Seminar

QualitecFarma® REGULATORY & BUSINESS STRATEGIES

FORUM

Marketing Authorisation Outside the ICH Region

Dossier, CPP-requirements, submission and maintenance

Your speakers

Dr Bettina Fiedler
Bayer AG,
Berlin, GERMANY
Head RA Eastern Europe, Middle East & Africa

Seda Kadioglu
Independent consultant on drug development, clinical trials and regulatory affairs, TURKEY

With local expert know-how from the MENA region and Turkey

Ayaz Hameed Khan
Grünenthal GmbH,
Aachen, GERMANY
Director, Regulatory Affairs IRPL – GRA

Dr Stefanie Lietsch-Dallwig
PharmaLex GmbH,
Mannheim, GERMANY
Director, Principal Consultant Regulatory & Special Projects

Dr Mohammed Saleem
Boehmert & Boehmert Representation Office Middle East and North Africa, JORDAN
General Director of SIPS

19 - 20 September 2017 in Berlin

Tuesday, 19 September 2017 from 09:00 – 17:00

09:00

Regulatory affairs outside the ICH region – the key principles

Dr Bettina Fiedler

- Regions/countries adhering to the Q, E and S ICH guidelines
- Countries adhering to the WHO guidelines
- Countries requiring solely European or US marketing authorisation
- The difficult ones: those with their own approach

10:00

Countries with or without CPP-requirements

Ayaz Hameed Khan

- Overview of CPP-dependent and non-CPP-dependent countries
- Regulatory submission strategy based on CPP
- Potential parallel filing in emerging markets
- Marketing authorisation recognition
- Peculiarities of Latin America and Asia

11:00 Coffee break

11:15

CPP-requirements in the Middle East

Dr Mohammed Saleem

- Marketing authorisation dossier for Middle Eastern countries
- GCC countries – case: CTD Module 1 in Saudi Arabia
- North Africa – case: CTD Module 1 in Algeria

12:15 Lunch

13:30

Marketing authorisation application – with external help!

Ayaz Hameed Khan

- Role of affiliates and agents in global submission strategies
- External consultants, third-party evaluations and local scientific support in submitting and obtaining a marketing authorisation
- Health-agency interactions in non-EU countries and their impact on regulatory strategy
- Peculiarities of Latin America

14:30

Example of a marketing authorisation application in the Middle East and North Africa

Dr Mohammed Saleem

15:30 Coffee break

16:00

Regulatory strategy

Dr Bettina Fiedler

- Which regions should be addressed first, from a regulatory affairs point of view?
- Rapid roll-out of submissions to international markets

17:00 End of day one

Wednesday, 20 September 2017 from 09:00 – 17:00

09:00
Marketing authorisation application in Turkey
Seda Kadioglu
- Access to the Turkish market
- GMP audit obligation
- The procedures for various products
- Module 1 in Turkey explained

10:45 Coffee break

11:00
Marketing authorisation dossier – CTD/eCTD
Dr Stefanie Lietsch-Dallwig
- Is the CTD always in accordance with ICH requirements?
- Peculiarities in Asia and Latin America
- Transition to eCTD or other electronic submission
- Other documents requested in addition to the dossier (product information, GMP certificate, etc.)

12:00 Lunch

13:15
Dossier requirements in the Middle East and North Africa
Dr Mohammed Saleem

14:00
Dossier requirements in Turkey
Seda Kadioglu

14:45 Coffee break

15:00
Maintenance duties in the non-ICH countries at a glance
Dr Stefanie Lietsch-Dallwig
- Is there a variations system in place? Are renewals necessary?

15:45
Maintenance peculiarities in the various regions
Discussion: Seda Kadioglu, Dr Mohammed Saleem and Dr Stefanie Lietsch-Dallwig

16:30
Final discussion

17:00 End of the seminar

Your benefits
- International regulatory strategy know-how
- Focus on the MENA region and Turkey by two local experts
- Practical knowledge from business experts

Marketing Authorisation Outside the ICH Region

Aims and objectives

Are you preparing for business in international markets, including those in the non-ICH region? Then you shouldn't miss out on this seminar.

We will provide you with practical tips on the specific requirements of the various regions/countries and on where you might want to seek external help with regulatory affairs issues.

After having attended this seminar, you will be able to define your regulatory strategy and you will have better knowledge of the current challenges in the various regions of the world. Local experts will focus on the MENA region and Turkey, Latin America and Asia will also be addressed.

Who should attend?

This seminar addresses the needs of regulatory affairs professionals with marketing authorisations outside the EU or aiming for new marketing authorisations worldwide.

It is also useful to business development, clinical affairs and medical affairs professionals.

Working knowledge of the European marketing authorisation system is a prerequisite.

Registration: +34 91 372 83 99 or email: formacion@qualitecfarma.com

Yes, I will attend the seminar

☐ **Marketing Authorisation Outside the ICH Region**

Name

Position/Department

Company

Street address

Postal Code/City/Country

Tel. No.

E-Mail

Contact person at the office

Date/Signature

- **Registration: +34 91 372 83 99**
- **Conference-No. 17 09 231**

- **Date/Venue:**

19 - 20 September 2017
8:30 registration; 9:00-17:00 seminar
Crowne Plaza Berlin City Centre
Nürnberger Str. 65 · 10787 Berlin
Tel. +49 30 21007-0 · Fax +49 30 2132009

- **Fee:**

€ 1,890.00 (+German VAT) incl. course documentation (incl. free download) as well as mid-session refreshments, lunch and certificate.

- **Questions and information:**

Mr. Pablo García
Conference Manager (QualitecFarma®)

Tel. +34 91 372 83 99 formacion@qualitecfarma.com

- **Cancellation Policy:**

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