ACCEL for Regulatory Information Management

POWERED BY windchill + thingworx

KALYPSO

Accelerate the **Regulatory Submission Process** in **Medical Device**

Medical device companies face **several key imperatives** as a result of the growing complexity and evolving nature of global regulations:

- **Expand and accelerate international sales** – Reduce time, effort and expertise required to register products; know where products are registered and salable
- **Reduce regulatory risk** – Prevent shipment of unauthorized or non-compliant products; understand the impact of design changes; respond quickly to changing regulations; know where to report adverse events or conduct product recalls
- **Make better decisions** – Improve planning and strategic decisions with better information
- **Reduce manual effort of strained resources** – Free up people to focus on higher value work

Medical device companies can **transform their regulatory submission process** with integrated product lifecycle and quality management systems. **Accel for Regulatory Information Management** provides a single, global source of truth for product registration planning and tracking to **accelerate regulatory submissions**.

PLAN
Specify which products you plan to register in which countries, by when, by whom, etc.

EXECUTE
Compile and submit submission packages efficiently using country-specific templates, formatting, rendering, and advanced collaboration and content management features

IMPROVE
Use advanced searching, reporting and auditing features to analyze cycle times, spot trends, and identify problems

INTEGRATE
Synchronize with master product data; provide downstream systems with information to control salability and shipping

TRACK
Keep track of agency correspondence, registration status by part number and location, expiration dates, certificates, licenses and more

Accelerate Regulatory Submissions with Accel for Regulatory Information Management

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Integrated platform for regulatory information management (RIM) to more effectively manage and comply with product registrations and regulations, **deployed via an accelerated, leading-practice delivery model**

Designed to quickly deploy foundational RIM capabilities through agile methods

Pre-configured for rapid implementation with a "production-ready" validated software system

Based on industry-leading practices and implementations in RIM

Built on PTC Windchill PLM platform + PTC ThingWorx internet of things (IoT) platform to provide an integrated approach that leverages IoT

Accel for RIM **Benefits**

- **Reduced implementation cost and risk**
- **Faster time to deploy** with "production-ready" validated software system, pre-defined security model, and reusable attributes and workflows
- **Minimized configuration effort**
- **Improved user adoption** via out-of-the-box capabilities and prepared training materials
- **Faster realization of business objectives**, benefits and ROI

Foundational **Capabilities**

Registration Planning & Tracking

Country-Specific Registration Data	Status by Part Number & Sellable Location	Part-Specific Registration Data	Dependency Management
Agency Correspondence	Content Management	Declarations, Certificates, & Licenses	Workflow Automation
Effective & Expiry Dates	Notifications & Subscriptions	Advanced Searching & Reporting	Regulatory Compliance
Role-based Security & Approvals	Part 11 Compliant Signatures	Full Audit Trail & History	

Registration Execution & Submission

Document Sharing to International Medical Device Regulators Forum	Country-Specific Package Templates	Formatting, Rendering & Printing	Electronic Submissions
Submission Workflow Automation	Secure Distributor & Dealer Collaboration	Integration to External systems (e.g. ERP shipping flags)	Workflow Automation

Accel for RIM **Advantages**

Greatly enhanced **user experience**

Scalable accross large organizations

Rapidly configurable to new requirements

Upgradeable to new versions of Windchill and ThingWorx

Accelerate Your Regulatory Information Management Journey

For more information, contact:

Van Gresham
North America
van.gresham@kalypso.com

Sajesh Murali
North America
sajesh.murali@kalypso.com

Nils Kruse
Europe
nils.kruse@kalypso.com

kalypso.com/accelRIMptc