Regulatory Intelligence

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Put science on your side.
A New Buzz Word
or
Good Regulatory Working Practice?
The Definition: Regulatory

regulate (verb),
control maintain the rate or speed of machine (or a process)
regulare (latin) from regula, the rule (or law)
direct, regulate
The Definition: Intelligence

Intelligence (noun),
1. the gathering of information (of military or political).
2. the ability to acquire and apply knowledge and skills.
The Definition: Regulatory Intelligence

The act of processing targeted information and data from multiple sources, analysing data in its relevant context and generating a meaningful output- e.g. risks and opportunities- to the regulatory strategy. The process is driven by business needs and linked to decisions and actions.

This is a never ending activity as the regulatory environment is constantly changing.
The Process

Start with a Question

Search and collection

Surveillance

Review new information

1. Summary
2. Analysis
3. Interpretation
4. Integration
Sources of Information

- Web pages of Regulatory Bodies (e.g. EU Commission, CFDA, SFDA)
- Newsletters from Regulatory Bodies (e.g. Irish Medicine Board)
- Conferences (e.g. AHWP, Informa)
- Consultants
- Magazines (e.g. Regulatory Affairs Journal)
- Professional Societies or Associations (e.g. RAPS)
- Manufacturing Associations (e.g. EDMA, EUCOMED)
- Daily/weekly/monthly feeds from Professional Services (e.g. Tarius)
- Local staff members in countries
- In writing or verbally
Be Aware

- You will be overwhelmed by the available information
- You may miss some important information - one day
Maintenance of Information

- Extreme large data base
- Concentration on the most important subjects - filter information
- How to preserve the most important data (e.g. regulations), create your own data base (e.g. share point)
- Define ownership within your company or share work
- Constant impact assessments to product line
- Limit your risk of missing an important aspect
Communication

• How to communicate and who to communicate to/with
• When to communicate
• What is the shelflife of the information
• Consider a cross-functional team
• Reduce surprises and avoid panic
• Prioritize (relevant, important, urgent)
• Send effective messages (show solutions compliance)
• Foster regulatory knowledge across organization
• Consider continuous knowledge sharing with R&D (critical to successful product development)
How to Use the RI Information

• Design input for new products
• Develop Regulatory Strategy for product life-cycle
• Dilemma: Need to know or anticipate what is required in 3 or more years depending on the design cycle
• It has to cover all aspects of the product, such as:
  • Submission routes
  • Performance specification
  • Ingredients
  • Packaging and labeling
  • Traceability to reference material
• In the end a decision has to be made, where to make a cut and the design is frozen until market launch
How to Use the RI Information

• For products on the market:
  • Impact assessment is key
  • Define the strategy
  • When to change an existing product and bring it back to design process (change control)?
  • What are the deadlines?
  • What does this mean to the customers?

• Is it worthwhile considering to re-design and launch a new product?

• What is the impact to production lines and processes? → Integrate (e.g. Efficiency in case of country-specific requirements)?

• Can the product stay on the market?
Lessons Learned

• There is plenty of information available
• You may miss some important aspect one day
• Build your strategy to demonstrate you have done the best to your knowledge
• Establish a process and consider to involve others
• Look for outside help
• Follow the process consistently
• Do not surprise your Manager
It is:

- Key duty of a Regulatory department
- Vital to maintain compliance
- Critical to product development
- High interactive