

TOPRA module 1

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# Strategic planning in Regulatory Affairs

A presentation by Christine Degeling, Head of Regulatory Affairs,  
Teva Pharmachemie



ENABLING AND PROMOTING EXCELLENCE IN THE HEALTHCARE REGULATORY PROFESSION

# Learning Outcomes



- **Understand the importance of a regulatory strategy**
- **Understand which factors play a role in designing a regulatory strategy**
- **Understand how current trends in pharmaceutical industry may influence the regulatory strategy**

# **In This presentation we will cover**



- **What is a regulatory strategy?**
- **Why and when is a regulatory strategy needed?**
- **The aspects of a regulatory strategy**
- **What are the current trends in pharmaceutical industry?**
- **How will these trends in pharmaceutical industry affect the regulatory strategy?**

# What is a Regulatory Strategy?



- **Strategic planning:**
  - **Process of defining strategy or direction**
  - **Making decisions on resources to pursue this strategy.**
  - **control mechanisms for guiding the implementation of the strategy.**
  - **Involves many parties and research sources in the analysis of the goal, the organization and its relationship to the environment in which it competes.**

# What is a Regulatory Strategy?



- **Regulatory Strategy:**
  - **Plan for developing the product with the goal of obtaining regulatory approval in desired markets**
  - **Plan for lifecycle management/maintenance post approval**

# Why a Regulatory Strategy?



- **For alignment of development, commercial and regulatory goals:**
  - **Development: CMC, non-clinical and clinical development plan**
  - **Commercial: key product label attributes and positioning**
  - **Regulatory: scientific advice, procedure, legal basis, exclusivity**

# Why a Regulatory Strategy?



- **Understand the regulatory landscape**
  - **Guidelines**
  - **Stakeholders**
  - **Emerging policies**
  - **Precedence**
  - **Drive the development and identify hurdles so they can be solved proactively**

# Why a Regulatory Strategy?



**Tracking tool: summarize key agreements with project team and with authorities**

**Planning tool: documentation of timelines and topics to be discussed with health authorities**

**Risk register: keep track of issues that may affect timelines, costs or commercial value**



# When a Regulatory Strategy?



- **Always.....**
  - **Development: new molecular entities (chemical and biopharmaceutical), drug rediscovery**
  - **Lifecycle management: maintenance of existing products, new indications, new API suppliers, new markets, line-extensions, site transfers**

# When a Regulatory Strategy?



- **Start early in development, e.g. before regulatory non-clinical studies**
- **Start with the end in mind, e.g. with a target product profile**
- **Regulatory strategy should be a living document**

# Aspects of a Regulatory Strategy



- **Overview of guidelines and precedents: covered in the lecture on regulatory intelligence**
- **Plan for interaction with authorities: covered in the lecture on scientific advice**
- **Knowledge on requirements in the regions of interest**

# Aspects of a Regulatory Strategy



- **Key product label attributes**
- **External influencing**
- **Global submission strategy: know the requirements in each region**
- **Pharmacoeconomics**
- **Target submission and approval dates**
- **Options for accelerated approval pathways: covered in the lectures for the various regions**

# Aspects of a Regulatory Strategy



**Provides guidance on how to work with other disciplines:  
covered in the lecture on project management**

# Aspects of a Regulatory Strategy



**What is designing a regulatory strategy about?**



or



# Aspects of a Regulatory Strategy



**Design of a regulatory strategy requires the regulatory professional to have:**

**a certain degree of technical and scientific know-how  
AND**

**Soft skills:**

- **Negotiation skills**
- **Problem-solving**
- **Creativity and flexibility**
- **Understanding of and insight in interests of stakeholders**

# Trends in Pharmaceutical Industry



- **Personalised medicine**
- **Shift to emerging markets**
- **Unmet medical need: Alzheimer's disease, obesity/diabetes type II**
- **Need for prevention of diseases versus treatment (vaccines for developing countries, e.g. malaria)**
- **Companion diagnostics**



# Trends in Pharmaceutical Industry



- **Mergers and acquisitions**
- **In- and out-licensing**
- **A big pharma company handles the strategic planning differently than a small enterprise**

# Effect of Trends on the Regulatory Strategy



- **For personalised medicine, a different regulatory strategy is needed when compared to a blockbuster.**

**How?**

# Effects of trends on the Regulatory Strategy



- **Emerging markets are also in the picture for development and manufacturing activities hence requiring management skills.**

**What are the specifics in the regulatory strategy?**

# Effects of Trend on the Regulatory Strategy



- **A drug is developed for an unmet medical need.**

**What are the strategically important aspects?**

# **In This presentation we covered**



- **Why and when is a regulatory strategy needed?**
- **The aspects of a regulatory strategy**
- **What are the current trends in pharmaceutical industry?**
- **How will these trends in pharmaceutical industry affect the regulatory strategy?**

# Recommended references



- **TOPRA Regulatory Rapporteur February 2014**
- **Worldwide Update, FDA and NIH heads outline plan for personalised medicine; RAJ Vol 21 No 8 August 2010, page 520**
- **Porter M.E. (1980) Competitive Strategy; Techniques for Analyzing Industries and Competitors. London, Free Press**

# Take home message



- **Regulatory strategy is indispensable**
- **As a regulatory professional you are in a unique position:**
  - **You can influence company policy**
  - **You are an active stakeholder in company policy, development and life cycle management**
  - **You contribute to the success of your company!**
  - **You have added value**
- **It is an underestimation to consider the regulatory profession only as filling out forms and shoving paper around.**



**QUESTIONS?**





## Contact details

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**Name:** Christine Degeling

**Tel:** #31235147820

**Email:** [christine/degeling@tevapharmachemie.com](mailto:christine/degeling@tevapharmachemie.com)