

# Regulatory strategy

A therapeutic product's regulatory strategy is a key component of product development. It is important that the regulatory strategy be developed very early in the drug-development process. As soon as the target product profile (TPP) has been determined, the regulatory strategy can be worked out as a pathway to support the TPP. The regulatory strategy is a reverse-engineered document such that once one has developed a TPP (i.e., the objective is established), one can then work backward to determine what information is needed to achieve the goal.

Within a company, there are usually many players from a variety of departments who work on developing the regulatory strategy. Since this strategy involves all aspects of a drug, individuals with expertise in chemical synthesis, toxicology, biology, clinical and regulatory affairs, marketing, government affairs, and reimbursement should all provide input into the regulatory strategy to ensure it is as comprehensive as possible.

The clinical trial program should support the regulatory strategy. In other words, if the outcome of a clinical trial is not providing information that is supportive or pivotal to a future marketing application, its value should be questioned – at least in the early stages of drug development or in situations where cost plays a major role.

The main activities involved in creating and achieving a regulatory strategy include:

- conducting intelligence-gathering activities
- obtaining and managing documentation
- obtaining necessary approvals to conduct pre-clinical and clinical studies
- preparing for and attending regulatory authority meetings
- planning, preparing and maintaining regulatory submissions and correspondence
- responding to Agency queries and deficiency letters<sup>1</sup>

## Importance of the label and label claims

As part of the target product profile, a draft label will have been prepared. This will list the main proposed claims of the manufacturer. The regulatory strategy can then be developed to support these claims. Thus the TPP dictates key aspects of the clinical trial program.

## Key aspects of a good regulatory strategy

A good regulatory strategy involves understanding the key guidelines and emerging policies, as well as the relevant stakeholders that stand between drug development and drug approval. A good regulatory strategy identifies the pathway and the potential hurdles, and creates a plan that will proactively address any issues that may arise. A good regulatory strategy includes potential regulatory solutions for possible roadblocks.

Novel approaches or drugs with new mechanisms of action can present opportunities. With ongoing developments in science and medicine, the landscape continues to evolve and it is important for regulatory affairs professionals to engage an educational approach with regulators. Those who best understand a new drug are usually those who have developed it. Thus it can be critical to educate regulatory agencies on how a drug or its mechanism may be unique, and that the existing regulatory guidelines and policies may not necessarily directly apply. Novel endpoints may be needed if the indication is new. This can pose challenges for drug development, but also it presents an opportunity to potentially identify new benefits and new strategies for obtaining marketing authorization.

Based upon the needs of regulators, a good regulatory affairs professional needs to be able to carefully evaluate

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<sup>1</sup> Moffitt, J. A. (2008, March). *Developing Regulatory Strategy* [PowerPoint slides]. Retrieved February 26, 2010, from <http://www.blueskybroadcast.com/client/RAPS/0308/pdf/Developing%20Regulatory%20Strategy.pdf>

development options and potential issues and challenges. The regulatory affairs professional is the communications intermediary between regulators and the rest of the drug development and marketing team. These individuals should be key members of the drug development team in order to best address any potential issues with regulators.

### Regulatory strategy document

The regulatory strategy document has three main purposes. It needs to be:

- a tracking tool to summarize key agreements reached with health authorities
- a planning tool that documents timelines and lists topics to address in future meetings with health authorities
- a risk register to record key issues that could impact timelines, costs or commercial value for the project<sup>2</sup>

Key components of a regulatory strategy could include:

- a summary of relevant guidelines and precedents
- a strategy to optimize product label claims
- lifecycle management
- a global submission strategy
- target submission and approval dates
- special populations and special safety evaluations
- implications of licensing agreements
- regulatory risks
- details on exclusivity
- accelerated development and approval options
- trademark information
- a plan for future interactions with regulatory authorities
- key product-label attributes
- external influencing
- table of advice from regulatory authorities and outstanding commitments<sup>3</sup>

In conclusion, there is no set way to develop a regulatory strategy. However, the strategy chosen needs to take into account the company's goals, over both the short and long term. Bear in mind there can be trade-offs between speed and cost of development. The regulatory strategy must strike a balance between what the company can afford, what is needed to take the product to market with the identified TPP, and how fast the company can achieve drug development. The regulatory strategy document should be a living document that evolves as drug development progresses and more is learned about the product.

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<sup>2</sup> Ammann, M. (2008, October 1). *Developing a Regulatory Strategy*. Retrieved February 26, 2010, from <http://appliedclinicaltrialsonline.findpharma.com/appliedclinicaltrials/Drug+Development/Developing-a-Regulatory-Strategy/ArticleStandard/Article/detail/556208>

<sup>3</sup> Ammann, M. (2008, October 1). *Developing a Regulatory Strategy*. Retrieved February 26, 2010, from <http://appliedclinicaltrialsonline.findpharma.com/appliedclinicaltrials/Drug+Development/Developing-a-Regulatory-Strategy/ArticleStandard/Article/detail/556208>