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**
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.”

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...

- Sirius
- FDA
- Pipeline Informa
- Community Register
- PHARMAPENDIUM
- ISIS
- European Medicines Agency
- CORTELLIS
Introduction to RI

Overall benefits of RI activities include
- Identifying regulatory opportunities
- Reduced time to market
- Reduced development costs
- Increased compliance

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

Development concept
- Disease area/landscape analysis
- Due diligence

Target Product Profile
Competitor benchmarking

Clinical Trials
- Filings - Design

Regulatory pathway
Lead agency
Acceleration opportunities

Advisory committees, Agency meetings

Risk minimisation

Regulatory policy

Post-development: life cycle management

RI input for regulatory strategy & product development

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

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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

- “Sharing regulatory intelligence: Are newsletters here to stay or is social media the future?” *Regulatory Rapporteur - TOPRA*, 8(5), May 2011, p5-8
QUESTIONS?