

ACUTA announces the release of ACUTA Regulatory Information Management (ARIM™) version 3.0.1

Marlborough, MA – April 17, 2017 – ACUTA announced the release of ACUTA Regulatory Information Management (ARIM) version 3.0.1 – a next-generation solution that redefines how Life Science companies manage regulatory information. ARIM brings together the data, content, and interactions with agencies needed to deliver a fully informed Regulatory Information Management (RIM) solution. Designed to work in the cloud or on premise, ARIM provides a centrally coordinated user experience while ensuring compliance. It supports the processes of Regulatory Affairs and Operations, regardless of their complexity or geographic location, and offers global access.

“At ACUTA we follow a User-centered design process. We involve our end users in all aspects of product development. This release is a classic example as the key features introduced in this release are the result of that effort.” said Shy Kumar, ACUTA’s Founder, President and CEO. “Our goal is to keep our users happy, we work very closely with our customers, listen to them and try to bring in features and functionalities they need on a day to day basis.”

ARIM is designed to assist Life Science companies in managing their regulatory information more efficiently and cost effectively. This v3.0.1 release includes a significant list of new capabilities including:

- **Support for South Africa’s** use of eCTD through the version 2.1 being implemented May 1, 2017
- **Support for Veeva Vault** document repositories
- Foundational data **support for IDMP** (Identification of Medicinal Products), a set of ISO standards for registration of products currently being implemented in Europe
- Viewer and Publisher users are now able to create and **manage comments** at the module, section, document and page level.
- Users can now **update multiple correspondence and commitments records** at the same time, with the bulk update features.
- And many additional improvements to existing features and functionality

These features advance the previous version’s rich user interface and architecture built on native HTML5 without browser plug-ins, greatly reducing the effort for IT departments to implement.

Support for IDMP is built on the Formulation and Registration data model, expanding from ARIM version 3.0.0. This enables detail to be entered for product registrations in sync with regulatory submissions and approvals. New data elements include packaging, ingredients and market authorisations. *Joel Finkle, Director of Regulatory Innovation and IDMP Strategy points out, “ARIM provides a way for companies to ease into IDMP with data entry that reflects the in-house processes instead of forcing regulatory to follow the convolutions of the ISO standard. At the same time, ACUTA Regulatory & Clinical Services (ARCS) personnel, using the ARIM tools, can supplement life sciences staff during the enormous effort needed to convert paper documentation into the structured IDMP format.”* ACUTA solution offerings now include IDMP readiness analysis, and education on the standards and implementation in Europe.

The ARIM Cloud offering is powered by Microsoft Azure and advances the Life Science industry’s urgent drive for an affordable solution using technology tailored to small and medium size company needs, with increased efficiencies and cost savings.

For more information on ARIM, please visit <http://www.acutallc.com/arim>

About ACUTA, LLC

ACUTA was founded in 2012 to assist Life Science companies in complying with ever changing regulatory requirements that guide the product lifecycle through approval and maintenance. ACUTA’s founder Shy Kumar and his team members are well known in the industry, with over 20 years of experience. They have successfully deployed state-of-the-art solutions that were well received by industry and users.

ACUTA’s vision is to develop innovative solutions to assist Life Sciences and related companies with their regulatory information management, which ultimately benefit everyone and specifically the needs of patients around the world.

ACUTA is headquartered in Marlborough, MA, USA with offices in Bangalore, India. For more information, visit www.acutallc.com.