In This presentation we will cover

- **Introduction to Regulatory Intelligence (RI)**
  - What it is and the challenges involved
- **RI input for regulatory strategy & product development**
  - Overview
  - Case study examples
- **Influencing regulatory guidance development**
- **Closing remarks**

Introduction to RI

EU RING definition:

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

Introduction to RI

Why Regulatory Intelligence?

- **Pharmaceutical industry heavily regulated**
- **Companies operating globally & need to be compliant**
  - **New legislation/guidelines cannot be ignored, whether local or regional**
  - **Complex environment, ever increasing changing/new requirements**
- **Influence future regulatory framework**
  - **Supporting policy and advocacy activities**

Introduction to RI

Key responsibilities of a RI function include

- Rapidly identify and communicate significant *changes in the regulatory environment* to key internal stakeholders
- Conduct and deliver unique and insightful *analyses* that facilitate strategic decision-making
- Serve as internal regulatory consultants and respond to *ad-hoc intelligence requests*
- Facilitate access to high-value and frequently referenced *regulatory intelligence sources*
- Enable effective advocacy work through managing 'one-voice' *commenting* on draft regulatory authority documents

Introduction to RI

Sources and resources…

Introduction to RI

Overall benefits of RI activities include

- Identifying regulatory opportunities
- Reduced time to market
- Reduced development costs
- Increased compliance

Introduction to RI

Challenges for RI professional include

- Ever increasing growth of information
- Regulatory Authority transparency initiatives
  - EMA sharing information on medicines during various stages of MA process; meetings and workshops; other outcomes
- Regional differences
  - External regulatory environment across the Globe
- Information flow- reaching the right people in your company
  - Push versus pull of information

Introduction to RI

Over last ten years there has been a strong trend towards companies having a dedicated RI function

- **Fast, efficient response to queries:**
  - Expert knowledge of information sources/data mining tools/RI databases
  - Frees up RI professional time
  - Ability to leverage existing information
- **Positioned to see trends across internal projects/apply lessons learned**
- **Unique perspective across therapy areas, regions, functions and project teams**

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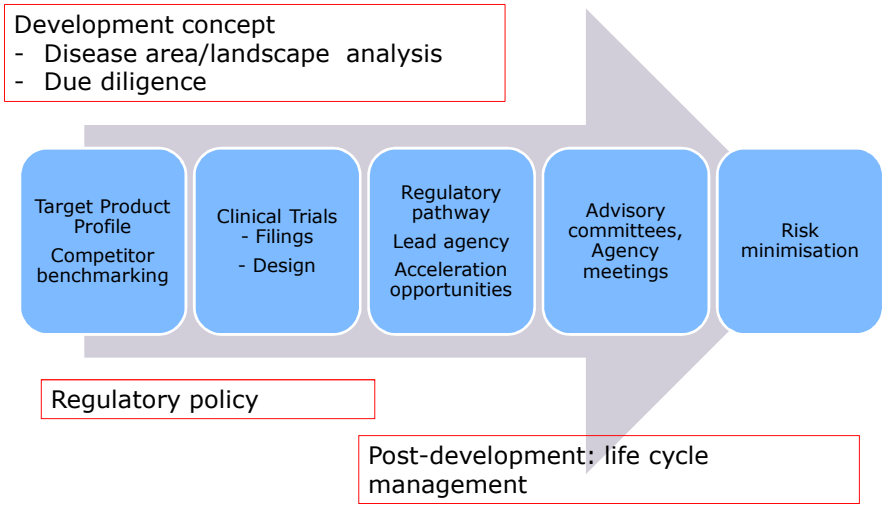
RI input for regulatory strategy & product development



RI input for regulatory strategy & product development

Type	Description	Value
Competitor intelligence	Regulatory status or regulatory evaluation of a competitor product	Determine likelihood of success of own strategy. Timing may also be important if need to be 'first across the line'
Environmental intelligence	Existence, implementation and use of legislation, regulatory frameworks, tools or initiatives on a particular pharmaceutical topic	Enables identification of requirements, rewards and incentives, as well as regulator acceptability and competence
Due diligence support	Scenario and risk management planning in relation to an in-licensing opportunity	Enables identification of potential risks that may impact on regulatory success. Aids go/no-go decision-making
Procedural intelligence	Practical experience on the interpretation or application of regulatory provisions that relate to a particular regulatory procedure	Clarifies whether your situation falls within known instances. Shapes dialogue with regulators if need to justify position
Regulatory precedents	Known instances of a novel regulatory approach or deviation from normal practice (success or failure)	Helps determine likelihood of success and any key differentiators that might persuade regulators to accept your position
Metrics	Mathematical occurrence of a regulatory event or time span for a particular regulatory procedure	Aids submission and launch planning and internal benchmarking against industry standard

RI input for regulatory strategy & product development

Example 1: Procedural intelligence (EU region)

Query description: **Practical experience on the interpretation or application of regulatory provisions that relate to a particular regulatory procedure**

Context: **New formulation of approved influenza product, need to determine eligibility for the centralised procedure**

Action: **Review industry-wide Article (3)(2)(b) filings to see what has previously constituted scientific, technical or therapeutic innovation and "in the interests of the community"**

Data processing: **EU MAA metrics tables and relevant EPARs**

Application of response: **To support asset team decision on which head of the optional route to use and provide justification to EMA on eligibility**

RI input for regulatory strategy & product development

Example 2: Regulatory Precedent (US region)

Query description: **Known instances of a novel regulatory approach or deviation from normal practice (success or failure)**

Context: **For an ultra rare paediatric disease, need to understand the FDA acceptance of clinical outcome assessments as primary endpoints in the absence of extensive validation work**

Action: **1) A list of approved products for ultra rare diseases in pediatric populations and 2) examples where "soft" endpoints (e.g. biomarkers, PROs, ClinROs, performance-based assessments) were used to demonstrate efficacy to treat an ultra rare disease (adult or pediatric)**

Data processing: **Publication searches using Embase and general internet search**

Application of response: **Review of endpoints used to support the approval of ultra rare disease therapies for application to development plans**

RI input for regulatory strategy & product development

Example 3: Environment Intelligence (EU & US regions)

Query description: **Existence, implementation and use of legislation, regulatory frameworks, tools or initiatives on a particular pharmaceutical topic**

Context: **SOP on volumetric imaging in development. What are the EMA and FDA views on volumetric imaging for cancer tumours?**

Action: **Investigation of whether FDA or EMA have issued any sort of guidance on volumetric imaging or sponsored any meetings/workshops**

Data processing: **Review of EMA and FDA websites; relevant EPARs and conference notes/presentations**

Application of response: **Facilitate drafting of internal SOP**

RI input for regulatory strategy & product development

Example 4: Competitive Intelligence (EU & US regions)

Query description: **Regulatory status or regulatory evaluation of a competitor product**

Context: **EU country approval status of therapies used in the treatment of myasthenia gravis (MG)- asset in development for MG and support needed for preparation of briefing document for scientific advice**

Action: **Establish approval status of nine different MG therapies in 10 EU markets.**

Data processing: **Requested support from Regulatory colleagues in Operating Companies to search national compendiums; consolidate response**

Application of response: **Treatment and approval information consolidated into a detailed table**

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Influencing regulatory guidance development (EU example)

- **Draft legislation and guidance is available from various different places**
  - CHMP- Q,S,E; published following monthly meetings
  - EMA, CMD(h)- procedural
  - EU Commission- implementing guidance for legislation, ad-hoc
- **Takes variety of forms**
  - Reflection papers
  - Concept papers
  - Draft guidance
- **Approach taken for release of drafts for review will often vary..**

Influencing regulatory guidance development- Internal process

- **Identify experts and 'comment co-ordinator'**
  - Challenge is that guidance review is not prioritised
- **Provide guidance on how to provide high quality comments**
  - Appropriate templates
  - Prioritise key comments
  - Suggest alternative wording- don't just pose questions back to regulators
  - Advise about resolving any conflicts
- **Ensure consolidated company response is submitted on time**

Influencing regulatory guidance development- comments and feedback

- **Provision of comments**
  - Trade associations
    - Consolidation into industry response
    - Discussion meetings with regulators
  - Directly to regulators
  - Present at Industry-Regulator workshops
- **Transparency of comments**
  - Comments & affiliation can be made public
  - CHMP publish comments and why (not) taken on board

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Concluding remarks

- Valuable regulatory intelligence can be extracted from the sea of information and applied for business advantage

Learning outcomes

- **Description of regulatory intelligence activities and challenges**
- **How RI can be used to support regulatory strategy and product development**
  - Examples of specific types of RI query
- **Support that RI can provide for commenting activities on draft guidelines which influencing the regulatory environment**

Recommended references

- **"The company regulatory intelligence (RI) function," *The Regulatory Affairs Journal - Pharma*, October 2007, 18(10), p671-73, at p672.**
- **"Providing good quality comment on consultation documents," *The Regulatory Affairs Journal – Pharma*, June 2008, p389-90**
- **"Sharing regulatory intelligence: Are newsletters here to stay or is social media the future?" *Regulatory Rapporteur* - TOPRA, 8(5), May 2011, p5-8Bullet point here, text size between 12pt and 22pt;**


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QUESTIONS?