ECA
European Compliance Academy

Latest News about the new
Generic Drug User Fee Act - GDUFA

Getting Approval of Generics in the EU and USA

Dossier Requirements and strategic Considerations

15 – 16 November 2012, Vienna, Austria

Speakers:

Dr Mohamed Baccouche
IPMB, Germany

Dr Michael Braun
Exalon, Germany

Dr Birka Lehmann
BfArM, Germany

Wiebke Gesine Kamp
Alfred E. Tiefenbacher, Germany

Dr Helmut Vigenschow
Merckle, Germany

Highlights

- The role and of Generics in Europe and the US
- Handling regulatory procedures of Generics in the European Union
- The ANDA procedure of Generics approval in the US
- Key points to be considered for development and filing of Generics in Europe and the US
- GDUFA – FDA's new fee regulation and its impact on Generic and API companies
- Best practice of eCTD submission in the EU and USA

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

Getting Approval of Generics in the EU and USA

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Objectives

The objective of the course is

- to describe the regulatory procedures for the approval of generics in the US (ANDA) and in the EU,
- to discuss the key points to consider for a successful development of and filing for generics in the US and in the EU,
- to learn from practical case studies,
- to get to know best practices of electronic submissions.

This course will provide you with the focussed description and analysis of the regulatory procedures for generics in the US and Europe.

Background

The patent of several key block busters is going to expire in the next few years. The success of generic introduction is significantly depending on time to market and proper development and successful regulatory submission. Despite of the achieved international harmonisation there are still significant differences between the regulatory environment of generic s in the US and Europe.
In October 2012 the new **Generic Drug User Fee Act (GDUFA)** came into force. Generic companies and API manufacturers have now to cope with an additional fee burden when trying to get FDA's approval for marketing Generics in the US.
It is therefore necessary for a globally acting generic industry to consider the key aspects for regulatory procedure properly.

Target Audience

This education course is designed for all persons involved in the compilation of pharmaceutical dossiers for marketing authorisations in the EU and USA especially for generic applications. Furthermore the courses will be of interest to personnel from Regulatory Affairs, Quality Assurance, Quality Control and Production.

Moderator

Dr Mohamed Baccouche

Programme

Getting Generics approved in the EU – Regulatory Procedures and strategic Considerations

- Legal requirements in the EU
- EU Reference Product
- Dossier requirements in the EU

Getting Generics approved in the US – Regulatory Procedures and strategic Considerations sections [505 (j), 505(b)(2)] of the FD&C Act

- Legal requirements in the US
- US Reference listed drug
- Dossier requirements in the US

Specific Dossier Requirements for Generic Applications in Europe

- The Reference Product
- Common European requirements
- European diversity
- Process validation

Key points to be considered for Development of Generics – Pharmaceutical Development

- Originator and competitor patents
- Quality by Design
- Pharmaceutical Development Report
- Stability testing

Drug price Competition and Patent Term Restoration Act

- Hatch-Waxman Amendmends
- Statutory provisions
- Data protection
- Marketing exclusivity
- „Orange Book" listings
- 505(b)(2) applications under section 505(b)(2) of the FD&C Act
- Initiative on improving access to generic drugs

Programme

The new Generic Drug User Fee Act (GDUFA) – How it works

- Status of GDUFA implementation at FDA
- GDUFA program scope, performance goals and procedures
- ANDA review efficiency enhancements
- Fees and how they are being calculated
- Impact on API manufacturers and the Generic Industry

Getting Generics approved in the US – Key Points to consider

eCTD Submission in the EU & USA – Differences and best Practice

- Current status of electronic submissions in EU vs. USA
- Key points to consider during submission planning
- Specific requirements in the different jurisdictions and how to address them
- Reducing efforts by realizing synergies – best practice
- Future outlook

Conclusion

Speakers

Dr Mohamed Baccouche, *IPMB GmbH, Germany*
Dr Baccouche is CEO of the Institute for Regulatory Affairs and Pharmaceutical Services IPMB. He was head of global regulatory affairs and scientific information at Byk Gulden and Altana for 19 years. Since 1999 he is lecturer of Drug Regulatory affairs at the University of Bonn.

Dr Michael Braun, *Exalon GmbH, Germany*
Since July 2007, Michael Braun is managing partner of Exalon eCTD-Experts where he also works as a Consultant Drug Regulatory Operations. He has been responsible for many international electronic submission projects for clients in the pharmaceutical industry. Prior to Exalon, Dr Braun has been working as Regulatory Affairs Manager at Altana.

Dr Birka Lehmann, *BfArM, Germany*
She joined the Federal Institute for Drugs and Medical Devices (BfArM) in 1986 and served in different positions with a 4 years secondment to the European Commission, Directorate-General Enterprise and Industry (2002 – 2006) as expert in the unit 'Pharmaceuticals'. Since 10/2011 she is head of EU & International Affairs at the BfArM.

Wiebke Gesine Kamp, *Alfred E. Tiefenbacher GmbH & Co. KG*
Since June 2007 Ms Wiebke Kamp is Manager Regulatory Affairs at Alfred E. Tiefenbacher in Hamburg. Before she joined AET she has been working in the Regulatory Affairs Department of Desitin Arzneimittel GmbH and prior to that she was the Responsible Pharmacist at Medio-Pharmacy, both in Hamburg, Germany.

Dr Helmut Vigenschow, *Merckle GmbH, Germany*
Dr Vigenschow serves in the ratiopharm / Merckle group of companies (now part of Teva) since 26 years. He filled leading positions in QC, Project Management, Clinical Studies, Regulatory Affairs and Pharmaceutical Development. For 3 years he lived in India to set up the ratiopharm R&D centre as a Greenfield project. His present position is Head of Quality Assurance in Germany.

Social Event

On 15 November 2012, 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

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
Thursday, 15 November 2012, 9.30 – 17.30 h
(Registration and coffee 9.00 – 9.30 h)
Friday, 16 November 2012, 9.00 – 15.00 h

Venue
Renaissance Wien Hotel
Linke Wienzeile/Ullmannstraße 71
1150 Wien
Phone +43 (0)1 89 102
Fax +43 (0)1 89 102 300

Conference fees
ECA Members EUR 1,490.- per delegate plus VAT
APIC Members EUR 1,590.- per delegate plus VAT
Non-ECA Members EUR 1,690.- per delegate plus VAT
EU GMP Inspectorates EUR 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 CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the conference. Please use this form for your room reservation or be sure to mention "ECA" to receive the specially negotiated rate (single room € 129,- per night, incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 3 October 2012. Early reservation is recommended.

Registration
Via 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
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For questions regarding content:
Dr Gerhard Becker (Operations Director) at +49-62 21/84 44 65, or per e-mail at becker@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Mr Ronny Strohwald (Organisation Manager) at +49-62 21/84 44 51, or per e-mail at strohwald@concept-heidelberg.de

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Registration form (please complete in full)

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☐ Mr ☐ Ms Title _____

First name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Purchase Order No. (if applicable)

Street / P.O. Box

City Zip Code Country

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General Terms of Business
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 % of the registration fee.
- until 1 week prior to the conference 50 % of the registration fee.
- within 1 week prior to the conference 100 % of the registration fee.

CONCEPT 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 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. **You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed)!**