Innovative Solutions for the Life Sciences

ACUTA Regulatory Information Management

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Preface

Competitive Life Science business strategies require a company to be able to coordinate operations across dispersed and often outsourced research, manufacturing, marketing, and regulatory functions. For Regulatory Affairs to meet this challenge it must be collaborative, efficient and compliant with constantly changing regulations. Yet many departments struggle with unifying critical data and processes to form a sustainable whole.

Order can be brought to chaos. Regulatory information management (RIM) is a strategy that successful Life Science companies can use to remedy the problem. With an effective RIM solution your company can remain compliant and efficient as you move products from concept to market entry and beyond.

An effective RIM strategy is one that enables you to develop, store and access electronic information with confidence. Combined with a knowledgeable workforce, RIM can satisfy the drive to launch quickly in global markets, meet regulatory filing requirements, monitor products and product approvals, plan resources, and continuously adapt to the demands of health authorities.

ACUTA Regulatory Information Management (ARIM)

The ARIM System is a fully integrated solution developed with the latest technologies and processes to ensure effective, compliant management of regulatory information.

ARIM is designed to assist Life Science companies in managing their regulatory information more efficiently and cost effectively. It covers all aspects of the RIM process and offers a cost-effective solution to companies of all sizes.

ARIM has five core modules that are essential to the regulatory information-management lifecycle.

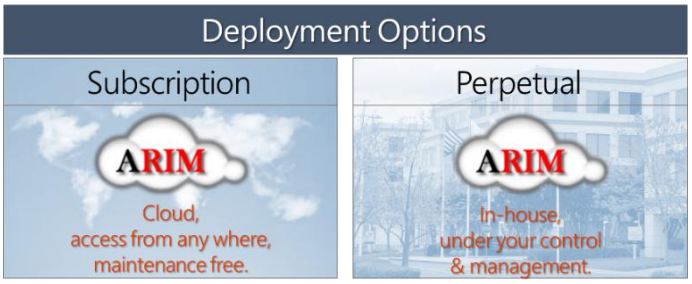
- Correspondence and Commitments
- Publishing & Validation
- Submission Planning
- e-Submission Viewer
- Product Registration and Tracking

ARIM is our solution to meet the current and future demands of life science companies.

KEY BENEFITS

- ✓ Provide a link between agency communications and regulatory submissions.
- ✓ Manage and track correspondences with health authorities along with the resulting commitments and status.
- ✓ Manage and track regulatory reporting processes including product safety update reports (PSURs).
- ✓ Ensure faster response time.
- ✓ Provide real-time access to relevant health authority correspondence and commitment information to all the individuals involved in the process.
- ✓ Increase speed and accuracy of commitment responses.
- ✓ Eliminate redundant systems and reduce repetitive and manual data entry.

ARIM is designed for cloud-based and in-house deployment. It supports Regulatory Affairs and Operations processes regardless of their complexity or geographic location, and it offers global access 24 x 7 x 365. With the cloud model, there is no need to purchase hardware or software, and no installation or maintenance is required. In other words, for the first time you can have a fully compliant system up and ready to use in a matter of hours.



ACUTA's goal is to offer software and services that enable you to adhere to strict standards set by regulatory authorities around the world, and help you launch and manage your products with compliance and reliability. We guarantee your ability to maintain data and information quality, accuracy and integrity.

Module Overview

Correspondence and Commitments

The ARIM Correspondence and Commitments module provides a rapid and efficient method for electronically archiving, tracking and responding to health authority communications. With it you can upload internal and external correspondence, link them to each other and to submissions, assign metadata, create follow-up actions and bring actions to a close.

Benefits

- Provides access to regulatory correspondence, and to associated commitments and their status
- Eliminates spreadsheets and tedious manual data-entry and linking processes
- Reduces operation costs by eliminating redundant systems
- Creates comprehensive status reports
- Increases accuracy of commitment responses
- Improves data control and data consistency
- Supports operations from on-site and remote locations
- Can be used on mobile devices

Publishing & Validation

The ARIM Publishing and Validation module is used to create, edit and validate eCTD and NeeS submissions. With it you can seamlessly import existing applications from legacy systems into ARIM. The module supports all DTD versions required by agencies around the world, including the FDA in its upcoming Regional DTD v3.2.

Benefits

- Simple and easy-to-use interface
- Built-in PDF Viewer and basic Editor (internal and external hyperlinking and bookmarking)
- Study Autoloader
- Creates and validates submissions with a single tool
- Scales to user volume
- Integrates with EDMS applications such as SharePoint and Documentum
- Optimizes and integrates with all other modules

Submission Planning

The ARIM Submission Planning module provides preparation, workflow and management tools of key importance to regulatory operations. With it you can add efficiency and cost effectiveness to the process of planning, creating and tracking agency submissions. The Submission Planning module addresses regional and global-dossier planning, as well as resource and time management.

When integrated with the Correspondence and Commitments module and the Publishing and Validation module, it enables you to keep track of internal submission deadlines and monitor your entire submission-building process.

Benefits

- Eliminates spreadsheet reliance and manual tracking
- Eliminate multiple, redundant systems and significantly increases project efficiency
- Provides real-time access to relevant submissions and associated commitment information
- Decreases submission timelines
- Increases speed and accuracy of commitment responses
- Streamlines regulatory-operation workflows through a single, accessible tool
- Includes submission start-to-end workflow management and resource allocation capabilities

e-Submission Viewer

The ARIM e-Submission Viewer module enables you to read and navigate through eCTD and NeeS submissions in a variety of views. It is compatible with national and regional submission formats, particularly those developed by the FDA, EMA, Health Canada, Swiss Medic, and the Japanese Health Ministry.

The e-Submission Viewer includes features and functionalities based on recommendations from ***Options for the Presentation of eCTD Messages***, as developed by the ***IRISS Life Cycle Topic Group***. (http://iriss-forum.org).

Benefits

- Simple, easy-to-use interface
- Read submissions in folder view, sequential view, cumulative view and current view
- Navigates through lifecycles and cross-references easily and intuitively
- Auto-registers new submissions
- Searches across documents in accordance with user-defined parameters
- Has granular security to manage access to submission content
- Integrates with all other ARIM modules.

Registration and Tracking

The ARIM Registration and Tracking module provides universal, multi-level tracking and reporting capabilities across your product portfolio. When combined with process-oriented planning, it gives instant access to vital clinical and CMC product information, such as approved labeling, indications, dosages, manufacturing sites, distribution paths and other user-defined product attributes.

Benefits

ARIM Registration and Tracking module catalogs and retrieves data on all of the following:

- Active Ingredient details such as strength, pharmacopoeia, raw materials, biological sources, and suppliers
- Records and reports on excipient details such as strength, role, pharmacopoeia, and suppliers
- Manufacturers and functions, such as API production, stability testing, and pre-dosage processing
- Indications, such as full label indications along with brief indication keywords for reporting and quick searches
- Labeling details, such as package insert, carton label, and hospital inserts
- Packaging details, such as primary, secondary, packaging types, and descriptions
- Country-specific details, such as storage conditions and shelf life.

About ACUTA

ACUTA offers innovative software solutions to the life sciences and related industries. Our solutions are intended to make Regulatory information management (RIM) compliant, effective and more efficient.

ACUTA focuses on three strategic lines of business: integrated Regulatory solutions, process consulting, and technology development. We combine knowledge with technical capability to pass on to our valued customers a complete set of RIM capabilities. By keeping abreast of regulatory standards as they emerge and evolve, our products and services remain innovative, relevant and cost effective.

The ACUTA team has over 100 combined years of experience in developing innovative solutions for the life sciences industry.

Our vision is to benefit you and the patient populations you ultimately serve. Our mission is to be the partner of choice for collecting, managing and sharing regulatory information in ways that put you squarely within compliance of internal and external regulations.

ACUTA was founded in November 2012 to help life science companies comply with ever-changing regulatory requirements that guide product approval and maintenance. ACUTA's founder and technical team are well known in the industry. With over 20 years of experience, we have deployed state-of-the-art solutions that are well received by the market and users themselves.

The pharmaceutical industry is looking at emerging market expansion and growth potential of 12 percent year on year, and the biologics market is expected to grow to $41 billion by 2014.

There will be continued and accelerated consolidation through M&A activity, including spin-offs to allow increased focus on corporate strategy and core competencies. And because of the volatility of the market, cost reduction programs will become more rigorous and closer to the bone.

- Outsourcing in the Pharmaceutical Industry: 2011 and Beyond - Charles Arnold & Vicki Phelan, KPMG