LIFESPHERE®

ArisGlobal

Regulatory

Speed. Quality. Collaboration.
Delivered in one simple unified platform.

LifeSphere® Regulatory delivers end-to-end regulatory information management in an all-new, fully unified cloud platform that accelerates speed to market, enhances data quality and streamlines collaboration across teams.

Move fast without sacrificing data quality.

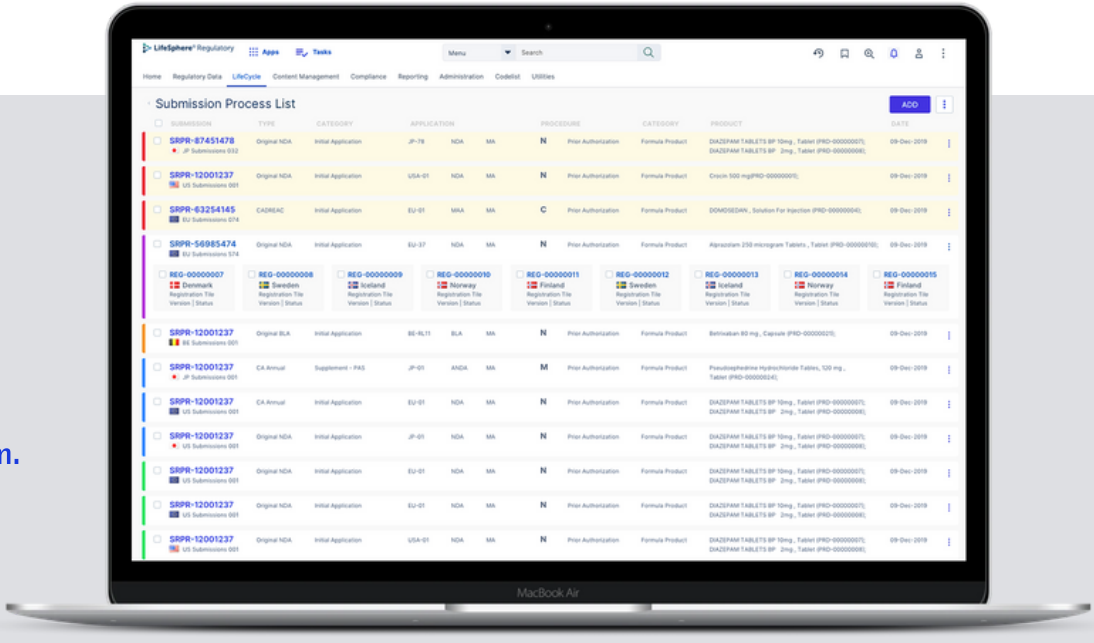
Accelerate speed to market by planning, executing, and tracking all regulatory activities in a single, unified RIM application, with seamless access to regulatory documents and full support for all major eCTD submission requirements. Built-in automation streamlines workflows to reduce administrative burden and provide greater confidence in product registration data quality.

Future-proof your compliance.

Reduce risk and stay compliant with the latest regulatory requirements thanks to scalable cloud architecture that provides continuous innovation via free and seamless upgrades. LifeSphere Regulatory has been built from the ground up with a deep understanding of the regulatory lifecycle, offering a best-in-class standard configuration with full support for xEVMPD and IDMP data standards.

Streamline collaboration.

LifeSphere Regulatory is a fully unified regulatory platform designed to streamline collaboration across the entire organization, including headquarters and affiliates, and clinical, safety and quality teams. Leveraging the cloud document management capabilities of LifeSphere® EasyDocs, LifeSphere Regulatory delivers a single source of truth for regulatory data and documents across R&D business processes. The result is real-time collaboration and visibility across the regulatory lifecycle.

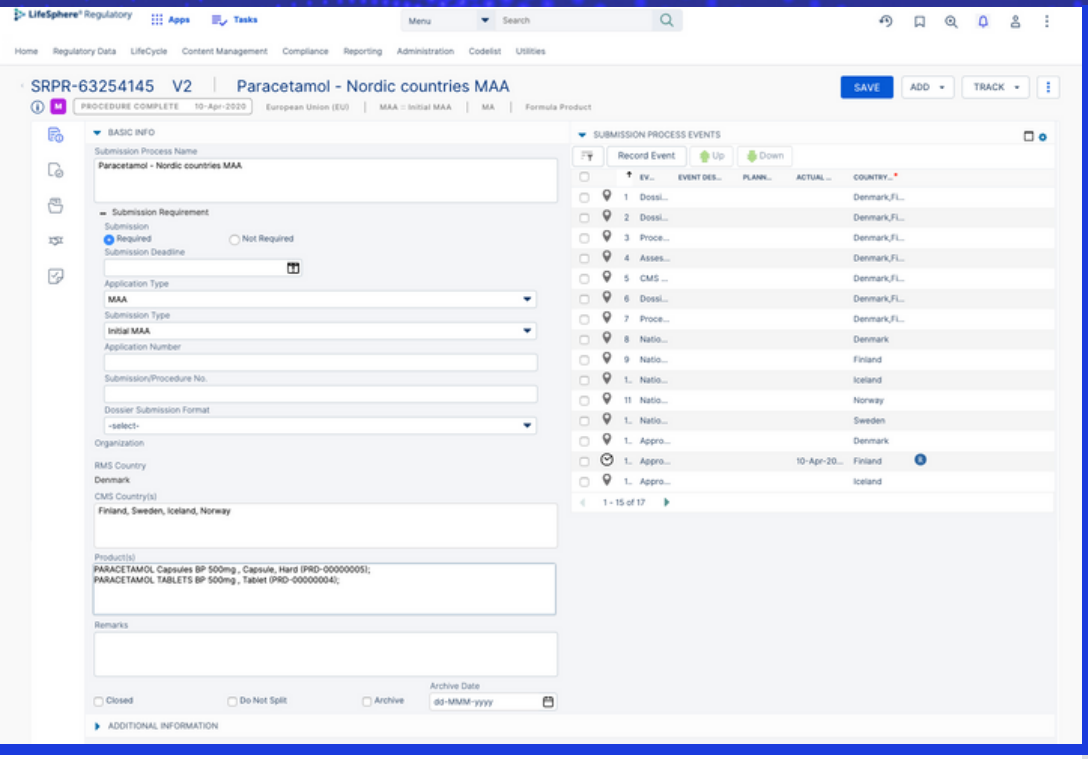


LifeSphere Regulatory

- RIM
- Publishing
- Document Management

One simple unified platform.

LifeSphere® Regulatory



DELIVERING RESULTS TO 250+ GLOBAL CLIENTS

30

YEARS AS A LEADER IN LIFE SCIENCES TECHNOLOGY

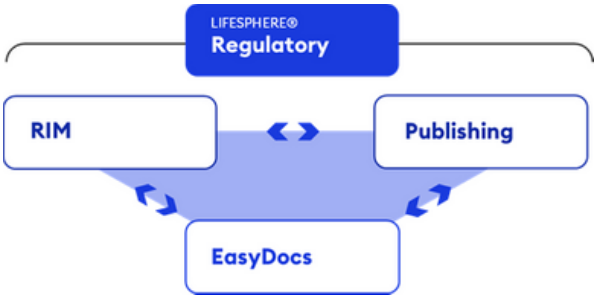
80%

OF THE TOP 50 GLOBAL PHARMA AS CUSTOMERS

100%

COMPLIANCE WITH GLOBAL REGULATIONS

Features



End-to-End Coverage

Manage the entire regulatory lifecycle in a single platform. Streamline planning and tracking of interactions, commitments and obligations, as well as document and dossier management, publishing, reporting, and data standards compliance.

Superior Automation Capabilities

Automation-assisted workflows – including intelligent task assignment, submission planning and performance tracking – and pre-configured templates help expedite regulatory submission and dossier planning.

Unified Documents and Data

Access up-to-date documents and data easily with LifeSphere® EasyDocs, as well as authoring and collaboration document management tools.

Easy Integration

Connects with existing systems via open architecture, leveraging API connectors and web services.

Worry-Free Implementation

Fast, knowledgeable teams adhere to industry best practices to get your teams up and running quickly.

Support for Medical Devices

Supports medical device registrations, submissions tracking, and compliance to FDA GUDID and EU EUDAMED UDI regulations.

xEVMPD and IDMP-Readiness

Full support for xEVMPD, with UDI and IDMP-readiness to ensure future compliance.

eCTD Submission Lifecycle Support

Manage the submission lifecycle, with full support for all major global eCTD requirements, including FDA applications and submissions.

No Extensive Training Needed

Designed to be easy and intuitive to use, with an interface designed for users of all skill levels.

About ArisGlobal

ArisGlobal transforms the way today's most successful life sciences companies develop breakthroughs and bring new products to market. Our end-to-end drug development technology platform, LifeSphere®, integrates our proprietary Nava® cognitive computing engine to automate all core functions of the drug development lifecycle. Designed with deep expertise and a long-term perspective that spans more than 30 years, LifeSphere® is a unified platform that boosts efficiency, ensures compliance, delivers actionable insights, and lowers total cost of ownership through multi-tenant SaaS architecture.

Headquartered in the United States, ArisGlobal has regional offices in Europe, India, Japan and China.

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