AMPLEXOR
AN ACOLAD COMPANY

LIFE SCIENCES SUITE

Streamlined Regulatory Information Management

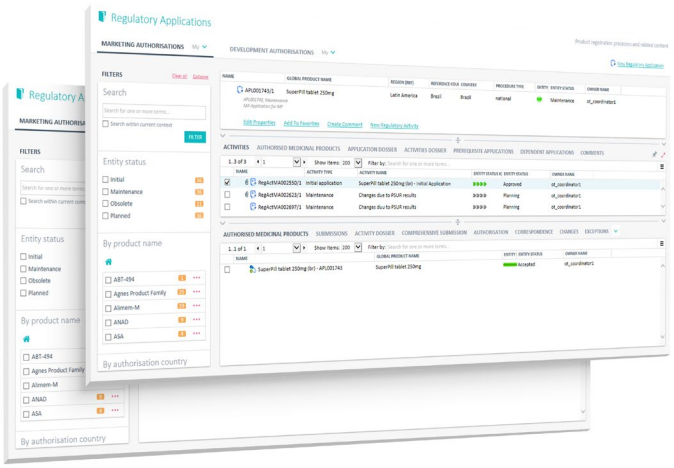
Plan ahead, make informed decisions, save time and streamline your regulatory processes

Life Sciences companies of all sizes strive to optimize efficiency and reduce overheads, which can most effectively be achieved by leveraging that most valuable of assets: data. Making it accessible, connected and actionable enables smarter, faster decision-making. Unfortunately, most companies are not in a position to utilize their data because they lack proper visibility and accuracy while data is generated in such huge volumes that making it useful is a challenge.

Much of the time, companies struggle with disconnected, duplicated and often inaccurate data, causing bottlenecks and adding unnecessary cost. At the same time, the regulatory and business environment in the Life Sciences industry is complex and continuously evolving. Reducing this complexity while improving data quality is a critical step to simplify compliance processes in global markets.

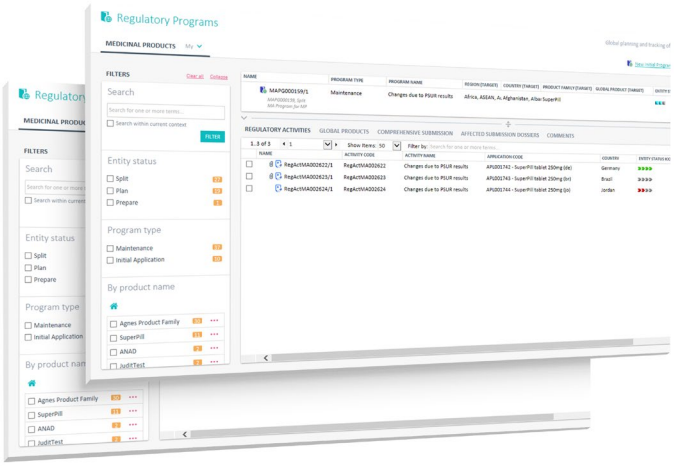
Amplexor offers a holistic RIM platform, which enables Life Sciences companies to manage regulatory data and content effectively and efficiently. Using it, companies can achieve long term business benefits beyond mere compliance.

Amplexor also offers best-in-class after sales service, as well as strong domain expertise, to guarantee successful deployments and operations.



Amplexor RIM platform delivers:

- A common, centralized master data model, which provides a solid foundation for a single source of truth
- Powerful automations, which minimize manual steps and data entry, while improving data quality
- Reusable data and content across all solutions and processes
- Increased enterprise-wide efficiency, standardization and collaboration
- Lower complexity, higher overall quality of data, and sustainable compliance



Amplexor RIM solution provides businesses with the tools to:

- Manage product information throughout the products lifecycle
- Plan and track regulatory applications and activities
- Manage all interactions with health authorities and other regulatory bodies
- Oversee the authoring, review and approval of submission documents
- Plan, compile, review, publish, submit and manage submissions
- Support global label management processes
- Manage product data and content in line with the IDMP target operating model (TOM)

Amplexor RIM Products

Product Information Management

ProductExpert™ addresses the planning, collection, management and submission of structured product data throughout the submission lifecycle, post-submission, and post-approval, following the IDMP target operating model according to stringent compliance and quality standards. Product information management is a seamless part of the end-to-end RIM experience.

Regulatory Planning & Tracking

RIMExpert™ is a powerful planning, tracking and reporting solution designed to standardize the data management process across your entire company. It provides a new, intuitive compliance structure with no double data entry, no extra effort and no time wasted, enabling a clearer picture for planning and scheduling, while seamlessly connecting to IDMP, eCTD and content management solutions for faster time to market.

Regulatory Content Management

R&DExpert™ promotes cross-functional collaboration and establishes a single authoritative document asset repository, covering all document management functionalities, including template management, collaborative editing, annotations and hyperlinking, flexible workflows, electronic signature and audit trail, advanced rendering, compound documents and role-based security.

Submission Management & Publishing

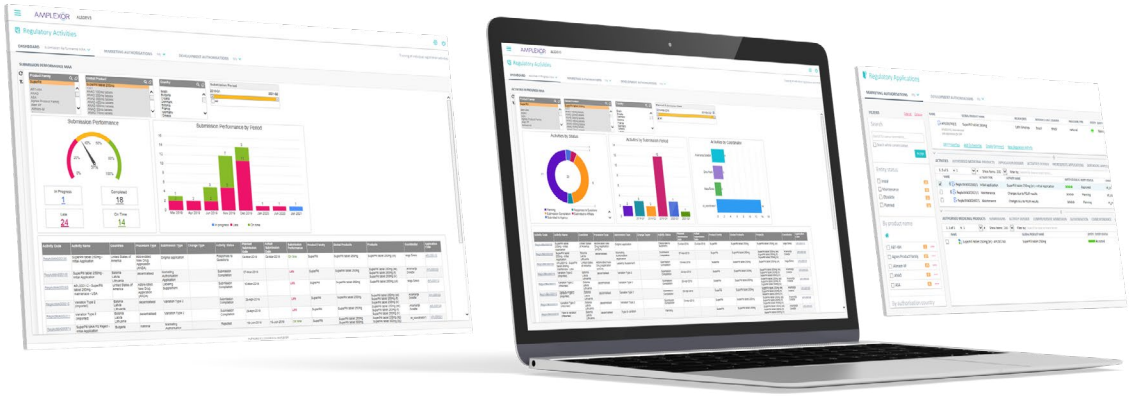
SubmissionExpert™ consolidates submission management and publishing capabilities within one unique solution. Leveraging built-in regulatory intelligence, it enables product information driven global and local submission content planning, submission pre-validation and publishing according to regional standards in eCTD, NeeS, PDF or EAEU format as well as versatile submission archive.

Labeling Management

LabelExpert™ focuses on the end-to-end labeling change process as well as activities such as the assessment, revision, approval, tracking and implementation of labeling changes, seamlessly connected with Regulatory Planning & Tracking as well as Regulatory Content Management capabilities.

Regulatory Analytics

RIMAnalytics™, ProductAnalytics™, SubmissionAnalytics™ and **LabelAnalytics™** consist of a preconfigured set of standard dashboards and reports as well as self-service analytics, meeting business tracking, reporting and analytical needs.



Please get in touch to find out more or visit us online.

solutions@amplexor.com **amplexor.com/rim**

ABOUT AMPLEXOR LIFE SCIENCES

Amplexor Life Sciences assists organizations developing pharmaceutical drugs, medical devices, and biotechnology with launching products and breaking into new markets quickly. Its proven solutions as well as professional and business services expedite the creation and delivery of consistent, compliant, high-quality and global content – both physical and digital. It boasts a rich 25+ year history of serving pharmaceutical producers, medical device manufacturers, and biotechnology companies.

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solutions@amplexor.com

www.amplexor.com