FACT SHEET

LifeSphere RIMS™

KEY BENEFITS

- Process-driven approach eases regulatory tracking
- Guided data entry aids even infrequent users through workflow tasks, wizards, alerts and more
- Cloud-based solution insulates against changing regulations and maintenance costs
- Powerful ISO IDMPcompliant product registration structure for complex regulated product information tracking
- Diverse application integration mechanisms enable inter-department process efficiencies
- Pre-validated Industry Standard Practices (content and process templates) deliver faster deployment and harmonized process implementation

Fueled by an expanding range of detailed requirements and the move toward IDMP electronic submissions, today's legacy regulatory information management systems (RIMS) are no longer adequate to support the volume and complexity of regulatory documentation and information required for global compliance and maintenance of global product lifecycles worldwide.

In their place, cloud-based RIM solutions now provide higher system availability and adaptability to changing regulations to provide the necessary scalability, integration, automation and more.

LifeSphere RIMS™: Based on Industry Standard Practices

LifeSphere RIMS (Regulatory Information Management System) is the SaaS-based Regulatory Information Management System (RIMS) that is fully IDMP-compliant. LifeSphere RIMS gives RA professionals the capabilities that will empower their workforce to get regulatory business activities done more quickly and efficiently. Utilizing a process and workflow-driven approach, LifeSphere RIMS provides intuitive, mobile-enabled handling of all regulatory affairs processes by headquarters, regulatory operations, regional managers and local affiliates.

- Core RA (regulatory affairs) tracking modules – Product Registrations, Submission Processes and Agency Interactions – give users a single solution for tracking all RA business processes. Real-time visibility of ongoing submissions, authorizations, commitments, open agency correspondence and upcoming renewals ensure your continued compliance.
- Additional modules for Clinical Trial Application Tracking, Global Change Management and Dossier Planning & Preparation are under development to further provide capabilities that extend beyond what other cloud-based solutions offer.

Comprehensive business process workflow automation enables demand forecasting, submission planning and performance tracking for improved decision making.

Out-of-the-box interfaces with a wide range of document management systems and configurable data exchange mechanisms result in improved cross-functional process efficiencies, collaboration, control and visibility of the "single source of truth."

A Modern Solution for Modern Challenges

Here are some specific ways that LifeSphere RIMS helps regulatory affairs teams succeed:

Mature, Proven Solution

LifeSphere RIMS is a well-researched and mature RIMS solution that clearly reflects customer situations, **built on 20 years of experience** with a thorough understanding of the complexity of regulatory data tracking processes.

Designed for Ease of Use

Whether they're power users or infrequent affiliate users, LifeSphere RIMS boosts end-user acceptance and product adoption with minimal product training. Improved collaboration with affiliates or infrequent users is made possible with a more **intuitive process-based user interface, role-specific workflow reminders,** tasks lists and wizard-based approach to data entry.

Workflow-Driven Approach

A **process layer on top of regulatory information** enables the entire regulatory department to effectively plan, track and have quick status visibility (with mobile apps) into all phases of regulatory submissions including strategic forecasting, pre-submission meetings, dossier preparation activities, submission milestones tracking, health authority questions on submissions, approvals and more.

Powerful Business Analytics

Visualize regulatory resource productivity and measure affiliate performance against expected KPI's with comprehensive business workflow tools and graphing capabilities.

Pre-Loaded and Fully IDMP Compliant

Users can leverage **collective industry intelligence and standard practices** for faster deployment and harmonized process implementation thanks to LifeSphere RIMS' built-in industry best practices drawn collaboratively, built and validated by customers.

Proactive and full support for IDMP data extraction, review, validation and electronic submission needs not just for EMA but also other regulatory bodies, including FDA, HealthCanada, SwissMedic and PMDA in future using the 100% ISO IDMP-compliant product data model.

Rapid Deployment

Quick deployment and use of the application is made possible by a **SaaS-enabled and pre-validated** solution on ArisGlobal's secure cloud platform to deliver a lower total cost of ownership. Customers benefit from easy upgrades and inexpensive fine-tuning for their specific needs to facilitate quick reactions to changing IDMP regulations.

ABOUT ARISGLOBAL®

ArisGlobal is a visionary technology company that's transforming the way today's most successful life sciences companies develop breakthroughs and bring new products to market. The ArisGlobal LifeSphere™ cognitive technology platform integrates machine-learning capabilities to automate the core functions of the product lifecycle. Designed with deep expertise and a long-term perspective that spans more than 30 years, our cognitive platform delivers actionable insights, boosts efficiency, ensures compliance, and lowers total cost of ownership through multi-tenancy.

Headquartered in the United States, ArisGlobal has regional offices in Europe, India and Japan. For more information, visit arisglobal.com or follow ArisGlobal on LinkedIn and Twitter.

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