Round Table

FORUM

# ExpertFORUM Regulatory Affairs

## Topics

**Towards a faster and more tailored marketing authorisation in Europe and in the US?**

- The EU and the US market: parallel or sequential marketing authorisations?
- The Future: breakthrough versus adaptive licensing
- The Present: accelerated/cond. approval, abridged procedures
- Marketing authorisation versus HTA/market access conditions

## Your speakers

### Dr Ulrich Granzer

**Granzer Regulatory Consulting & Services, Munich, GERMANY**

Owner

### Dr Tomas Salmonson

**Medical Products Agency (MPA), Uppsala, SWEDEN**

Chair of the CHMP, EMA

### Dr Max Wegner

**Bayer Pharma AG, Wuppertal, GERMANY**

Senior Vice President Head Global Development General Medicine

5 March in Frankfurt

# ExpertFORUM Regulatory Affairs

## Aims and objectives

Are you involved in your company's regulatory strategy? Then you won't want to miss out on this opportunity for a thorough discussion with three outstanding regulatory affairs experts.

This ExpertFORUM focuses on the current challenges when registering new products in Europe and the US.

- How does the marketing authorisation system (including the new option of adaptive licensing) fit with the HTA requirements?
- Are there shortcuts when pursuing an approval in the EU and the US?
- What about orphan drugs in these systems?

Here you'll get first-hand answers and valuable tips for your regulatory strategy!

## Who should attend?

This ExpertFORUM addresses the needs of regulatory affairs professionals in the pharmaceutical industry.

Especially those who are involved in the regulatory strategy (EU and/or the US) will benefit from the round table.

## Your programme 9h00 - 17h00

### The EU and the US marketing authorisation system in comparison
*Dr Max Wegner*
- Example: new molecular entities

### The EU and the US market: parallel or sequential marketing authorisations?
*Dr Ulrich Granzer*

### The Future: breakthrough versus adaptive licensing – will there be consequences for regulatory affairs?
*Dr Tomas Salmonson*
- The EMA project
- The FDA approach
- What are the benefits?
- Are there any risks?

### The Present: accelerated and conditional approval, exceptional circumstances and abridged procedures – experience gathered to date
*Dr Ulrich Granzer*
- EU and US experience
- Ultra-orphans – differences between the EU and the US

### Marketing authorisation versus HTA/market access conditions
*Dr Ulrich Granzer*
- Marketing authorisations with limited data: do they result in a unfavourable pricing?
- What can be done to get the right data on a limited budget?

### Scientific advice – the key to success?
*Dr Max Wegner*

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

☐ Yes, I will attend the round table:
**ExpertFORUM Regulatory Affairs**

Name

Position/Department

Company

Street

Postal Code/City/Country

Tel. No./ Fax No.

E-Mail

- **Registration: +49 6221 500-500**
- **Conference-No. 15 03 236**
- **Date/Venue:**
5 March 2015 in Frankfurt
NH Frankfurt City
Vilbeler Str. 2 · 60313 Frankfurt
Tel. +49 69 928859-0 · Fax +49 69 928859-100

- **Fee:**
€ 990.00 (+ German VAT)
The fee includes course documentation (incl. free download) as well as midsession refreshments, lunch and certificate.

- **Any Further Questions?**
Dr. Henriette Wolf-Klein
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- **Cancellation Policy:**
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