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# Single-Use Systems for Sterile & Biotech Applications

Materials, Qualification, Routine

## Speakers:



**Dr Simone Biel**  
*Merck*



**Dr Thomas Centner**  
*io-consultants*



**Dr Michael Eakins**  
*USP Expert Committee  
Member*



**Prof Dieter Eibl**  
*Zürich University of  
Applied Science*



**Prof Regine Eibl**  
*Zürich University of  
Applied Science*



**Steve Hughes**  
*BPL – Bio Products  
Laboratory*



**Bianca van Leeuwen**  
*Janssen Pharmaceutica*



**Dr Daniel Müller**  
*GMP Inspector, Local  
Government Tübingen*



**Dr Julian Roland**  
*GSK, Supplier Quality  
Manager*



State-of-the-Art GMPs for Single-Use  
Systems shown by actual case studies

Image: Merck

4-5 June 2019, Berlin, Germany

## Highlights

- Available SU technology: possibilities and limitations
- EU requirements for the usage of SU equipment
- Current and upcoming US / USP requirements
- Quality assurance for
  - Manufacture of single-use equipment
  - Pharma Manufacturing with single-use equipment
- Design and evaluation of a leachable/extractable study
- Facility design for single-use processes
- Case study Janssen: The conversion from traditional to 100% SU technology
- Case study BPL: Final fill with SU equipment



This conference is recognised for the ECA GMP Certification Programme „Certified Technical Operations Manager“. Please find details at [www.gmp-certification.eu](http://www.gmp-certification.eu)

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# Single-Use Systems for Sterile & Biotech Applications

4-5 June 2019, Berlin, Germany

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**Objectives** This course aims at giving an overview on available Single-Use Technology and how this technology can be implemented in the GMP manufacturing environment.

**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
- 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 are the consequences at the GMP Level?
- What about automation and process controls?
- How much responsibility can be transferred to the SU supplier?

These questions will be answered during the course by experts from pharmaceutical companies and leading suppliers and GMP authorities.

**Target Audience** The course is directed at staff from pharmaceutical industry and suppliers from

- Production
- Engineering
- Research & Development
- Quality Assurance

who want to learn about the technical possibilities offered by Disposables and how Single-Use Equipment can be implemented in a GMP-compliant way.

**Moderator** Prof Dieter Eibl, Zürcher University of Applied Science

## Programme

### **Single-Use Technology in biopharmaceutical production: An overview from USP to Fill&Finish technologies**

- Categorisation of available single-use systems
- Disposables in Upstream-Processing
  - Media preparation
  - Cell expansion and fermentation
- Disposables in Downstream-Processing
  - Filtration and chromatography
  - Buffer preparation and storage
- Disposables in formulation and filling
- Freeze technology
- Hybrid/closed technology platforms

### **Single-Use Systems - GMP inspector's view**

- Overview and evaluation of latest regulatory documents
  - Official guidelines, pharmacopoeias & other papers
  - Recent developments
  - Selected highlights
- Single-use systems versus multi-product equipment
  - important requirements for GMP-compliance
  - regulatory view on both types of systems
- Managing suppliers of single-use systems
  - requirements for supplier qualification
- GMP inspections
  - typical issues and deficiencies

## Quality Approach in Manufacturing of Single-Use Systems

### How to assure performance, robustness, and sterility of single use systems

- Single-use assembly validation
  - Qualification of components
  - Sterilization qualification
  - Manufacturing processes
- Quality control
  - Release testing
  - Certification
- Risk mitigation practices
  - Process particulate control
  - Operator training
- Leachables & Extractables
  - Patient safety evaluation, study design
  - Support by the supplier



Image: Merck

### The USP's Approach to Single-Use Components and Systems used in the Manufacture of Drug Products

- Review of USP's latest draft of Chapter <665> and the accompanying General Information Chapter <1665>
- Explanation of the assessment process, the initial assessment and the risk assessment for materials and systems
- Description and explanation of the extraction solutions
- Description of the extraction process for various components
- Comparison of the extraction solutions with other protocols

### The Role of Extractables Data in the Effective Adoption of Single-Use Systems

The successful adoption of single-use technologies in a biopharmaceutical process largely relies on confidently selecting the right components for use in the fluid path of a product, within a specific process. An important step in choosing such components requires generating an extractables profile, which can be done by carefully selecting the solvent streams and extraction conditions to model the product and process steps complemented with the right analytical strategy. This presentation will focus on:

- The approach to adopt the BioPhorum (BPOG) extractables protocol as a baseline testing strategy.
- How to apply extractables data to a specific process followed by a systematic, risk-based safety assessment approach used for comparing known safety concern thresholds.
- Important stages in the risk assessment process as demonstrated by case studies from typical drug manufacturing processes where single-use components were used.

### Facility Design Considerations for Single Use Processes

- Definition of project scope
- Overall layout and room classification
- Personnel and material flows
- Warehouse and waste management
- Differences from a stainless steel facility

### Case Study BPL - Final Fill using Single Use Technology

- Traditional vs Modern filling of sterile products
- Trials and Tribulations
- Implementation of a SU filling system in a GMP environment
- Final Design
- Continuous improvement & Lessons learned

### Case Study Janssen - From Traditional Manufacturing to 100% Single Use Technology

In 10 years from traditional stainless steel production to 100% SU technology

- Start-up of a 100% single use virus manufacturing facility
- Process development parallel to qualification of single use items
- Process-fit-to plant
- Partnership with vendors

## Case Study GSK Vaccines : Quality requirements for single use systems and filters for the pharmaceutical industry

- GSK Vaccines & QSIM : structure and mission
- Single Use Systems at GSK Vaccines
- Single Use Systems Compliance Qualification
- Concrete example of Compliance Qualification
- GSK Vaccines expectations

### Speakers



#### **Dr Simone Biel | Merck | European Field Marketing Specialist**

Simone Biel is European Field Marketing Specialist in Single Use Technology at Merck. In her role she investigates the market needs in single-use systems, product performance, regulatory compliance, and quality.



#### **Dr Thomas Centner | io-consultants | Business Unit Manager**

Dr Thomas Centner started his carrier at Medigene. He has been Head of Fermentation at Merckle Biotec/ratiopharm and Head of Upstream Development at Sanofi in Frankfurt. Now he is Business Unit Manager at io-consultants.



#### **Dr Michael Eakins | Eakins & Associates | USP Expert Committee member**

Dr. Michael N. Eakins is the Founder and Principal Consultant of Eakins & Associates. Michael was Senior Director of Product Internationalization for Bracco S.p.A. responsible for the strategic development of new packaging within R&D and then Senior Director of the Packaging Center for Corporate Worldwide Sales and Marketing. He is member of the USP Packaging and Distribution Expert Committee for the 2015-2020 cycle.



#### **Prof Dr Dieter Eibl | Zürich University of Applied Science**

Head of the department for Biotechnology and Cell Culture Technology at the Zürcher University of Applied Science. His research focus lies on fermentation and processes based on cell cultures as well as characterization of bio reactions with CFD.



#### **Prof Dr Regine Eibl | Zürcher University of Applied Science**

Professor at the Zürich University and the platform leader for "Single-use technology" of the Swiss Biotechnet. Prof Regine Eibl is a professor at the Zurich University of Applied Sciences, where she lectures in biotechnology and cell cultivation techniques. She is the platform leader for "Single-use technology" of the Swiss Biotechnet and a member of the DECHEMA (Society for Chemical Engineering and Biotechnology).



#### **Steve Hughes | BPL – Bio Products Laboratory | Steriles Technical Support Manager**

Stephen Hughes has 25 year of experience in pharmaceutical fill & finish, having worked for Sanofi, Genzyme and Martindale. Now he is Technical Support Manager at BPL and responsible for the introduction of SU final fill sets and SU filter Kits (PUPSIT).



#### **Bianca van Leeuwen | Janssen Pharmaceutica | Process Engineer**

Bianca van Leeuwen is a lead engineer on single use technology in the Vaccine Launch Facility, which belong to Janssen Biologics and Janssen Vaccines, which is part of the Johnson and Johnson group.



#### **Dr Daniel Müller | Local Government of Germany (Tuebingen) | GMP-Inspector and Head of the GMP Inspectorate Tuebingen**

Daniel Müller is head of GMP inspectorate (local competent authority) at Tuebingen, Germany. Since 2001 he has been working as GMDP inspector, conducting national inspections as well as EMA and overseas inspections. Before joining the authority Dr Müller was working in pharmaceutical industry, last serving as qualified person for sterile drug products. He is member of Germany's expert groups 'biotechnology & tissue' and 'quality assurance'.



#### **Dr Julian Roland | GSK | Supplier Quality Manager**

Dr Roland is working for GSK since 2013. He is responsible for the quality of Suppliers and Incoming Materials, and part of the Vaccines Quality Shared Services in Belgium.

## Social Event

In the evening of the first course day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.



## What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

## How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website <http://www.gmp-compliance.org>

## What Are the Benefits of ECA?

During the membership, you enjoy

- free access to the members' area where you always find the latest update of the "GMP Guideline Manager" online version – allowing you to access a GMP tree with guidelines sorted by topics or by authority. It lets you find relevant guidelines quick and easy. And as member you can also get to this detailed tree with the GMP WebApp on your smartphone or tablet PC.
- a 200,- Euro rebate for any ECA course and conference, plus the opportunity to complete the GMP Certification Programme with an internationally recognised certificate.

## GMP/GDP Certification Programme

This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

ECA Certified Validation Manager  
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ECA Certified API Production Manager  
ECA Certified Quality Control Manager  
ECA Certified Technical Operations Manager  
ECA Certified Computer Validation Manager  
ECA Certified Regulatory Affairs Manager  
ECA Certified Microbiological Laboratory Manager  
ECA Certified Sterile Production Manager  
ECA Certified Biotech Manager  
ECA Certified Pharmaceutical Development Manager  
ECA Certified GMP Auditor  
ECA Certified GDP Compliance Manager  
ECA Certified Packaging Manager  
ECA Certified Data Integrity Manager

On the internet at [www.gmp-compliance.org](http://www.gmp-compliance.org) you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to [info@gmp-compliance.org](mailto:info@gmp-compliance.org) or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

## Easy Registration

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

 **Reservation Form:**  
+ 49 6221 84 44 34

 **e-mail:**  
info@concept-heidelberg.de

 **Internet:**  
www.gmp-compliance.org

### Date

Tuesday, 4 June 2019, 09.00 to approx. 18.00 h  
(Registration and coffee 08.30 – 09.00 h  
Wednesday, 5 June 2019, 08.30 – 14.30 h

### Venue

TITANIC Hotels Berlin  
Chausseestrasse 30  
10115 Berlin, Germany  
Phone: +49 (0)30 311 6858-0  
email: Info.tcb@titanic-hotels.de

### Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

### Conference fees (per delegate plus VAT)

ECA Members € 1,590  
APIC Members € 1,690  
Non-Members € 1,790  
EU GMP Inspectorates € 895

The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch and dinner on the first day, business lunch on the second day and all refreshments. VAT is reclaimable.

### Registration

Via attached reservation form, by e-mail or by fax message.  
Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

### Conference language

The official conference language will be English.

### Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG  
P.O. Box 10 17 64  
69007 Heidelberg, Germany  
Phone +49 (0) 62 21/84 44-0  
Fax +49 (0) 62 21/84 44 34  
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www.concept-heidelberg.de

### For questions regarding content please contact:

Dr Robert Eicher (Operations Director) at  
+49-62 21/84 44 12, or per e-mail at  
eicher@concept-heidelberg.de.

### For questions regarding reservation, hotel, organisation etc. please contact:

Mr Niklaus Thiel (Organisation Manager) at  
+49-62 21/84 44 43, or per e-mail at  
thiel@concept-heidelberg.de.

If the bill-to-address deviates from the specification to the right, please fill out here:

Registration form (please complete in full)

+49 6221 84 44 34

### Single-Use Systems for Sterile & Biotech Applications

4-5 June 2019, Berlin, Germany

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If you cannot attend the conference you have two options:

1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
  - until 2 weeks prior to the conference 10 %
  - until 1 weeks prior to the conference 50 %
  - within 1 week prior to the conference 100 %CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.

If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

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The cancellation fee will then be calculated according to the point of time at which we receive your message.

In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).

German law shall apply. Court of jurisdiction is Heidelberg.

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