



# Regulatory Intelligence

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# **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 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**