Including a visit
to the production plant of
Datwyler in Alken, Belgium

Image: Datwyler Pharma

Elastomeric Closures for Injections

26 - 27 June 2013, Brussels, Belgium

SPEAKERS:

Dr Piet Christiaens
Toxikon Europe, Belgium

Dr Helmut Gaus
Rentschler Biotechnologie, Germany

Dr Renaud Janssen
Datwyler, Belgium

Dr Bram Jongen
Datwyler, Belgium

Dr Tobias Mundry
Bayer Pharma, Germany

Dr Patrick Scheidegger
F. Hoffmann-La Roche, Switzerland

Roelant Storms
Datwyler, 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

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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
- Closure integrity testing
- 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 Datwyler on 26 June 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

ROELANT STORMS, Datwyler

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, Datwyler

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
- Applicable 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 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 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 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, Datwyler

Elastomeric Closures in Pharmaceutical Manufacturing

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

DR PATRICK SCHEIDEGGER, F. Hoffmann-La Roche Ltd.

Visit of Datwyler 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 Datwyler** (former Helvoet Pharma) in Alken, Belgium. Datwyler 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 Datwyler are not allowed to visit Datwyler.
Thanks a lot for your understanding.

Speakers

Dr Piet Christiaens, *Toxikon Europe NV, 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, 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, *Datwyler, Belgium*
For over 20 years Renaud Janssen has been holding R&D, Technical Support and Quality functions at Datwyler Pharma Packaging where he currently acts as Global Director of Scientific Affairs. Renaud is a member of various standardization committees and task forces in the field of pharmaceutical rubber.

Dr Bram Jongen, *Datwyler, Belgium*
After his Masters in Polymer Chemistry at the University of Louvain, Belgium, Bram Jongen finished a Ph.D. in Water Soluble Polymers used for advanced drug administration. Bram started as Technical Support Manager for Datwyler about 8 years ago, supporting customers in a vast area from West-European countries to distant countries like India, Korea and South Africa. Thereafter, he was heading the Product Introduction & Support team, a global team of highly experienced and educated people, having each their expertise in the world of pharmaceutical closures. His team managed customer projects from technical nature and worked on Datwyler's product management and portfolio. Recently, he picked up a role as Head of Material Development in the R&D and Innovation group.

Dr Tobias Mundry, *Bayer Pharma AG, Germany*
Starting in 1999 at the Schering AG, Dr Tobias Mundry worked as lab head and Director in different units focused on the development of primary packaging, application systems and medical devices.Within Bayer Healthcare beginning in 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 drug products in clinical phases I-III.

Dr Patrick Scheidegger, *F. Hoffmann-La Roche Ltd., Switzerland*
Dr Scheidegger joined Roche 2005 to support Qualification and Validation activities as QA Manager in Quality Engineering Department of Drug Product Manufacturing Basel. 2010 he took over Head of Quality Engineering within the Quality Unit Drug Product Manufacturing Basel. Since 2007 Dr Scheidegger supported as Lean Six Sigma Black Belt several improvement projects with respect to primary packaging material. Especially he was focused on improvement activities on rubber stoppers used for Drug Products for Japanese market.

Roelant Storms, *Datwyler, Belgium*
Since 2001, Roelant Storms has been holding Technical Support, Quality and Sales functions at Datwyler Pharma Packaging, both in Europe and in the United States. In each of these roles Roelant has been supporting and advising worldwide customers in successfully using parenteral container closure systems. Currently he holds a position as Sales Director Europe.

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, 26 June 2013,
(Registration and coffee 08.30 h - 09.00 h)
09.00 h - 14.45 h Course Programme Day 1
14.45 h – 19.00 h Visit of Datwyler in Alken
(including bus transfer)

Thursday, 27 June 2013,
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 to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel. 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
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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.

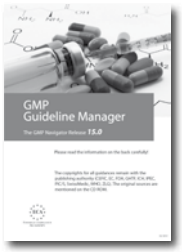
What Is ECA?

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 250 events will be organised by CONCEPT HEIDELBERG. ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

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Elastomeric Closures for Injection
26 - 27 June 2013, 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)!