Cabeus

Unearthing Potential

ReALM® GRIP

Cloud-Enabled Global Regulatory Intelligence and Planning (GRIP) System

Get a grip on RIM!

Dr. V. Bala Balasubramanian, Ph.D., MBA

Cabeus White Paper

September 28, 2018

Regulatory Affairs Lifecycle Management

Cloud-Enabled Global Regulatory Intelligence and Planning (GRIP) System

Get a grip on RIM!

1. Executive Summary

Life sciences, medical device and biotechnology companies are continuously looking into optimizing their regulatory submissions planning processes, while coping with increased workloads in order to support simultaneous global submissions and reducing time to market. At the same time, the breadth and depth of regulatory regimes are growing across most regulatory authorities, with increasing regulations and expectations. These drivers of complexity create intense demands on Regulatory Affairs teams, and require more meaningful ways of managing regulatory requirements, traditionally left to the devices of spreadsheets and checklists. The challenges encountered during downstream regulatory activities such as incomplete filings, significant last minute re-work, etc., are primarily due to lack of upfront understanding of regulatory requirements around regulatory activities and/or filings across the globe. Better approaches are required to increase efficiency, capacity and quality simultaneously around regulatory activities. Given the current challenges around regulatory requirements and planning across the Life Sciences industry, Cabeus has developed a suite of applications called Global Regulatory Intelligence and Planning (GRIP) based on a cloud-based Regulatory Affairs Lifecycle Management (ReALM®) platform.

Just as SalesForce and WorkDay have brought down the costs of information management in customer relationship management and human resource management areas of an enterprise, Cabeus' ReALM® Regulatory Cloud Suite delivers enterprise-class functionality for a modest monthly subscription fee with no infrastructure requirements or costs to Regulatory Affairs. ReALM® is designed from the ground up to integrate with any capabilities that already exist in an enterprise to enable other Regulatory Affairs activities.

Our seasoned experience building similar solutions for leading life sciences companies has informed our initial focus on Regulatory Intelligence and Submission Planning. The purpose of the Cabeus ReALM® Regulatory Cloud Suite is to provide access to "instant-on" technology that can have an impact on a team's productivity in a matter of weeks – with no capital costs. The ReALM® product rollout goes well beyond strategy and planning to support the full lifecycle of Regulatory Affairs activities and operations.

© Cabeus, Inc. All Rights Reserved.

2. Current Challenges around Regulatory Requirements and Content Planning

Figure 1 below shows a high-level overview of the Regulatory Value Chain within the Life Sciences industry. Cabeus is currently focused on addressing challenges around Regulatory Strategy and Planning phases.

While a significant portion of a company's regulatory strategy and plan to launch a new product is based on the overall business strategy, it also depends on a thorough understanding of regulatory requirements or regulatory intelligence across various markets.

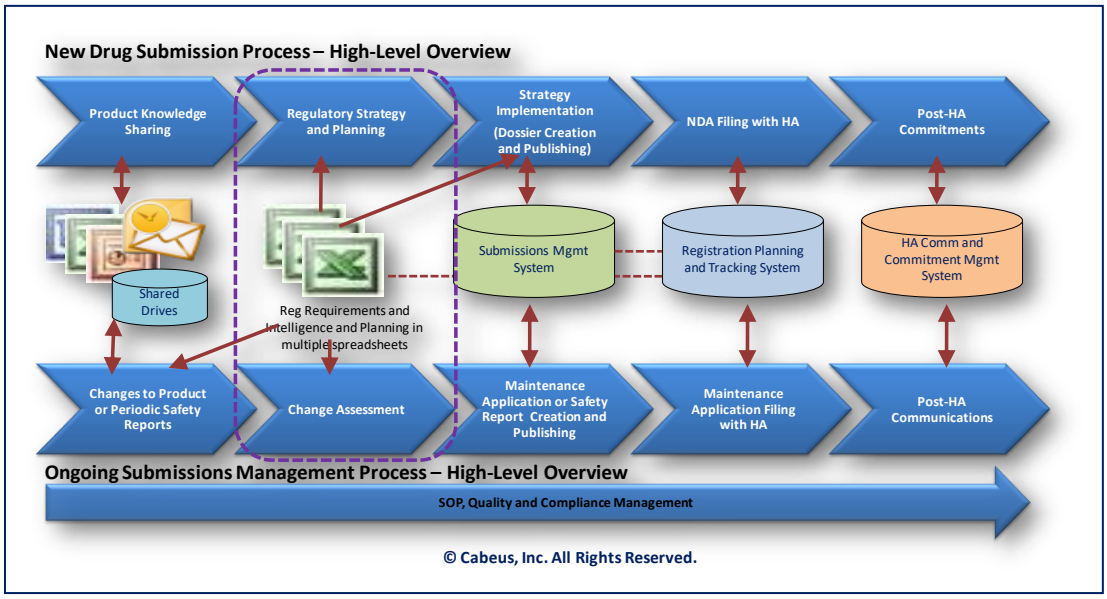

Figure 1. Regulatory Value Chain

The typical challenges faced by Life Sciences companies regarding regulatory requirements, intelligence and planning are:

- Keeping up with changing local/regional requirements at all levels of the organization combined with stretched resources at headquarters and local levels
- Identifying, collating, interpreting, and managing regulatory requirements and interpretations in an ever changing regulatory environment across the globe, especially in emerging markets, which are continuously trying to keep up with matured markets.
- Spreadsheets and checklists are widely used to manage requirements for various types of studies and submissions across different markets and these are no longer repeatable or sustainable for many organizations.
- In addition, other spreadsheets are widely used to manage submission plans, causing an immediate disconnect among strategy, regulatory intelligence, requirements management and planning.

© Cabeus, Inc. All Rights Reserved.

- Ever changing regulations and lack of harmonized processes to communicate requirements in a timely fashion between local/regional affiliates and headquarters.

The business impact of not having timely and detailed regulatory requirements and intelligence upfront is extensive:

- Delayed filings and potential loss of revenues
- Inaccurate or incomplete filings increasing health authority rejection risk and potential loss of reputation
- Significant re-work on submissions at local, regional and global levels
- Lack of content re-use due to non-availability of cross sectional views of regulatory requirements across multiple markets (for example, the inability to query "show me all markets that require Zone IV stability studies")
- Inefficiencies during planning and preparation of filings due to lack of timely communication

3. Cabeus' ReALM® Suite of Solutions

Cabeus is addressing a number of challenges across the Regulatory Value Chain with the ReALM® Regulatory Cloud Suite of Solutions. The first module released is a structured, yet flexible software framework and system called Global Regulatory Intelligence and Planning **(GRIP)**, to manage regulatory requirements and intelligence which include health authority guidelines, subject matter interpretations of those guidelines, as well as company experiences with various types of studies and submissions across the globe. The system provides a structured approach, to manage pre-defined templates of requirements sourced from a master library of global requirements for different types of submissions (NDAs, Variations, Renewals, maintenance Applications, Stability Studies, Inspection Requirements, Samples for Registrations, Certificates, etc.). These templates can be used as a starting point to bootstrap regulatory strategy and planning activities for a product in a given set of markets by local, regional and global regulatory leads in an organization. In addition to providing the software framework, Cabeus is working towards collation and curation of authoritative regulatory content by partnering with a network of regulatory experts across the globe, who will provide periodic updates on regulations and interpretations in their respective markets. The templates not only provide access to current regulations and interpretations at a granular level, they can be immediately applied to create an actionable plan where each activity in the overall plan is assigned to different individuals and tracked closely.

Figure below shows a conceptual architecture of ReALM® GRIP.

© Cabeus, Inc. All Rights Reserved.

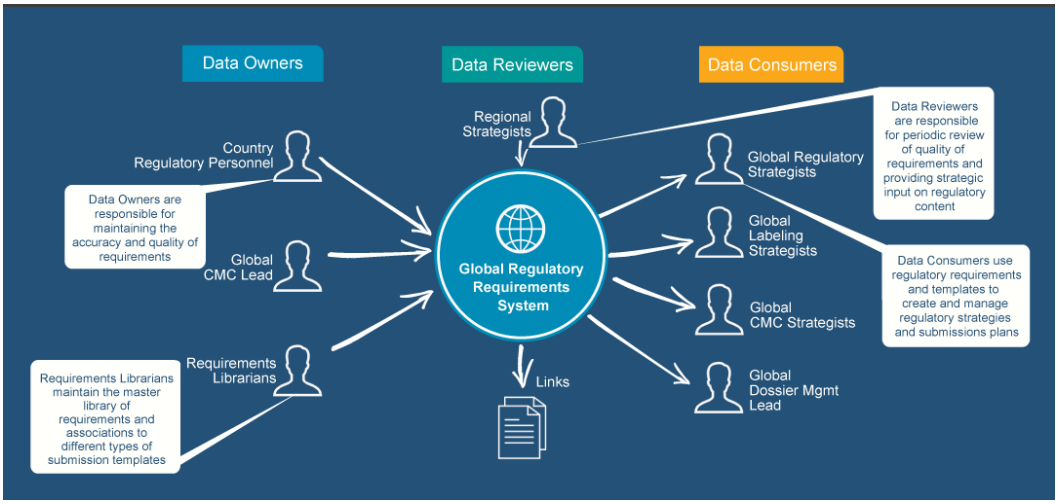

Figure 3. Conceptual ReALM® GRIP Architecture

4. Value Proposition

We have a tiered value proposition with ReALM® GRIP. First, the ReALM® GRIP Software Suite provides the basic software framework and application to capture and manage regulatory requirements, intelligence and enable content planning, thereby improving operational efficiencies. Second, through AI and ML techniques , Cabeus will capture regulatory requirements from different parts of the world, available separately as a regulatory content service, thus enabling compliance objectives. Third, Cabeus will provide subject matter expertise and interpretations on top of country regulations, in order to provide the additional knowledge and best practices for successful submissions and other regulatory activities. Fourth, when content is accumulated over a period of time, across different types of regulatory activities and submissions and across various regions, the potential exists for mining that content in order to provide regulatory intelligence that will give a strategic advantage and potentially impacting business objectives and revenues.

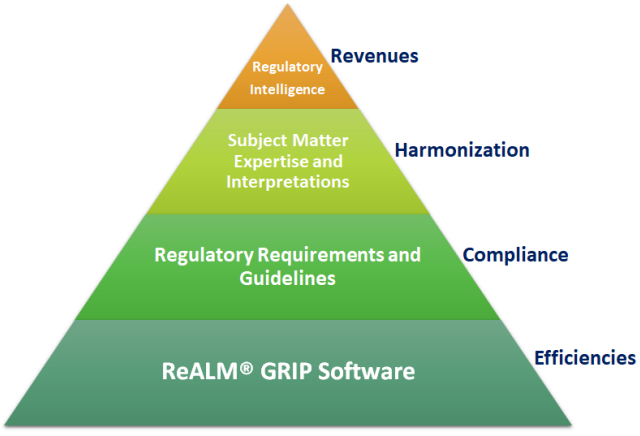

Figure 2. ReALM® Value Proposition

© Cabeus, Inc. All Rights Reserved.

5. ReALM® GRIP Objectives

The key objectives behind ReALM® GRIP are to enable regulatory strategy and planning activities by providing an integrated, authoritative, globally accessible, reference repository of regulations, guidelines, subject matter expertise, interpretations, best practices, lessons learned along with actionable content plans for a specific product.

Figure 3. GRIP Capabilities

6. Key Features and Benefits of GRIP

Following are representative features of ReALM® GRIP:

- Structured, table-of-contents approach to managing regulatory requirements and intelligence unlike other unstructured texts and sources commercially available in the market.
- Ease of use and granular searching of requirements across applicable countries, submission types, especially to facilitate content reuse.
- Creation and management of internal guidelines, interpretations and best practices for different types of submissions and regulatory activities.
- Linkage to internal and external health authority guidelines and other publicly available sources.
- Standard templates of requirements for different types of submissions, compiled from a master library of requirements.
- Creation of a product/country/submission-type specific combination of requirements, for easy insight into what was the regulatory strategy behind a specific product.
- Cloning or copying from existing requirements structures created previously for product/submission type combination for other countries.
- Creation of master plans and Gantt charts of submissions from requirements templates with activities, task assignments, milestone dates and deliverables.
- Dashboards with metrics of key submissions planning activities and status information.
- Management of master library of requirements and templates by content curators.
- Access to local, regional and global experts and internal/external stakeholders.

© Cabeus, Inc. All Rights Reserved.

- Access to a repository of subject matter expertise around regulatory guidelines and experiences from across the globe.

7. Conclusion

In this paper, we provided an outline of the typical challenges faced by regulatory during the early strategy definition and planning phases of the Regulatory Value Chain. Cabeus believes that most of the downstream challenges, inefficiencies, and issues of regulatory planning and submissions are a result of not having a structured approach to managing ever-changing regulatory requirements and plans. Our ReALM® GRIP suite of applications allows regulatory organizations to get a grip on the challenges and provides key capabilities to enable the management of regulatory requirements and intelligence for various types of submissions and regulatory activities, providing the platform for better planning and improved efficiencies throughout the entire regulatory value chain. ReALM® GRIP is available for evaluation by Life Sciences customers and we will be glad to arrange for a demonstration.

8. About the Author

Dr. V. (Bala) Balasubramanian is the President and Founder of Cabeus, an elite consulting firm and cloud services provider, enabling Life Sciences clients to unearth the full potential of their IT investments in Enterprise Transformation, Regulatory Information Management (RIM) Solutions, Pharmacovigilance Solutions, Enterprise Collaboration & Content Management (ECCM) solutions, and Mobile applications. Dr. Balasubramanian is a seasoned IT professional with over twenty-five years of research, development and management experience. In his career, Dr. Balasubramanian has successfully led the design and delivery of large-scale IM capabilities for BMS, Aventis, Roche, Merrill Lynch, AT&T, Bell Atlantic and IBM. He is responsible for vision, strategy, client engagement and re-usable frameworks and methodologies. His primary focus is on how information management, collaboration, content management, mobility, and social media can enable business transformation by increasing speed to market, providing agility and fostering innovation.

Dr. Balasubramanian holds a Ph.D. and MBA from Rutgers University, an M.S. in Computer Science from New Jersey Institute of Technology and a B.S. in Electronics Engineering from Bangalore University, India. He can be contacted at balasubv@cabeus.com.

Cabeus, Inc.| 101 Morgan Lane, Suite 304, Plainsboro, NJ 08536 | www.cabeus.com
Phone: 609-423-1889| Email: balasubv@cabeus.com

 © Cabeus, Inc. All Rights Reserved.