LifeSphere Regulatory™

KEY BENEFITS

- Improved efficiency and productivity via automation, actionable analytics and intuitive user experience

- Reduced TCO and insulation to changing regulations with multi-tenant cloud based solution

- Improved overall organizational compliance with regulatory information sharing via standard integrations and open architecture

For life sciences companies of all types, an increasingly complex and demanding regulatory environment can result in compliance issues that involve financial consequences and impact a company's reputation and market share. With every penalty and recall, life sciences companies become painfully aware of the increasing information gaps between regulatory department and other parts of the company. Pharmaceutical standards like ISO IDMP/xEVMPD and device standards such as UDI are being driven by different geographies, creating a global compliance challenge for all life sciences companies.

LifeSphere Regulatory™ Heralding the Era of RIMS and Regulatory Compliance Transformation

LifeSphere Regulatory is the multi-tenant cloud-based solution platform that offers an innovative, end-to-end approach for regulatory affairs, spanning core regulatory tracking and submission management capabilities, as well as integrations with document and dossier preparation, management and publishing. Our **LifeSphere modules** leverage industry-standard processes (ISPs) and cognitive computing capabilities to help efficiently integrate compliance with automated business processes over the entire product management lifecycle.

LifeSphere RIMS™	Multi-tenant SaaS solution for Regulatory Information Management and Standards Compliance
	An **ISP-based** Regulatory Information Management System that utilizes a **process and workflow-driven** approach for intuitive and comprehensive handling of **all regulatory business processes** like product and clinical trial registration management, submissions planning & tracking, dossier structure planning and compiling, agency correspondence, commitments and global change management. The application includes compliance module covering data standards like **XEVMPD, IDMP** and others. Built on an **open architecture**, the application is designed to exchange information with other departments to achieve process integration and improve the overall organization compliance.

LifeSphere IDMP™

Global Data Standards Compliance Solution

Multi-tenant SaaS solution that enables companies to not just become compliant with standards like **IDMP and XEVMPD** across the globe, but also enables them to leverage compliance-related investments for realizing multiple business benefits. The solution offers an optimal mix of **automated tools** and **workflow-controlled** manual intervention for extraction, review, coding and cleansing of structured and unstructured data. Using its **flexible integration module** and **NLP capabilities**, companies can collect information from different systems and documents into an IDMP and XEVMPD-compliant central data hub. Users can then review and enrich the data before extracting standard specific data sets, validating against specific business rules and **electronically submitting** to the regulatory authorities.

An Innovative Solution Suite for Today's Modern Challenges

Here are specific ways that LifeSphere Regulatory is designed to help regulatory affairs teams succeed:

Rapid Deployment and Lower TCO

LifeSphere Regulatory offers SaaS-enabled and pre-validated solutions on ArisGlobal's secure cloud platform, enabling quick deployment, lower total cost of ownership, easy upgrades, and inexpensive fine-tuning to facilitate quick reactions to changing regulations.

Optimized to Reflect Industry Standard Practices

ArisGlobal's Regulatory industry standard practices have been developed collaboratively, validated by customers, and implemented as out-of-the box features and functionalities to transform regulatory planning and tracking into a simpler, more intuitive process.

Designed for Improved Productivity and Ease of Use

With our RIMS solution, out-of-the-box interfaces with document management systems and configurable data exchange mechanisms resulting in improved cross-functional process efficiencies, collaboration, control and visibility of the single source of truth.

Intelligent, comprehensive business process workflow automation enables demand forecasting, submission planning and performance tracking for improved decision making. For example, with LifeSphere RIMS, configurable, role-based workflows, security and other configuration options enable the intuitive user interface to be easily tailored for global, regional and affiliate participation, ensuring a successful enterprise-wide rollout

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.