Regulatory Information Management

Why and How to Get Started

Why should we start looking at **Regulatory Information Management** (RIM)?

Historically, Regulatory information has been managed in a multitude of systems, file shares, as well as SharePoints and/or intranet sites across the global, regional and local Regulatory organizations. As a consequence, getting a global overview of key Regulatory information and data has been – and still is to a large extent – a significant industry challenge.

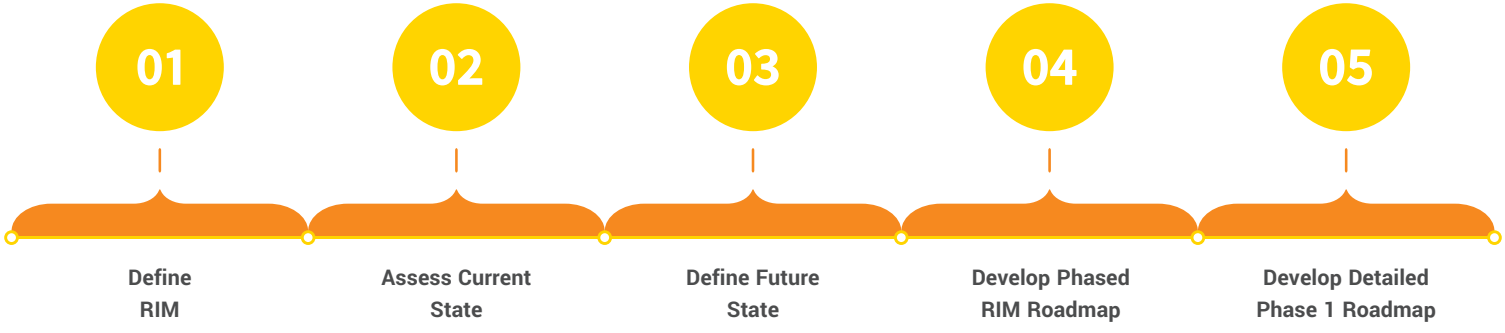
Combining this with: **1)** the ever increasing complexity of regulations and product portfolios, **2)** growing demand for data due to increased public and regulatory scrutiny, **3)** the trend of further global collaboration and standardization of formats and processes across the regulators, and **4)** increased use of partners and outsourcing, **it becomes clear that:**

01 **The challenge of getting a global overview of key Regulatory information and data is only going to grow, unless we start changing the way we work with and manage Regulatory information**

02 **Investing in robust, integrated Regulary systems utilizing the emerging standards will be key to ensuring continued compliance and efficiency**

At HighPoint we developed a 5 step process to help you get started on your RIM journey by:

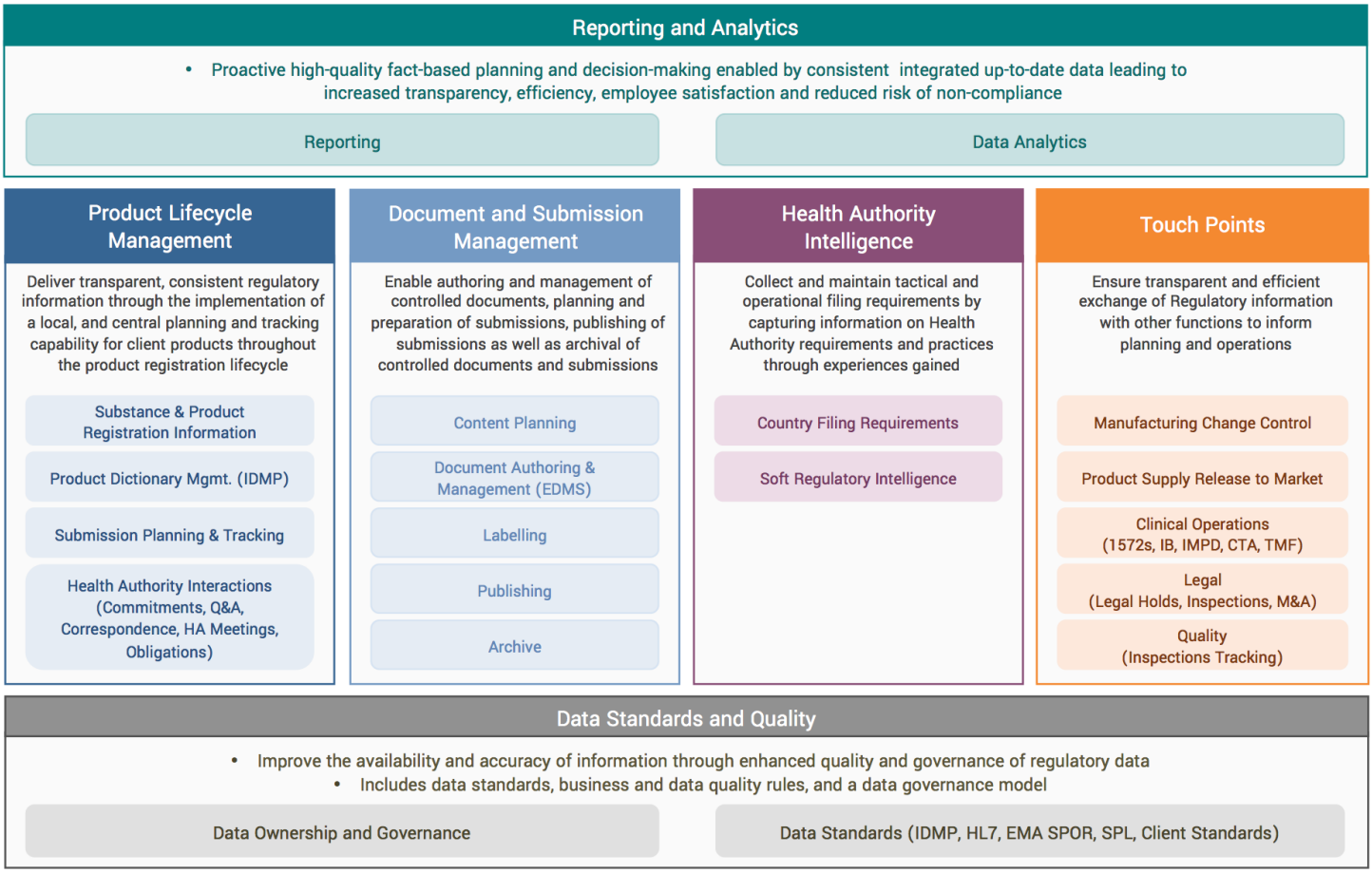
- Understanding where you stand today with regards to Regulatory Information Management
- Defining where you want to go with regards to Regulatory Information Management
- Developing the plan for how to get there



Step 1 – Defining what RIM means to your organization

Regulatory Information Management (RIM) is a term that was born back in the mid-2000s and which has been developing ever since. Essentially, RIM can be defined as the capability to support global regulatory activities. Meanwhile, this is not very specific, operational or actionable. At HighPoint, we have therefore defined a RIM Framework based upon which a client-specific RIM definition can be developed.

HighPoint RIM Framework



Step 2 – Defining your current state for phase 1

After defining a precise scope, the next step is to define and assess your current state with regards to people, process, techonology and data through documentation review, structured Discovery interviews, workshops and ad-hoc interactions:

- **People & Process:** Global Regulatory organization structure, high-level roles and responsibilities, current business processes, and current people and process related challenges.
- **Technology & Data:** Systems (incl. Excel trackers and SharePoint sites) currently used to support Regulatory business processes, data managed within systems, data flow between systems, and current technology and data challenges.

The current state assessment should produce the deliverables listed below:

1) As-is Global Regulatory organization structure, roles and responsibilities

2) As-is business processes

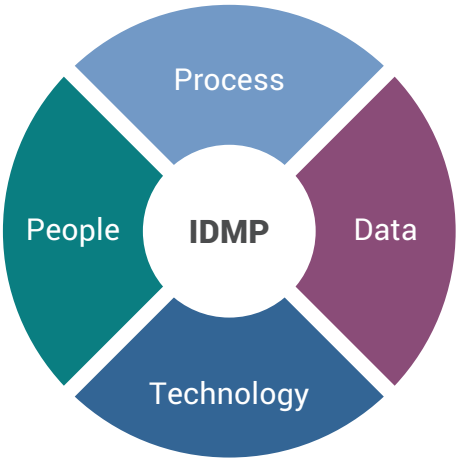
3) As-is IT architecture and data flow

4) Tangible challenges to be addressed

Step 3 – Defining your future state for phase 1

Based on your current state definition as well as Industry regulations and best practices, step 3 is to define your desired future state through a combination of structured Discovery interviews, workshops and ad-hoc interactions:

- **People & Process:** Global Regulatory organization structure, high-level roles and responsibilities, future business processes, and future people and process specific improvements.
- **Technology & Data:** Systems to be used to support Regulatory business processes, data to be managed within each system, data flow between systems, and future technology and data related improvements.



HighPoint recommends initiating the vendor selection process during this phase by conducting a request for information to get inspiration from the market and to make sure that the future state is "grounded" and can actually be implemented.

The future state definition should contain the following deliverables:

1) Global Regulatory organization structure, roles and responsibilities, **2)** to-be business processes, **3)** to-be IT architecture and data flow, **4)** RIM User Requirements and Use Cases, and **5)** tangible benefits to be delivered.

Step 4 – Defining a phased RIM roadmap

Once you have defined what RIM means to your organization, the next step is to look at that definition and break it down in a phased roadmap with a clearly defined scope per phase. This roadmap can cover your full RIM definition in multiple phases or it can consist of phase 1 with the the remaining phases to-be-determined if a long term RIM program isn't feasible in the current circumstances.

Step 5 – Defining the detailed phase 1 roadmap to bridge the gap

Once you have defined both your current and future states, the next logical step is to assess and define the gap between the two as well as the solution and plan for bridging the gap. At HighPoint, we highly recommend continuing the vendor selection process during this phase by conducting a request for proposal (RFP) to ensure robust and realistic resource and cost estimation as well as planning.

The planning phase should deliver the following:

1) RIM Roadmap and Charter **2)** RIM Project Business Case(s), and **3)** High-Level Project Plan

Conclusion

For both historic and contempory reasons, the challenge of managing Regulatory information ensuring compliance and efficiency is only going to grow. It necessitates us to change the way we work and start investing in robust, integrated Regulary systems supported by robust data management and utilizing emerging standards and technology developments.

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