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# Single-Use Systems for Sterile & Biotech Applications

Materials, Qualification, Routine

## Speakers:



Niels Alber  
*Triplan*



Dr Simone Biel  
*Merck*



Prof Dieter Eibl  
*Zürich University of  
Applied Science*



Prof Regine Eibl  
*Zürich University of  
Applied Science*



Oliver Küttner  
*Shire*



Dr Daniel Müller  
*GMP Inspector, Local  
Government Tübingen*



Dr Alicja Sobantka  
*Octapharma*



Dirk Tillich  
*Finesse Solutions*



Sue Walker  
*Merck Martillac*



Image: Merck

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

**25-26 October 2017, Vienna, Austria**

## Highlights

- Available Single-Use Equipment from DSP to fill & finish
- GMP requirements for the use of SU equipment
- Facilities for pharmaceutical SU operations
- Automation of single-use equipment
- Leachables & Extractables
- Qualification and Validation
- Case Study Merck Martillac: Bioproduction
- Case Study Novartis: Single-Use filling
- Quality Assurance: testing, qualification & certification of suppliers and equipment



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# Single-Use Systems for Sterile & Biotech Applications

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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
- 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

### **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

### **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

### **Flexible Automation of Single Use Equipment**

- What are the requirements for the process control of Single Use equipment?
- How to adopt the automation to new process requirements, i.e. for CMOs or multi-product suites?
- What is needed for a fully continuous GMP production in Single Use?
- Is Industry 4.0 a matter to consider for the Facilities of the Future?
- Can Single Use facilities utilise MES systems in a meaningful manner?
- How to get a GMP production facility planned and running at a minimum of risk, time and investment?

### **Structured approach for efficient implementation of a single-use system for filling of large volume parenterals**

- Overview structured approach: breakdown of requirements, classification and assignment of accordant tasks
- Expenses vs. benefits
- Challenges
- Role / involvement of supplier
- Extractables & leachables, i.e.: product and patient safety

### **Case Study: Merck Biodevelopment - Key Learnings from Five Years of Operation of a Single-Use MAb Production Facility**

- Description of the facility and staged conversion from stainless steel to single use
- Process template and associated equipment
- Validation considerations
- Daily operation
- Logistics

### **Case Study Novartis: Single Use equipment for Fill/Finish**

- Challenge of filling low volumes / Rational for the change to a peristaltic pump
- Project timelines
- Cooperation with the supplier: allocation of tasks
- Implementation of the new filling system in the GxP environment
- Pros & Cons of the peristaltic filling technique in combination with SU equipment
- Business Case: what has been the added value of the project

### **Quality Assurance concerning SU suppliers & incoming inspections**

- Supplier qualification
- Incoming inspection: own testing vs. supplier certificates
- Handling of changes at the single-use supplier (materials, facility, ..)

## Speakers



### **Niels Alber, TRIPLAN Ingenieur AG**

Niels Alber was Process Expert PU Vials at Novartis in Stein. He studied pharmaceutical technology and started his career at the Fraunhofer IGB (Institute for Interfacial Engineering and Biotechnology). Later he joined Biologische Heilmittel Heel as Production Engineer. Now he works for Triplan again where he had already worked from 2011-2013.



### **Dr Simone Biel, Merck Chemicals GmbH**

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. Simone holds a PhD from the University of Frankfurt in Microbiology.



### **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 Regine Eibl, Zürich University of Applied Science**

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).



### **Oliver Küttner, Shire**

During the past years, he's been working for Baxter and Baxalta in local and global Quality Management positions. Currently he is in charge of the Material Life Cycle Management for raw, starting and packaging materials in EU and Asia at Shire.



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

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



### **Dr Alicja Sobantka, Octapharma Pharmazeutika Produktionsges.m.b.H**

At the Octapharma Pharmazeutika Produktionsges.m.b.H. Alicja is responsible for material qualification at corporate level encompassing monitoring and assessment of physical, functional, biological, chemical and regulatory requirements for optimal choice of processing and packaging material. In this context, Alicja also performs extractables and leachables assessments including the planning and supervision of extractables and leachables studies."



### **Dirk Tillich, Finesse Solutions AG**

Dirk Tillich has a degree in Electrical Engineering and is working more than 25 years on sensors, analyzers and process control systems for biotech applications. He directed the Marketing and Sales of HAMILTON's sensors business for 11 years. In 2008 he joined Finesse 2008 to establish the business in Europe.



### **Sue Walker, Merck Martillac**

Sue Walker is a chemical engineer and she is currently on the Provantage End-to-End Solutions Delivery team at Merck. Prior to her current position, she has over 25 years of technical experience touching on all major aspects of biopharmaceutical processing including R&D, Process Development, Clinical Manufacturing, Materials Management, Validation, and QA. Her experience has included both chemical and biological processing and over a decade of experience with single use technologies.

## Social Event

In the evening of the first conference 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  
ECA Certified QA Manager  
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

Wednesday, 25 October 2017, 10.00 to approx. 18.00 h  
(Registration and coffee 09.30 – 10.00 h)

Thursday, 26 October 2017, 08.30 to approx. 14.30 h

### Venue

Austria Trend Hotel  
Park Royal Palace Vienna  
Schlossallee 8  
1140 Vienna, Austria  
Phone +43/1/89110 9 200  
Fax +43/1/891 109 050  
Email park.royal.palace@austria-trend.at

### 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, dinner on the first day, lunch on both days 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  
info@concept-heidelberg.de  
www.concept-heidelberg.de

### For questions regarding content:


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.:

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

25-26 October 2017, Vienna, Austria

Mr  Ms Title \_\_\_\_\_

\_\_\_\_\_  
First name, surname

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Company

\_\_\_\_\_  
Department

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

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69007 Heidelberg  
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.  
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■ 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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**Important:** This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing.

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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