ECA Certified Quality Control Manager Course*

Including a visit of the new production plant of Helvoet Pharma in Alken, Belgium

Image: Helvoet Pharma

Elastomeric Closures for Injections

8-9 February 2011, Brussels, Belgium

SPEAKERS:

Dr Piet Christiaens
Toxikon Europe, Belgium

Dr. Helmut Gaus
Rentschler Biotechnologie, Germany

Dr Renaud Janssen
Helvoet Pharma, Belgium

Dr. Bram Jongen
Helvoet Pharma, Belgium

Dr. Tobias Mundry
Bayer Schering Pharma, Germany

Dr Lars Sukowski
F. Hoffmann – La Roche, Switzerland

Rutger Vandiest
Helvoet Pharma, Belgium

PROGRAMME:

- How to Manufacture Elastomeric Closures
- Regulatory Requirements (Ph.Eur., USP, FDA, etc.)
- Quality Testing of Rubber Parts
  - Acceptable Quality Limits (AQL)
  - Risk-based Approach of Testing
  - Reduced Testing
- Siliconisation
- Extractables and Leachables Testing
  - Analytical Techniques
  - Dos and Don'ts in Extractables and Leachables Studies
- Container Closure Integrity
- Ready-to-Use Injection Stoppers and ISO 11137
  - Irradiation
  - Validation
- Elastomeric Closures in Pharmaceutical Manufacturing

ECA
EUROPEAN COMPLIANCE ACADEMY

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

Elastomeric Closures for Injection

8-9 February 2011, Brussels, Belgium

Learning Objectives

Elastomeric closures are key packaging components for sterile pharmaceutical dosage forms like syringes or vials. They are, or may be, in direct contact with the drug product. Elastomeric closures can be of natural or synthetic origin with a complex mixture of many components.

Due to the criticality of elastomeric closures as primary packaging materials for sterile dosage forms, this education course deals with all important steps in the manufacturing and testing of elastomeric closures as well as with the use of these parts in pharmaceutical manufacturing.

Topics that will be covered include:

- Pharmacopoeial requirements
- The Defect Evaluation List as a help in the quality control of stoppers
- How to test incoming closures
- Elastomeric closures in pharmaceutical manufacturing
- Siliconisation of rubber stoppers
- Extractables / leachables testing – why information from compendial methods may not be sufficient

Additionally, this course offers the participants the opportunity to see and learn how elastomeric closures are manufactured by the visit of a well-known manufacturer of elastomeric closures in Alken, Belgium.

Target Group

This GMP Education Course on elastomeric closures for injections is directed at employees in pharmaceutical quality control departments who are responsible for sampling, testing, approval and control of rubber stoppers. The course is also intended for personnel dealing with elastomeric closures in pharmaceutical development, quality assurance and manufacturing.

Social Event

After the site visit at Helvoet Pharma on 8 February you are cordially invited to a dinner in the Novotel Brussels Airport Hotel. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Programme

An Introduction to Elastomeric Closures

- Most commonly used ingredients
- Main production steps
- Specific IPCs
- Tendencies:- Ready to sterilize
  - Ready to use
  - Coated closures
  - Evolution in drug delivery

RUTGER VANDIEST, Helvoet Pharma N.V.

Regulatory Requirements for Elastomeric Closures

- Pharmacopoeial requirements
- FDA Guidances
- Miscellaneous requirements
  - BSE/TSE
  - Heavy metals
  - REACH
  - .....
- Labeling on Ferrules and Cap Overseals

DR RENAUD JANSSEN, Helvoet Pharma N.V.

AQL Testing of Rubber Parts

- Defect Evaluation List for Rubber Stoppers
- How to establish a Defect Evaluation List (DEL)
- Editio Cantor DEL and/or more?
- Border line samples, how to use them in the vendor/customer relationship
- Vendor Contract versus Defect Evaluation List

DR HELMUT GAUS, Rentschler Biotechnologie GmbH

Quality Testing of Elastomeric Closures

- Certificate of compliance and certificate of analysis
- Approving and setting specifications
- Sampling and inspection of incoming components
- Selection and approval of supplier
- Risk-based approach of testing
- Reduced testing

DR HELMUT GAUS, Rentschler Biotechnologie GmbH

Siliconisation of Rubber Stoppers

- Goals and application fields of rubber siliconisation
- Regulatory requirements
- Analytical methods for evaluation of siliconised rubber components
- Siliconisation techniques at suppliers and pharmaceutical manufacturers
- Validation of siliconisation processes
- Silicone migration in pharmaceutical products
- Influence of sterilization processes on silicone (Autoclave, Gamma, EO)
- Silicone free rubber stopper developments
- Case reports

DR TOBIAS MUNDRY, Bayer Schering Pharma AG

Extractables and Leachables Testing for Elastomeric Closures

- Introduction
- Regulatory aspects
- The physics of polymer migration
- Analytical techniques used for extractable and leachable testing
- Dos and don'ts in extractable studies
- How to focus on the right extractable compounds during the design of a leachable study
- Dos and don'ts in leachable studies

DR PIET CHRISTIAENS, Toxikon Europe NV

Container Closure Integrity Testing

- Definition of integrity & leakage
- Regulatory requirements regarding closure integrity
- Integrity testing vs sterility test in stability studies
- Factors influencing closure integrity
- Test methods (physical & microbiological) – application fields, strengths & weaknesses
- Development testing and in process control
- Case reports

DR TOBIAS MUNDRY, Bayer Schering Pharma AG

Validation of Ready-to-Use Injection Stoppers

- Ready-to-Use and ISO 11137
- Influence of irradiation on stopper properties
- Influence of irradiation on properties of packaging material for closures
- Validation of irradiation process

Dr BRAM JONGEN, Helvoet Pharma N.V.

Elastomeric Closures in Pharmaceutical Manufacturing

- Storage and shelf life
  - Storage conditions
  - Storage time
  - Retesting
- Washing/sterilization
- Handling within the sterile compartment
- Common issues

DR LARS SUKOWSKI, F. Hoffmann-La Roche Ltd.

Visit of Helvoet Pharma in Alken, Belgium

In the afternoon of the first conference day all participants and speakers are invited to a guided tour of the **new production plant of Helvoet Pharma** in Alken, Belgium. Helvoet Pharma is the world's second largest manufacturer of elastomeric closures and aluminium/plastic caps for pharmaceutical applications.

The number of participants for the plant visit is limited. Please note, that participants from direct competitors of Helvoet Pharma are not allowed to visit Helvoet Pharma. Thanks a lot for your understanding.

Speakers

Dr Piet Christiaens

Toxikon Europe NV, Heverlee, Belgium

In 2001, Dr Christiaens joined Toxikon Europe where he holds the position of Scientific Director. In this position, he develops analytical methods and protocols for both extractables and leachables studies for the Medical and Pharmaceutical Industries. Mr Christiaens oversees all laboratory operations at Toxikon Europe and is also giving support to the European business development.

Dr Helmut Gaus

Rentschler Biotechnologie GmbH, Laupheim, Germany

Dr Gaus started at Merckle/ratiopharm, in 2001 he took over at Novartis Generics, the position of Qualified Person and Head of Quality Control. From 2003 to 2006 he was Head of Quality Control at Vetter Pharma. Since 2006 he is Qualified Person and Vice President Quality Control at Rentschler Biotechnologie. Within his various positions in the pharmaceutical industry the incoming inspection of packaging components was always part of his responsibility.

Dr Renaud Janssen
Helvoet Pharma Belgium N.V., Alken, Belgium
For over 20 years Renaud Janssen has been holding R&D, Technical Support and Quality functions at Helvoet Pharma. He currently is Global Director of Scientific Affairs for Helvoet Pharma worldwide. Renaud is a member of various normalization committees in the field of pharmaceutical rubber.

Dr Bram Jongen
Helvoet Pharma Belgium N.V., Alken, Belgium
After his Masters in Polymer Chemistry at the University of Louvain, Belgium, Bram Jongen successfully finished a Ph.D. in Water Soluble Polymers used for advanced drug administration. Bram started as Technical Support Manager for Helvoet Pharma about 6 years ago, supporting customers in a vast area from West-European countries to distant countries like India, Korea and South-Africa. Since 2010, he leads the Product Support team, a team of experts in the world of pharmaceutical closures. Within Helvoet Pharma, he further specializes himself in the world of Extractables and Leachables including the coordination of all internal and external E&L studies.

Dr Tobias Mundry
Bayer Schering Pharma AG, Berlin, Germany
Dr Tobias Mundry started at the Schering AG in 1999 in the Pharmaceutical Development (Container Development) organization. Starting in 2003 he has been working as Director in the Department Packaging & Application Systems Development. From 2006 he was head of an Analytical Development laboratory unit and responsible for analytical method development for investigational and marketed active ingredients and drug products. Since 2010 Dr Mundry is Director of a Project Lab responsible for analytical development, quality control and release of investigational and marketed drug products (oral, parenteral, inhalation) in clinical phases I-III.

Dr Lars Sukowski
F. Hoffmann-La Roche Ltd., Basel, Switzerland
Roche is running several Parenterals facilities in Switzerland, Germany, the US and Shanghai. Dr Lars Sukowski serves as Technical Operations Support for the European based manufacturing sites within Roches global Biologics network. Since 2001 after joining Roche Dr Sukowski was holding different positions in the areas Galenical manufacturing, quality control and API manufacturing.

Rutger Vandiest
Helvoet Pharma Belgium N.V., Alken, Belgium
Rutger Vandiest joined Helvoet Pharma 2 years ago as Marketing and Business Development Manager. In his position he holds global responsibilities for framing the short and long term strategic marketing plan for the parenteral containers segments and the creating of business cases to support this marketing plan. Before joining Helvoet Pharma Rutger Vandiest held for more than 15 years in the pharmaceutical industry leading positions in sterile filling operations, validation and product management.

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, 8 February 2011, 09.00 h – 14.45 h
Course Programme Day 1
(Registration and coffee 08.30 h - 09.00 h)
14.45 h – 19.00 h Visit of Helvoet Pharma in Alken
(including bus transfer)

Wednesday, 9 February 2011, 08.30 h – 16.00 h
Course Programme Day 2

Venue

Novotel Brussels Airport
Bedrijven Zone Diegem - Vuurberg
Leonardo Da Vincilaan 25
1831 Diegem
Belgium
Phone +32 2 714 56 26
Fax +32 2 721 39 58

Fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT (does not include ECA Membership)
Non-ECA Members € 1,690.- per delegate plus VAT
EU GMP Inspectorates € 845.- 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 "VA 6875 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 20 December 2010. 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
D-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 Günter Brendelberger (Operations Director) at +49-62 21 / 84 44 40, or per e-mail at brendelberger@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.

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities.

The ECA will provide 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.

What Are the Benefits of ECA?
First benefit:
During the membership, you enjoy a 200 € discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit:
The GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

How Do You Become a Member of ECA?
By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website **http://www.gmp-compliance.org**

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG. ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Elastomeric Closures for Injection
8-9 February 2011, Brussels, Belgium
☐ 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)

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 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.
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)!