Course

FORUM

Value Added Medicines

Repurposing, Market Analytics and Pricing

Business development, regulatory affairs and market access – the core elements for VAM success!

Your topics

- Repurposing existing marketing authorisation dossiers
- Drug repurposing and IP protection
- Market analytics and portfolio management
- Value added innovations – tips and rules for the EU5
- Value added generics – pricing and contracting

Your speakers

Petra Gerecke
mibe GmbH Arzneimittel, Brehna, GERMANY

Dr Thomas Hille
LTS Lohmann Therapie-Systeme AG, Andernach, GERMANY

Michael Schaub
ASPHALION S.L., Munich, GERMANY

Dr Martina Steiper
PharmaLex GmbH, Mannheim, GERMANY

Dr Marc Christian Bauer
Tesaro Bio GmbH, Zug, SWITZERLAND

Christian Hill
MAP BioPharma Limited, Cambridge, GREAT BRITAIN

Dr Jing Shao
Sandoz International GmbH, Holzkirchen, GERMANY

Düsseldorf, 22 - 23 November 2018

Your speakers

Petra Gerecke
mibe GmbH Arzneimittel, Brehna, GERMANY

Head of Regulatory Affairs/Pharmaco-vigilance; QPPV Dermapharm Group

Dr Thomas Hille
LTS Lohmann Therapie-Systeme AG, Andernach, GERMANY

Director Research & Development

Michael Schaub
ASPHALION S.L., Munich, GERMANY

Director Munich Office

Dr Martina Steiper
PharmaLex GmbH, Mannheim, GERMANY

Senior Director;
Principal Consultant Development & Regulatory Strategy

Programme: 09:00 – 17:00

Old Marketing authorisation dossier: Is it fit for new markets in the EU?

Petra Gerecke

- Extension of old existing products – regulatory possibilities (RUP, duplicate DCP, duplicates and other procedures)
- Challenges of an old dossier in new regulatory procedures
- Pitfalls of licenced products

Repurposing existing marketing authorisation dossiers

Dr Martina Steiper

- Reformulation: new strengths, new route of administration, modified release
- Repositioning: new indication, etc.

Drug repurposing vs drug discovery

Dr Thomas Hille

- IP protection: De jure vs de facto!
- APIs in new dosage forms. Stories of business success: nicotine, buprenorphine...
- When is a chemical entity considered to be a new active substance (NAS)?
- How can a final drug product containing an established API be qualified?
- Investments in development vs benefits of real patent protection

Pitfalls of clinical development

Dr Martina Steiper

- PIP or new clinical data essential?

Combination products

Dr Martina Steiper

Leaving the EU – is the dossier usable for ROW marketing authorisations? Key questions to be addressed

Michael Schaub

Day 2: Market Analytics and Pricing in the EU 5

Programme: 09:00 – 17:00

Market analytics and portfolio management from the generics perspective

Dr Jing Shao

- Situation and competitor analysis
- Market landscapes and insights
- Forecasting and strategic planning

Pricing of generics in the EU 5

Christian Hill

- FR, DE, UK, IT, ES – an overview
- Pricing transparency
- Innovative contracting models as part of tenders or direct purchasing

Value added medicines from the originator perspective

Dr Marc Christian Bauer

- How to get a product value added
- Pricing rules for value added innovations
- Combination products and fixed combinations
- Are there different pricing rules compared to monosubstances?
- How to implement these prices in the EU 5
- How to avoid tendering

Value added generics or innovation – distinguishing between rules in the EU 5

Christian Hill

- Generics with an additional benefit for patients: Different reimbursement rules?
- Examples in the EU 5
- Value added generics, HTA assessment and where innovative pricing models fit in

Your speakers

Dr Marc Christian Bauer
Tesaro Bio GmbH, Zug, SWITZERLAND

Vice President; Head of Legal and Compliance International

Christian Hill
MAP BioPharma Limited, Cambridge, GREAT BRITIAN

Chief Executive Officer

Dr Jing Shao
Sandoz International GmbH, Holzkirchen, GERMANY

Global Portfolio Manager Value Added Medicines

Aims and objectives

Reformulation, repurposing, repositioning – these are some of the options available for known substances, to develop and sell value added medicines.

This course focuses on the development, regulatory affairs and market access activities in creating and selling these pharmaceuticals in Europe (and beyond).

Day one will familiarise you with the regulatory challenges of the marketing authorisation and the necessary expertise to overcome the development hurdles (PIP required? IP protection?).

Day two initially focuses on analytics and strategic planning, then on pricing and reimbursement, which help you answer the crucial question: 'Does the repurposed or repositioned drug receive appropriate reimbursement in Europe?'

Who should attend?

This course addresses the needs of all those working with reformulated, repurposed or repositioned drugs, particularly in drug development, business development, regulatory affairs and market access.

Registration: +49 6221 500 555 or email: service@forum-institut.de

Yes, I will attend:

☐ **Day 1: Regulatory Affairs Challenges** (Seminar No. 18 11 232)

☐ **Day 2: Market Analytics and Pricing in the EU 5** (Seminar No. 18 11 281)

☐ Yes, I agree that FORUM Institut may inform me about events and relevant expert content by:
☐ email; and/or ☐ telephone.
I may withdraw my consent at any time.

Name

Position/Department

Company

Street address

Postal Code/City/Country

Tel. No.

E-Mail

Contact person at the office

Date/Signature

Registration: +49 6221 500-500

Date/Venue:
Düsseldorf, 22 - 23 November 2018
Leonardo Royal Hotel Düsseldorf Königsallee
Graf-Adolf-Platz 8–10 · 40213 Düsseldorf
Tel.: +49 211 3848-0 · Fax: +49 211 3848-390

Fee:
One seminar day €1,090 (+ German VAT)
Both seminar days: €1,990 (+ German VAT)
The fee includes seminar documentation (including free download) as well as midsession refreshments, lunch and a certificate. Invoice and confirmation will be forwarded to you

Questions and information:
Dr. Henriette Wolf-Klein
Tel. +49 6221 500 680 · h.wolf-klein@forum-institut.de

Cancellation Policy:
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