CHAPTER 5 How to Set Up an RI Department

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Why would a company have an RI Department?

The need for a dedicated RI function within companies is increasing because:

• The pharmaceutical and medical device industries are heavily regulated and becoming more complex, requiring dedicated staff to maintain surveillance on regulatory changes and their impact on the company.

• Companies must comply with the ever-changing regulatory requirements in all countries in which they operate.

A broad range of RI-related activities fall within the RI department remit, as shown in Figure 5-1.

First Things First

No one is expected to be an expert on all the regulations on a global level, but it is important to consider the RI deliverables needed by the organization in terms of scope (countries, topics), output, and communication path.

To set up an RI department, it is essential to map the different internal ‘customers’ of the department (e.g., regulatory affairs, R&D, marketing, corporate) to better understand their goals, how RI can help achieve these goals, and how they use RI.

Connecting with internal subject matter experts is the key to supporting further regulatory activities’ impact analysis. The person setting up the RI department will have to map RI activities, roles, and responsibilities. Therefore, drawing up a skills inventory of current regulatory staff can provide an understanding of the strengths and gaps required to fulfill the mission. These preliminary steps should help identify relevant resources (people and tools) to ensure an appropriate workflow and system.

The steps described above and shown in Figure 5-2 should be reassessed on a regular

Figure 5-1. RI Department Activities

- To rapidly identify and communicate significant changes in the regulatory environment to key internal stakeholders
- To conduct and deliver unique and insightful analyses that facilitate strategic decision-making
- To serve as internal regulatory consultants and respond to ad-hoc intelligence requests
- To facilitate access to high-value and frequently referenced regulatory intelligence sources
basis to meet the demands of an evolving regulatory environment.

A significant task of any RI function or department is to develop and maintain good stakeholder engagement as shown in Figure 5-3.

The internal regulatory staff are the primary customers of an RI department.

- Engagement and communication are essential, and methods of receiving intelligence may differ based on personal preferences.
- Internal customers should know how to contact the RI department and the level of support they can expect to receive.
- The RI department should conduct training and raise awareness for any internal processes or tools to avoid duplication of effort in gathering RI.

Other internal functions, such as R&D, manufacturing, management, etc., also can be customers and subject matter experts within an RI department.

- Subject matter experts should understand why their contributions to impact analysis are valuable
- The RI department should advise subject matter experts on how to provide quality insights.

The external, broader regulatory affairs community will be a good source for information on initiatives not yet published and common practices or tools that can facilitate daily RI activities.

**Core Investment**

Regardless of company size, organizing an RI department is possible, even on a limited budget. The minimum requirements are described in Figure 5-4.

**Should the RI Department be separate from other regulatory groups?**

The short answer is not necessarily.

- Different companies may have different organizational structures and needs, depending on the company size (e.g., different needs and capabilities) and overall structure (e.g., human drugs and
biologics companies may differ from a medical device company).
- In small companies, RI may fall within the regulatory affairs department remit.
- In larger companies, RI may be part of a global policy function.

- Given the pace of regulatory changes, it is important to have staff dedicated to RI activities, so the rest of the regulatory staff is not overburdened.
- Regardless of the companies’ organizational structure, it is essential for the RI department and other regulatory affairs department staff to collaborate on working towards a common goal. RI staff often lead the effort in sharing experience and best practices across the regulatory affairs department.

**Recommending an RI Department to Management and Demonstrating its Value**

A proposal should be prepared that outlines the features of the RI department, its value and expected impact on the company, the required tools, and the budget. Please see Chapter 21 for a discussion on measures of success.

RI is often conducted informally within a company, but its value is not always recognized. Establishing a formal department can be challenging, as it means formally recognizing the need for RI work as well as creating a proposed budget for resources (tools, people, and possibly contractors or consultants). To help establish a department, the RI professional should outline the expected deliverables and hold informational meetings with internal stakeholders. What intelligence deliverables would make their life easier? These benefits are shown in Figure 5-5.

Once management understands the needs of internal stakeholders, a proposal for the RI department can be drafted, including a discussion of budgetary issues. The main factors to consider when setting up an RI department are shown in Figure 5-6 and include:

- **Staff:**
  - Who will perform the function (will the position be part-time or full-time)? It would be best to find a person with excellent research skills (this cannot be stressed enough).
  - What are the RI professional’s job description and overall responsibilities?
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Figure 5-5. Benefits of an RI Department

- More insight on the regulatory environment
- Increase compliance
- Identification of regulatory opportunities
- Reduce development costs
- Improve the drive to be right the first time
- Reduce the time to market

Figure 5-6. Factors to Consider When Setting Up an RI Department

- Staff
- Budget
- Tools
- Activities
○ How much of the RI work will be outsourced, and how much of it will be done in house?

• Tools:
  ○ What tools will be purchased for the function (databases, websites, consultants, etc.)?
    ▪ A five-year plan can be created, outlining what tools will be purchased and what output will be expected in each of the first four years, and after full implementation in the fifth year, including how performance will be measured.
  ▪ Tools, especially those critical to making the RI professional’s life easier, can be expensive. It often is necessary to demonstrate the value of the tool by time saved (a vendor can often provide this information), which typically is significant (20–80+ hours saved). When the workload increases, and the RI department is asked to do more work with the same number of people, tools are essential. (the individual justification can vary but should be based on time and money saved). If a department starts with only free tools, management should be made aware that productivity might be lower, as more manual work will be required.
  ▪ To which journals should the company subscribe, and will they be archived electronically?

• Activities:
  ○ What will be monitored? (See Chapter 7 Monitoring and Surveillance)
  ○ How will new information be evaluated against prior information?
  ○ How will new information be integrated into current processes?
  ○ How will new regulations, forms, or guidance documents be distributed?
  ○ What activities can be outsourced, considering confidentiality issues, and what knowledge of portfolio and internal priorities is necessary to perform an accurate impact analysis?
  ○ What are the expected deliverables?
    ▪ How will work be communicated to stakeholders?
    ▪ How will work be stored and managed?
    ▪ How will job function and output be measured? (See Chapter 21 RI Metrics)

• Budget:
  ○ What is the annual budget? This should include:
    ▪ Basic costs
    ▪ People, including external resources such as contractors or consultants
    ▪ Tools
    ▪ Infrastructure (computers, intranet, software, etc.)
  ○ Annual vs. onetime costs for subscription and consulting fees and tools

Once the RI Department is set up, its return on investment (ROI) should be demonstrated by showing how RI has:
  • Reduced time to market
  • Increased compliance
  • Reduced costs of development
  • Reduced or abolished costs of noncompliance (financial, staff, operational, and regulatory)

Small Versus Large Companies’ Organization

Small companies with one person conducting RI part-time, and large companies with dedicated RI departments of 3–15 all have similar-
ities and differences as illustrated in Table 5-1. How each company addresses their needs varies based on experience, deliverables, and budget. However, the RI process remains the same regardless of size.

Outsourcing

Depending on the size of the RI department and expected activities, outsourcing may be a good option, at least on an ad hoc basis. Outsourcing can solve resource availability challenges, including lack of competency or language skills to monitor the regulatory landscape. Outsourcing basic and repetitive activities can free up time for internal staff to work on more value-added activities.

Knowledge Management

How to Manage and Store Data and Data Requests

RI output must be managed, stored, and shared to learn from experience and avoid duplication of effort. For small companies, an intranet site (such as SharePoint) is an effective way to manage and share data, including requests. Larger companies can use an intranet site or dashboard and databases (in-house, custom or off-the-shelf) and more-efficient systems for managing information requests, fulfilling requests, posting hot topics, and distributing new regulations or guidance documents.

Intranet/SharePoint Site

What typically is contained on an intranet or SharePoint site? The following content, at minimum, has proven to be highly useful (a link on the home page to the site and a separate page for each topic):

- **What’s New**: A section to list the most recent regulatory agency updates (by country), provide links to recently published newsletters, or to the newsletter main page.
- **Links to RI database and any other databases or RI tools available companywide**: These include regulations, guidelines, standards, forms, templates by country, whether they are final or draft.
- **Research requests**: These include instructions and forms for the request; past and popular requests.
- **Therapeutic area and product approvals background**: Strategy, articles, competitive analysis, past product precedents, drug approval/summary basis of approval summaries, presentations, etc.
- **Training and presentations library**: Typically organized by subject and then by category.
- **Reviewer and inspector profiles**: Listing of all reviewers and inspectors and links to their profiles.
- **Commenting**: Items relevant to the organization; subject matter experts who can provide a company perspective for the impact analysis.
- **Enforcement/inspection databases**: Inspector profiles can be stored here as well as Warning Letters, inspection outcome reports, and GXP trending information.
- **Articles**: This can be a link to reference managing software or can provide articles the RI department considers to be of interest not falling under the scope of a therapeutic area or hot topic.
- **RI department-related information**: Metrics, contact information for RI personnel at affiliate offices with their respective responsibilities listed.
### Table 5-1. Comparison of Small and Large Companies’ RI Departments

<table>
<thead>
<tr>
<th>Small Company</th>
<th>Large Company</th>
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<tbody>
<tr>
<td><strong>RI Structure</strong></td>
<td><strong>RI Structure</strong></td>
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<tr>
<td>• Needs to be creative and flexible.</td>
<td>• Dedicated, experienced team to perform a wide range of RI functions.</td>
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<tr>
<td>• More dependent on colleagues (network) and consultants.</td>
<td>• Workload divided by therapeutic area and/or region for each RI analyst.</td>
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<tr>
<td>• Needs to do more with less, due to limited resources and tools.</td>
<td>• Well-honed processes, forms, and maintenance procedures.</td>
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<tr>
<td>• Is a part-time role; there are more distractions while performing RI function.</td>
<td>• RI performed daily, enabling the company to catch issues affecting product development or approved products immediately and to implement change.</td>
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<tr>
<td>• Needs to learn information quickly, as development programs are dynamic.</td>
<td>• For some projects, ability to dig deeper and provide in-depth RI coverage and analysis.</td>
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<tr>
<td>• Reactive: often performed only when a question is asked, or a topic needs to be researched (such as how to file a CTA in Canada, Australia, and the EU).</td>
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<table>
<thead>
<tr>
<th><strong>Advantages</strong></th>
<th><strong>Disadvantages</strong></th>
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<tbody>
<tr>
<td>• Can move quickly and nimbly from topic to topic, depending on day-to-day needs.</td>
<td>• Fewer resources.</td>
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<tr>
<td>• Agility in developing strategies (from searches to strategic decision).</td>
<td>• May not have an electronic system to help archive or store information.</td>
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<td></td>
<td>• Due to time constraints, the RI professional cannot dig as deeply or research as extensively as preferred because day-to-day maintenance regulatory work also needs to be completed.</td>
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<td></td>
<td>• Little to no access to paid tools/databases, increasing the time and labor required to complete RI activities.</td>
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<th><strong>Advantages</strong></th>
<th><strong>Disadvantages</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Multiple tools and databases used to perform, communicate, and manage RI output efficiently.</td>
<td>• Segmented work, depending on company organization.</td>
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<tr>
<td></td>
<td>• Knowledge management databases bought or created to manage the wide variety of regulatory information.</td>
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<td></td>
<td>• Intranet or SharePoint portals for company-wide information sharing.</td>
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<td></td>
<td>• Dedicated affiliates to help conduct surveillance and provide relevant information.</td>
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### Conclusion

When establishing a regulatory intelligence (RI) department, it is essential to map internal ‘customers’ of the department and to understand their goals, how RI can help achieve these goals, and how RI is used. A proposal outlining the features of the RI department, its value, and expected impact on the company, and the tools and budget needed should be presented to management. Different companies may have different organizational structures and needs, but given the pace of regulatory change, it is imperative for the company to hire a dedicated staff for consistent RI activities. Depending on the size of the RI department and expected activities, outsourcing may be an option, at least on an ad hoc basis. Regardless of the organization put in place, the RI function will need to have efficient knowledge management.

### Reference