TOPRA module 1

Strategic planning in Regulatory Affairs

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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 indispensible
- 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?

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