ECA Academy
Your GMP/GDP Information Source

Speakers

Dr Simone Biel
Merck

Prof Dr Regine Eibl
Zürcher University of Applied Science

Dr Daniel Müller
Local Government of Germany (Tuebingen)

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Single-Use Disposables – What you need to know

Live Online Training on 20 February 2024

Image: Sartorius

Highlights

- Available SU Technology: Possibilities and Limitations
- GMP Requirements for the Usage of SU Equipment
- Quality Assurance for Manufacture of Single-Use Equipment
- Design and Evaluation of a Leachable/Extractable Study
- Case Study Merck: Single-Use Technology in Aseptic Drug Product Manufacturing

Technology, Quality and GMP-Requirements

Objective

This online training course gives 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
- High flexibility

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?
- How much responsibility can be transferred to the SU supplier?
- How should Leachable&Extractable Data be evaluated?

These and other questions will be discussed and answered during the course by experts from university, pharmaceutical industry 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 how Singe-Use Equipment can be implemented in Biotech and Sterile Operations in a GMP-compliant way.

Moderator

Prof Dr Regine 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

The Role of Extractables/Leachables in the 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

Case Study Merck: Single-Use Technology in Aseptic Drug Product Manufacturing

- Reasons for using SUT
- Process: pooling, filtration, filling
- Project: facility and equipment pre-requisites, qualification and implementation of SUS
- Risk identification when using SUT and mitigation strategy (e.g. integrity assurance)
- Lessons learned and best practice when moving from traditional filling to SUT

Your Benefits

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...“. This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.


CERTIFICATE

Speakers

Dr Simone Biel
Merck

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.

Prof Dr Regine Eibl
Zürcher University of Applied Science

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).

Dr Daniel Müller
Local Government of Germany (Tuebingen)

Daniel Müller is head of GMP inspectorate (local competent authority) in 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’.

Nicola Rutigliani
Merck

Nicola Rutigliani is a Senior Project Manager and is leading the start-up phase for the three new filling lines under isolator at Merck - Bari site. Before, he was holding various positions in manufacturing, QC, Technology Transfer and has variegated experiences in NBE/Biosimilars launches, commercial products life cycle management, process & cleaning validation and GMP manufacturing process design for both stainless steel and SUT.

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Reservation Form (Please complete in full)

Live Online Training: Single-Use Disposables – What you need to know, 20 February 2024

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
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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 July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training

Tuesday, 20 February 2024
09.00 to approx. 17.15 h CET

Technical Requirements

We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members €990
APIC Members €1.090
Non-ECA Members €1.190
EU GMP Inspectorates € 595
The conference fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Conference language

The official conference language will be English.

Organisation and Contact

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