LifeSphere® Regulatory

Heralding the Era of RIMS and Regulatory Compliance Transformation

An increasingly complex and demanding regulatory environment can result in costly and damaging compliance issues. To avoid penalties and recalls, companies must overcome information gaps between regulatory departments and other parts of the company and ensure enterprise-wide readiness for standards such as IDMP and xEVMPD for pharmaceuticals and UDI for devices, as well as address different geographical requirements and demands.

LifeSphere Regulatory is a multi-tenant cloud-based solution platform that offers an innovative, end-to-end approach for regulatory affairs, spanning core regulatory information and lifecycle management, submission planning and tracking, dossier assembly and publishing as well as integrations with document management and other systems.
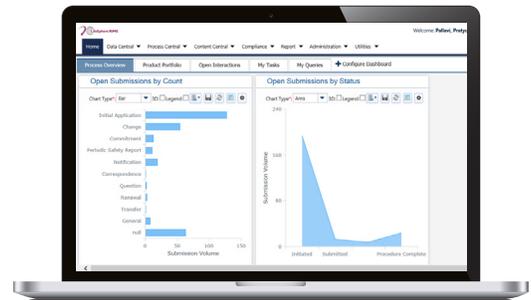
An Innovative Solution Suite for Today's Regulatory Challenges

Amid the pressure to bring products to market more rapidly, regulatory departments are struggling with lack of centralization of product data, poor collaboration with affiliates and partners, inefficient and manual ways of extracting information, and time-consuming upgrades to stay up-to-date with changing regulations.

ArisGlobal's end-to-end regulatory platform LifeSphere Regulatory leverages industry-standard processes (ISPs) and cognitive computing capabilities to help efficiently integrate compliance with automated business processes over the entire product management lifecycle.
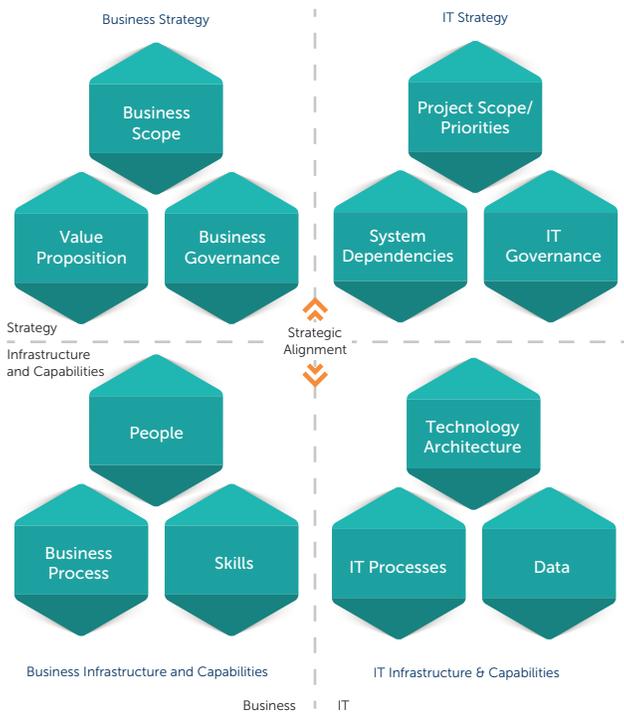
LifeSphere Platform for Cross Functional Integration

LifeSphere Regulatory enables easy integration of compliance and business processes over the product management lifecycle. Armed with configurable web services over an open architecture, the solution allows companies to build and maintain interfaces for exchanging information with other departments to achieve process integration and improve overall organization compliance.

LifeSphere Regulatory improves organizational compliance with regulatory information sharing via standard integrations and open architecture, while automation and actionable analytics drive efficiency and productivity.

ArisGlobal Regulatory Automates Core Business Processes with Cognitive Computing

Business Strategy

Business Scope

Value Proposition

Business Governance

IT Strategy

Project Scope/ Priorities

System Dependencies

IT Governance

Strategy

Infrastructure and Capabilities

Strategic Alignment

People

Business Process

Skills

Technology Architecture

IT Processes

Data

Business Infrastructure and Capabilities

IT Infrastructure & Capabilities

Business | IT

The solution enables quick deployment, lower total cost of owner-ship (TCO), easy upgrades and inexpensive fine-tuning to facilitate quick reactions to changing regulations.

Regulatory Information in One Place

Integral to the platform is a regulatory information management solution, LifeSphere RIMS™, which leverages a process-based approach with Industry Standard Practices for planning and tracking all regulatory affairs business processes in a single solution. The solution supports clinical trial and product registrations, dossier planning, compiling and publishing, lifecycle submissions, agency correspondence, commitments, obligations and global change management.

A Holistic Approach to Data Standards

LifeSphere IDMP™ is a complete solution to handle the technical, business and compliance challenges companies face with data standards like xEVMPD and IDMP as well as to support internal compliance. 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. The solution also supports IDMP and xEVMPD specific business rules validation and E2B electronic submission with health authorities.

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.