vetter Pharma-Fertigung*	Glove management *Kathrin Holtei, hameln ph*
17.00 h	Break	Break	Break	Break
17:15 h 17.30 h	Applying the H_2O_2 process in a vacuum sterilizer for alternative use in the transfer of materials and components *Leopold Gruber, SBM Scholler-Bleckmann Medizintechnik*	Inspection of pre-filled syringes incl. methodology for preparing samples *Michael de la Montaigne, Bosch Inspection Technology*	Panel Discussion on current Glass Issues	Implementation of a – a case study *Dr Andreas Reicke, Vetter*
17:45 h 18:00 h	Final Discussion	Final Discussion	Final Discussion	Final Discussion
18.30 h	Social Event for Congress Delegates, Speakers and Exhibitors			

Programme 20 March

arrier Systems	ECA Conference Current Aseptic Technologies	ECA Conference Glass – Glass Breakage – Delamination	ECA Conference Barrier Systems	Time
	Trends in parenteral packaging and the application of QbD-principles to Primary Packaging development and manufacturing *Sascha Karhöfer, West Pharmaceuticals Services*	Final Quality Inspection of primary glass containers for pharmaceutical products *Dr Heino Prinz, Wilco*	Production and validation concepts of an isolator filling line *Stefanie Trudel, Boehringer Ingelheim Pharma*	9.00 h 9:15 h 9.30 h
un a RABS clean *Pharma-Fertigung*	Break Wireless Temperature Measurement in Sterilizers and Parametric Release *Dr Andrea Weiland-Waibel, Explicat Pharma*	Break Minimizing glass container damage with a linear inspection machine *Dr Thomas Jahnen, HEUFT Systemtechnik*	Break Production thinking by H_2O_2 decontamination in isolators; Relevance of critical parameters on the efficiency of the decontamination cycle *Christian Doriath, Skan*	9:45 h 10.00 h 10:15 h
	Break	Break	Break	10.30 h 10:45 h
ator and Cleanroom operating experience *r L+S*	TD-NMR spectroscopy – a new technology for filling weight determination of parenteral drug solution *Dr Tobias Posset, Roche Diagnostics*	Case Study: Safe glass handling - possibilities for risk mitigation *Dr Ingo Presser, Boehringer Ingelheim*	Absorption and Adsorption of Vapor Phase Hydrogen Peroxide on Various Filling Components *Sokhorn Yim, Genentech*	11.00 h 11:15 h 11.30 h
ss a barrier *chnologies*	Break Challenges in Implementing On-line TOC Instruments for Real Time Testing *Jamie Thompson, GE Analytical Instruments*	Break Case study "New parenteral drug product plant at Roche": Design measures of filling machines to minimizes cosmetic defects *Maik Häring, F. Hoffmann-La Roche*	Break Development for Biological Indicators for Hydrogen Peroxide Decontamination *Dr Daniel Scherzinger, Skan*	11:45 h 12.00 h 12:15 h 12.30 h
	Break	Break	Break	12:45 h 13.00 h 13:15 h 13.30 h 13:45 h
ns in Aseptic cal-Toxic products in *ll / PHSS*	Robotics in aseptic processing *Paul Stone / Benoit Verjans, Stäubli / Aseptic Technologies*	Crack Prevention and process controls in pre-fillable syringe manufacturing *Dr Andrea Behrenswerth, Gerresheimer Bünde*	Microbiology in Filling Isolators *Dr Christian Vogt, Novartis Pharma Stein*	14.00 h 14:15 h 14.30 h
isolator glove: Glove time study *obert Bosch*	Break	Break	Break	14:45 h 15.00 h
	Continuous inline blending technology under aseptic conditions with PAT inline analysis *Heiko Bütehorn, GEA Diessel*	Glass Breakage! Solutions in present-day pharmaceutical machine design *Edgar Bauer, Bausch + Ströbel*	Case study: Qualification of an isolator with fast airlock *Dr Christian Vogt, Novartis Pharma Stein*	15:15 h 15.30 h 15:45 h
harmaceuticals	Break Sterile air filtration in critical, high temperature and oxygen-enriched applications *Dr Dirk Sievers, Pall*	Break Cosmetic and critical Impacts of fill- and finish lines to glass containers (incl. a case study) *Dr Wenzel Novak, groninger*	Break Is aseptic filling under isolator realistic in the context of multi-products, multi-formats and high flexibility? *Matthias Poslovski / Dominique Sierakowski, OPTIMA pharma / Octapharma*	16.00 h 16:15 h 16.30 h 16:45 h
sterility test isolator *Pharma-Fertigung*	Final Discussion	Final Discussion	Final Discussion	17:00 h 17:15 h 17:30 h 17:45 h 18:00 h 18:30 h

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- ☐ ECA Conference Sterile Fill & Finish
- ☐ ECA Conference Current Aseptic Technologies
- ☐ ECA Conference Glass – Glass Breakage – Delamination
- ☐ ECA Conference Barrier Systems (Isolators/RABS)

☐ I would also like to take part in the Social Event on the evening of 19 March 2013.

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- ☐ ECA Conference Current Aseptic Technologies
- ☐ ECA Conference Glass – Glass Breakage – Delamination
- ☐ ECA Conference Barrier Systems (Isolators/RABS)

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