ECA
European Compliance Academy

Visit the newest parenterals facility in Europe

Image: Roche

Modern Sterile Facilities 2011

New Roche Parenterals Facility

15-16 November 2011, Basel, Switzerland

SPEAKERS

IRMHILD BERNHARD
Roche

MARTIN EISENHAWER
Swissmedic

FRIEDRICH HAEFELE
Boehringer Ingelheim

JÖRG LÜMKEMANN
Roche

STEFAN MERKLE
Cilag

NUBIA MORALES
Roche

RAINER SCHMIDT
Roche

MICHAEL SCHNEIDER
Roche

PHILIP SCHNEIDER
Roche

ALEXANDER STERCHI
Roche

SIMON STOCKER
Roche

HIROKAZU SUGIYAMA
Roche

HIGHLIGHTS:

- The new Roche Parenterals facility in Kaiseraugst
  - Project Scope
  - Barrier Systems
  - Environmental Monitoring
  - Decontamination System
  - Prefilled Syringes
  - Operational Excellence
  - Manufacturing Execution System
- Case Studies:
  - New Roche research & development building
  - SCF syringes line at Cilag
  - Boehringer Ingelheim Isolator Project
- EU GMP Guide Annex 1: Interpretation by inspectors

This conference is recognised for the ECA GMP Certification Programme „Certified Technical Operations Manager". Please find details at www.gmp-certification.eu

Modern Sterile Facilities 2011

15-16 November 2011, Basel, Switzerland

Objectives

- You will get first hand information on the newest European parenterals facility
- You will have the opportunity to visit the new plant to discuss directly on-site the technological solutions
- Three additional case studies from other facilities and companies will show you different approaches on how to transfer GMP requirements into practice.

Background

GMP requirements for the manufacture of sterile pharmaceuticals have been increasing for years now. In many cases these current requirements can not longer be integrated economically into existing production facilities. The construction of a new greenfield factory allows to optimally combine the latest GMP requirements with production and logistical concepts.

In the year 2006, F.Hoffmann-La Roche Ltd. in Basel decided to invest more than 200 Mio. CHF to build a new parenterals facility in Kaiseraugst – close to the Basel headquarters.

Some of the highlights of the new facility are:

- Use of Advanced Aseptic Technology
- Isolator and RABS for filling to ensure aseptic handling and to avoid particles
- Isolators for compounding and unloading of freeze dryers for high potent / hazardous materials
- MES supporting a "paperless" factory
- Quality by design to avoid loss of products: particles, scratches on glass and cosmetic defects

Target Audience

The event is designed to address executives and experts from the fields of production, technology, engineering and quality assurance responsible for implementing current regulations in sterile operations. It also addresses planners and suppliers in the area of sterile pharmaceuticals.

Due to the plant tour the number of participants is limited.

Programme

Project Scope

- Design strategy of new parenterals facility
- Future extension possibilities
- Existing process technologies
- Personnel and material flow
- Project execution
- Time schedule of project
- Lessons learnt

RAINER SCHMIDT, SIMON STOCKER

Experiences with Isolator Technology and RABS

- Decontamination cycle
- Set-up and change over
- Aseptic connections
- Glove handling and testing
- Interventions
- Media Fills

PHILIP SCHNEIDER

Environmental Monitoring in a new Parenterals Production

- Microbiological clean room qualification: From qualification to routine
- Implementation and documentation of monitoring data

IRMHILD BERNHARD

Design, Construction and Qualification of a Room Decontamination System for Aseptic Filling Room with RABS

- Design
- Distribution of hydrogen peroxide
- Decontamination of a room in overpressure
- RABS

ALEXANDER STERCHI

Programme (cont'd)

Plant Tour

On the afternoon of the 1st day you can visit the new Roche parenterals facility in Kaiseraugst closed to Basel. You will see the different parts of the facility (technical areas, production areas, barriers systems etc.) in detail.

Prefilled Syringes: From start-up to product validation – the owner's view

- Start-up
- Qualification Process/Product validation
- Media Fill experience
- Lessons learnt

NUBIA MORALES

Operational Excellence in Sterile Drug Product Manufacturing – Case Study in New Parenterals Production in Kaiseraugst

- Framework of the „Parenterals Excellence at Kaiseraugst (PEaK)"
- Bottom-up improvement with „Excellence Circle"
- Top-down improvement using Lean Six Sigma

HIROKAZU SUGIYAMA

A Manufacturing Execution System (MES) as basis for the paperless factory and efficient processes

- Successful data integration from the planning system to automation
- Do's and don'ts during the introduction of a new MES
- Cost-benefit analysis for paperless batch documentation
- Review by Exception and the paperless authority inspection

MICHAEL SCHNEIDER

New building for reseach & development in Basel: Process development for parenterals and requirements for production of clinical material

- Overview layout
- Defined performance and formats for liquid vials and prefilled syringes
- Filling of technical batches / process development; clinical supply; analytical reference samples
- Integration into the Containment (characteristics of zone B as background)
- Feature: Possibilities for interventions (deplete individual compartments, etc.)
- Sampling mode for vials, syringes and bulk solution
- Defined filling technique (piston pump/peristaltic pump)
- Measures to avoid scratches and particles (i.e. tunnel feed)
- Sampling mode for lyophilisation
- Design of filling equipment / CIP/ SIP/ DIP system -> reduced surfaces with product contact

JÖRG LÜMKEMANN

Case Study: Implementation of a compact SCF syringe filling line in isolator technology

- Nested syringe filling
- Technology selection
- Isolator Technology
- E-Beam surface decontamination
- Qualification strategy
- Start up challenges
- Performance optimization

STEFAN MERKLE

Programme (cont'd)

Case Study: BI Isolator Project: Aseptic Processing Unit 5 - a modular concept for capacity expansion

- Project Challenges
- Regulatory Aspects
- Where we come from...
- Project Rationale
- Basic Requirements, Scope and Timelines
- Project Implementation
- Vision 2012

FRIEDRICH HAEFELE

Annex 1 Interpretation by PIC/S / EMA, Implications in Aseptic Manufacturing

- Interpretation of the most important changes of the last revision of Annex 1
- Consequences of the implementation of ISO 14644
- Qualification vs. Monitoring
- Requirements for environmental monitoring
- Bioburden
- New requirements on the environment of crimp-capping operations, grade A air supply

MARTIN EISENHAWER

Speakers

IRMHILD BERNHARD
F. Hoffmann-La Roche AG, Basel. Head of Microbiological Quality Control
Since 2007 I. Bernhard is heading Microbiological Quality Control. She is holding a degree in hygiene technology and a Master degree in biomedical engineering at the University of Sigmaringen, Germany.

MARTIN EISENHAWER
Swismedice, Bern, Switzerland
He has several years of experience working for the pharmaceutical industry, especially in the field of stable blood products and parenterals. During these years he occupied several functions, e.g. Head QA and Head QC. Since seven years he is working as a GMP-inspector for the Swiss National Regulatory Agency, Swissmedic. He has several mandates with WHO and is the main author of PIC/S technical interpretation of Annex 1, PI 032.

DR FRIEDRICH HAEFELE
Boehringer Ingelheim Pharma GmbH & C. KG, Biberach. Vice President in the business domain Biopharmaceuticals
Dr Haefele has been in the pharmaceutical industry for almost 20 years now. In May 2006 Dr Haefele joined Boehringer-Ingelheim Pharma where he is responsible for the department Biopharma Operations, managing the Aseptic Processing of Biopharmaceuticals to Drug Products filled into Vials and Prefilled Syringes.

DR JÖRG LÜMKEMANN
F. Hoffmann-La Roche AG, Basel. Building 97 & New Technologies
Since 2010 J. Lümkemann is heading the department for implementation of new technologies and engineering support for parenteral production. From 2001 – 2009 he was responsible for process development of new products, the manufacturing of clinical products and the technical transfer to commercial production. Since 2006 he is supporting the planning and execution within a project for a new building (97) for technical development in Basel

DR STEFAN MERKLE
Cilag AG/Johnson & Johnson, Schaffhausen. Director of the Parenteral Business Unit of J&J's Global Pharmaceutical Supply Group at Cilag AG.
Stefan Merkle is responsible for fill and finish of all J&J parenteral biotech compounds manufactured in Europe and sold in all major markets. He's been with Johnson & Johnson for 18 years, in Pharmaceutical Development, Clinical Supplies Manufacturing, Technology Transfer and Operations

DR NUBIA MORALES
F. Hoffmann-La Roche AG, Basel. Head of Prefilled Syringes line
N. Morales is heading the prefilled syringes line. She joined the Parenterals Facility project team in 2008 as head of filling for prefilled syringes, liquid and lyo Vials. Prior she was responsible for the water system in the parenteral production at Roche in Basel. N. Morales is pharmacist by training and is holding a Ph.D. from University Leipzig, Germany.

Speakers, cont'd

DR RAINER SCHMIDT
F. Hoffmann-La Roche AG, Basel. Business Owner
Since 2006 R. Schmidt is Business Owner of the New Parenterals Plant in Kaiseraugst. He started his career 1989 at Schwarz Pharma, Germany. In 1994 he joined Roche and was holding different functions in quality and drug product manufacturing. R. Schmidt is pharmacist by training and is holding a Ph.D. from University Tübingen, Germany.

DR MICHAEL SCHNEIDER
F. Hoffmann-La Roche AG, Basel. Head of Production Data Management
Michael Schneider leads the Production Data Management team, responsible for the electronic systems managing the production data. Michael joined the Parenterals Facility project team in 2007 as MES implementation project manager. Before that, he was user representative for the implementation of MES and automation of a green field biotech plant. Michael holds a PhD and a Master in Chemical Engineering from ETH Zürich. He joined Roche in 2004 as a Technical Operations Trainee.

PHILIP SCHNEIDER
F. Hoffmann-La Roche AG, Basel. Head of Production Start-up
Since 2008 Ph. Schneider is heading production start-up. During more than 18 years of professional experience he was holding different function within Quality at Siegfried Pharma, DSM, Genzyme and Roche. He is holding a B.Sc. in analytical chemistry from university for applied science Isny, Germany and an MBA from University St. Gallen, Switzerland.

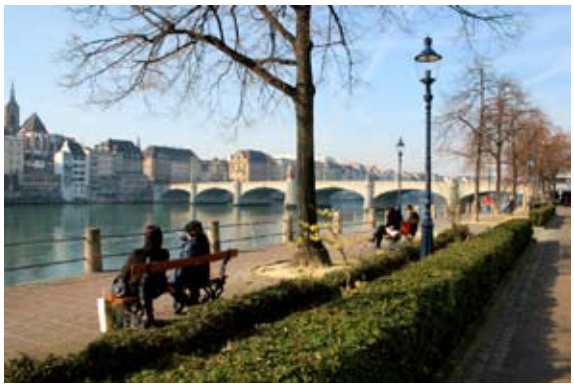
DR ALEXANDER STERCHI
F. Hoffmann-La Roche AG, Basel. Head of Logistics, Services & Infrastructure
Since 2008 A. Sterchi is heading Logistics, Services & Infrastructure. From beginning of planning and construction for the new facility in Kaiseraugst in 2006 he was the user-representative for building and infrastructure within the project. A. Sterchi joined Roche in 1999 as a training manager in the parenterals production in Basel before he took over the "Support and Training" group in the same facility. A. Sterchi is pharmacist by training and is holding a Ph.D. in pharmaceutical analytics from ETH Zürich, Switzerland.

SIMON STOCKER
F. Hoffmann-La Roche AG, Basel. Head of Parenterals Process Engineering Kaiseraugst
From 2006 - 2010 S. Stocker was Technical Project Manager of the New Parenterals Plant in Kaiseraugst. During more than 25 years of professional experience he was holding different functions in Engineering for solid and liquid dosage forms at Roche in Basel. S. Stocker is holding a Bachelor in Mechanical Engineering from University for Applied Science in Muttenz, Switzerland.

DR HIROKAZU SUGIYAMA
F. Hoffmann-La Roche AG, Basel. Head of Operational Excellence
Since 2009 Dr. Sugiyama is responsible for Operational Excellence within Roche's new Parenterals production facility in Kaiseraugst. Born and raised in Tokyo, Hirokazu Sugiyama studied chemical engineering at the University of Tokyo and earned his PhD from ETH Zürich. After his studies he joined F. Hoffmann-La Roche AG as a trainee within Galenical manufacturing in Basel/Kaiseraugst.

Social Event

On 15 November 2011, 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.



Easy Registration

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Internet:
www.gmp-compliance.org

Date
Tuesday, 15 November 2011, 9.00 h – 18.00 h
(Registration and coffee 8.30 h – 9.00 h)
Wednesday, 16 November 2011, 8.30 h – 17.00 h

Venue
Ramada Plaza Basel
Hotel & Conferece Center
Messplatz 12
4058 Basel, Switzerland
Phone +41 (0)61 560 40 00
Fax +41 (0)61 560 55 55

Fees
ECA Members € 1,590.- per delegate plus VAT
APIC Members € 1,690.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1,790.- per delegate plus VAT
EU GMP Inspectorates € 895.- per delegate plus VAT
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 hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation or be sure to mention "Concept-Heidelberg" to receive the specially negotiated rate (CHF 289,- per night, incl. breakfast + CHF 3,50 city tax per day and person) for the duration of your stay. Reservation should be made directly with the hotel not later than 14 October 2011. Early reservation is recommended.

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

Conference language
The official conference language will be English.

Organisation and Contact
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
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Dr Andreas Mangel (Operations Director) at
+49-62 21 / 84 44 41, or per e-mail at
mangel@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Ms Nicole Bach (Organisation Manager) at +49-62 21 / 84 44 22, or per e-mail at bach@concept-heidelberg.de.

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15-16 November 2011, Basel, Switzerland

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