Image:
ebeam Technologies

Including workshops and Live Demos at SKAN

E-Beam
for surface decontamination of pre-sterilized syringes

3-4 May 2016, Basel, Switzerland

SPEAKERS:

Manfred Holzer
SKAN

Steen Kreinbrink
ebeam Technologies

Arne Miller
DTU Nutech

Dr Daniel Müller
GMP/GDP Inspectorate Local Government

Liwia Rajpert
SKAN

Patrick Vanhecke
GSK Vaccines

Thomas Zinn
Sandoz

HIGHLIGHTS:

- Technology & Applications
- Dosimetry validation
- Validation of an E-Beam
- Regulatory requirements
- Case studies from
  - GSK Vaccines
  - Sandoz
  - SKAN

ECA ACADEMY

This education course is recognised for the ECA GMP Certification Programme „Certified Sterile Production Manager". Please find details at www.gmp-certification.eu

E-Beam for surface decontamination of pre-sterilized syringes

3-4 May 2016, Basel, Switzerland

Objectives

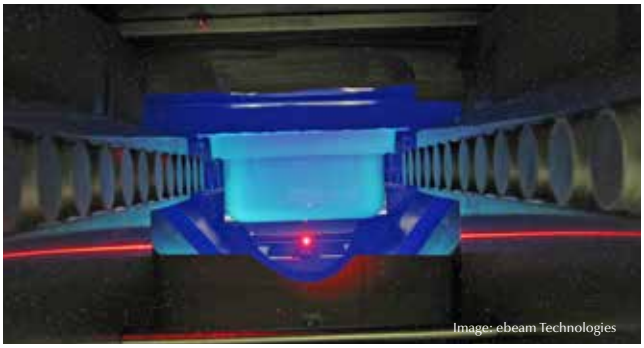
- You get to know the principles of using continuous E-Beam systems for the surface decontamination of tubs
- You become familiar with the critical process steps that have to be clarified within the framework of the qualification and validation of these systems
- In case studies you can share your colleagues' first-hand experiences
- In workshops / live demos at SKAN you can discuss the pros and cons of using these systems with experts from industry, authority and science

Background

With regard to sterile finished medicinal products, above all high-priced products in the field of biotechnology, there is a clear trend towards ready-to-use syringes.

The ready-to-use syringes in tubs are sterilised at the syringe manufacturer's site and distributed in bags. Still, when they are introduced into the isolator, certain microbiological risks arise for the filling process in the isolator. For this reason, after having been unwrapped, the tub is introduced into the isolator through an E-Beam tunnel in order to ensure the outer sterilisation of the tub.

Here, apart from the high costs caused by acquisition, operation and maintenance, the use of E-Beam systems also requires careful consideration of the consequences the radiation has for the packaging material and its environment.



Target Audience

The event is made for decision makers in pharmaceutical companies and their suppliers who use the E-Beam technology in connection with pre-filled syringes or who intend to do so in the future.

The number of participants is limited.
Please understand that, for competitive reasons, not all firms can register their employees for this event.

Programme

Technology & Application

- Technology history
- E-Beam technology
- Basic technology (Science)
- Construction lamp etc.
- Lifetime
- Application areas
- Sterilization
- Products

E-Beam from an inspector's point of view

- Relevant GMP guidelines (aseptic processing)
- Regulatory view on
  - pharmaceutical application of e-beam tunnels
  - alternative methods for material transfer (sterilisation, decontamination, disinfection)
- Experience from inspections (including observations & discussion points)

Nature of radiation and dosimetry basics

- Gamma / X-ray / E-Beam
- Types of radiation facilities
- Absorbed dose
- Dosimeters
- Calibration
- Measurement traceability and uncertainty
- Guide on the use of low energy electron beams for microbiological decontamination of surfaces

Case study GSK Vaccines

- GSK User Requirement Specifications
- Description of the line
- Design of E-Beam Tunnel
- IQ/OQ Qualification
- Performance Qualification
  - Dose Mapping
  - BI's sterilization
  - Ozone

Case study Sandoz

- Equipment selection
- Timeline
- Layouts
- Validation
- Project experience

Practical Validation of an E-Beam

- Dosimetry with dosimeter film
- Dosimetry with Biological Indicators
- Kill Kinetic
- Dosimetry Strategy
- Residuals
- Good Documentation Practice – E-Beam Validation

Workshops / Live Demos / Plant tour

E-Beam basic's, features, history, case studies

- Basics of E-Beams
- Features of an E-Beam line
- History & number of E-Beam world wide for pharmaceutical applications
- Latest layouts / case studies with E-Beam for pre-sterilized syringes (Layout / Room Concept)

Live Demos:

Detail explanation of electron accelerator Technology

- Complete engine
- EBLab

Detail demonstration of E-Beam syringe line

- Tub run through with dosimeter

Detail explanation of validation equipment

- Testing equipment incl. evaluation of dosimetry of tubs

Plant Tour at SKAN with different types of equipment

- E-Beam & isolator filling-line for pre-sterilized syringes
- Large scale vial and freeze dryer isolator line
- PSI-L clinical filling isolator
- PSI-M Sterility testing isolator
- Glove Testing Unit's
- SKANFOG Room-To-Room Material transfer hatch

The workshops / Live Demos / Plant tour will take place at SKAN AG in Allschwil on 4th May. At appr. 15.30 h, a bus shuttle service will bring the participants to the airport, the train station or the hotel.

Social Event

On 3 May, 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.

Speakers

Manfred Holzer,
SKAN AG, Allschwill, Switzerland
Engaged in the Pharma Isolator bussiness since 1995 he joined SKAN in 2000. In 2008 he launched the SKAN E-Beam and heads today the business development of the SKAN E-beam & RABS Systems.

Steen Kreinbrink,
ebeam Technologies, Flamatt, Switzerland
Steen has more than 15 years of experience as a business developer and CEO for companies doing engineering solutions for filling and packaging lines in the Pharmaceutical and Food industries.

Arne Miller,
DTU Nutech, Roskilde, Denmark
Arne Miller is head of the internationally recognized Risø High Dose Reference Laboratory at DTU Nutech, Technical University of Denmark, and he has worked in the field of high dose dosimetry for more than 40 years. Arne has is author or co-author of more than 100 papers, including the "Guide on the use of low energy electron beams for microbiological decontamination of surfaces.

Dr Daniel Müller,
GMP/GDP Inspectorate Local Government, Germany
Daniel Müller started working in the pharmaceutical industry in 1998. Among other positions he served as a Qualified Person of large volume parenterals. In 2001 he joined a German inspectorate at Tübingen.

Liwia Raijpert,
SKAN AG, Allschwil, Switzerland
is a Project Engineer at SKAN AG in the Department of Process Validation Microbiology. She is responsible for validation of E-beam surface decontamination, H_2O_2 microbiological qualification, customised scientific studies and acquisition of new research projects.

Patrick Vanhecke,
GSK Vaccines, Wavre, Belgium
Patrick Vanhecke joined GSK Bio in 1992 as Aseptic Filing Manager in Rixensart (Belgium). In 1998 he was transferred to the Wavre site (Belgium) as Aseptic Filling Manager and was in charge of a new project in Aseptic Filling based on Isolator technology. In 2002 he joined the Global Technical Services and today is in charge of Isolator and Aseptic Filling Technologies projects.

Thomas Zinn,
Sandoz AG, Schaftenau, Austria
Thomas Zinn joined Novartis in 2003 as manager in the sterile production in Stein and later as Head Quality Systems Chemical Operations Switzerland. Now he is Plant Head Bioinject in the Business Unit Sandoz Biopharmaceuticals.

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

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

E-Beam for surface decontamination of pre-sterilized syringes
3-4 May 2016, Basel, Switzerland

☐ Mr ☐ Ms

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **P.O. Number (if applicable)**

Street/P.O. Box

City | Zip Code | Country

Phone/Fax

E-Mail (please fill in)

CONCEPT HEIDELBERG
P.O. Box 101764
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D-69007 Heidelberg
GERMANY

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 2 weeks prior to the conference 10 %,
- until 1 week 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.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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)

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Date

Tuesday, 3 May 2016, 9.00 h – 17.30 h
(Registration and coffee, 08.30 h – 09.00 h)
Wednesday, 4 May 2016, 8.30 – 15.30 h

Venue

Dorint – An der Messe
Schönaustrasse 10
4058 Basel, Switzerland
Phone +41 61 6957-000
Fax +41 61 6957-100

The workshops / Live Demos / Plant tour will take place at SKAN AG in Allschwil on 4th May. At appr. 15.30 h, a bus shuttle service will bring the participants to the airport, the train station, or the hotel.

Fees (per delegate plus VAT)

ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
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.

Accommodation

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

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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bach@concept-heidelberg.de.