birlasoft

Global Product Registration

Medical Device Manufacturer

Summary

The Medical Device Industry is subjected to cumbersome requirements from regulatory bodies (FDA, EMA, etc.) and failure to comply is a significant risk threatening its ability to sell a product and earn revenue. Maintaining product registration and licensing becomes a challenge when faced with a global footprint and an extensive product portfolio, exponentially growing the effort associated with keeping products in the market. Birlasoft developed the Global Product Registration (GPR) platform to providing seamless management of regulatory registrations by integrating the regulatory process into Oracle's Agile Product Lifecycle Management (PLM).

Birlasoft's Global Product Registration accelerates and simplifies the regulatory processes by consolidating product data into single repository and automating the submission, tracking, recoding, and expiration of product registration.

Project Details

- **The Goal:**
  Streamline the management of regulatory registrations through a systematic, efficient platform
- **The Challenge:**
  Disconnected source systems, compartmentalized business processes, and regional requirements
- **The Solution:**
  Global Product Registration leveraging existing Oracle's Agile PLM Platform to integrate regulatory requirements into PLM process

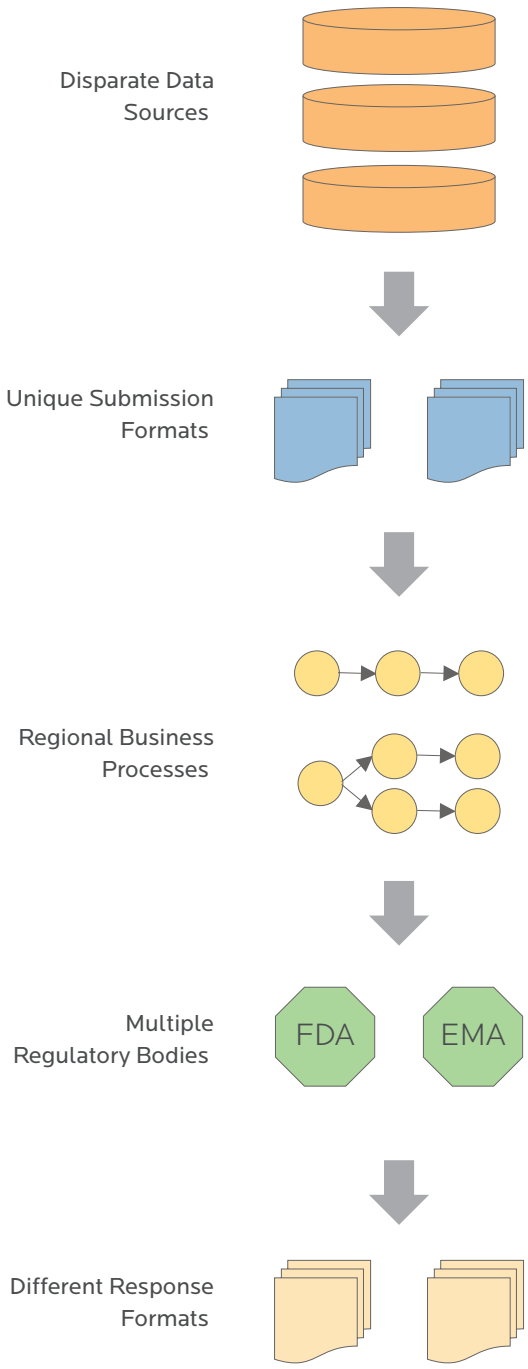
Customer Profile

A global medical device and medical technologies provider focused on developing solutions to improve the health and quality of life with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine, and respiratory care.

Customer Needs

Any company involved in the production and distribution of medical devices intended for commercial application face unique regulatory requirements (ISO, EN, GMPI, etc.) and failure to follow regulations would have a devastating impact ranging from significant fines to enforced barring of product distribution in regions or entire countries. Medical device organizations must apply for and maintain licenses or registrations that are subject to approval and renewal with global bodies for each product in that market.

The complexity of this challenge compounds in environments riddled with compartmentalized data and intermittent business processes. Due to their traditionally inorganic growth, medical device companies often have isolated business processes, varied data sources, divisional methods for creating registration and submission documentation, and inconsistent formats and templates for registration and submission documentation without a uniform methodology to track registrations for each finished good.

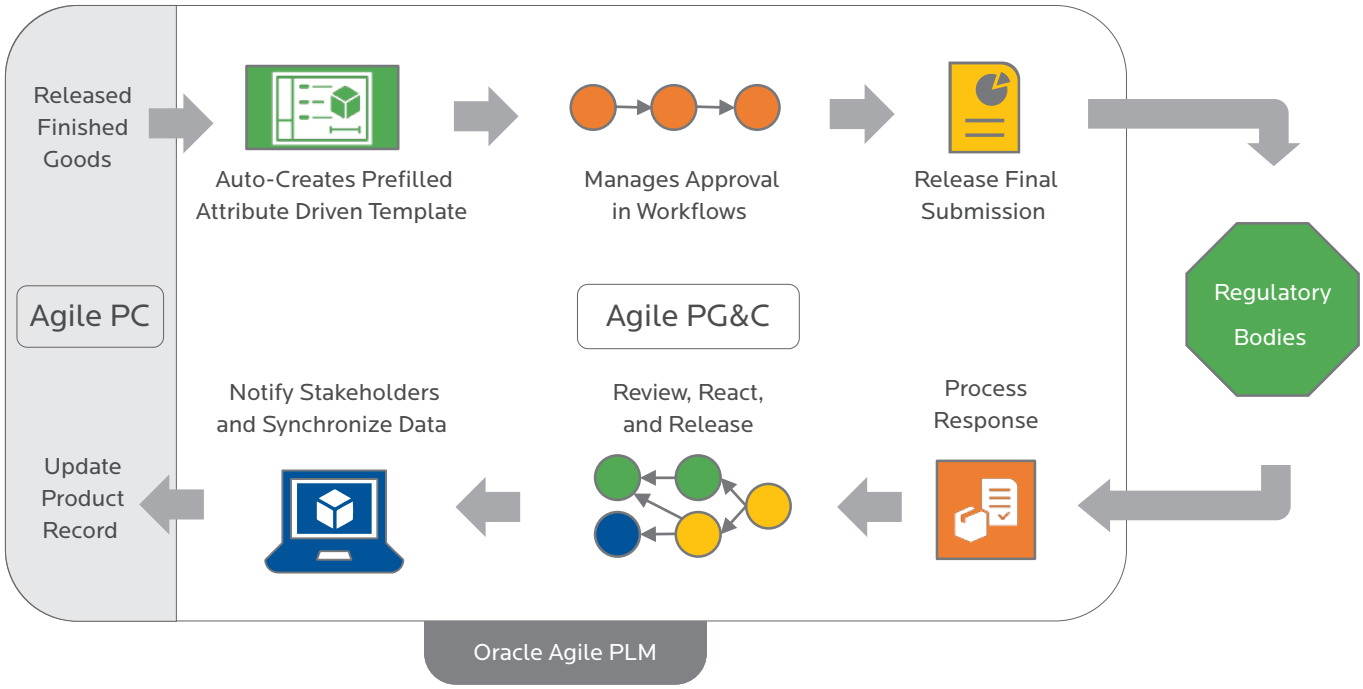


Facing similar challenges our customer recognized the importance of streamlining their Product Licenses/Registrations and sought a partner to design and implement a systematic method to provide end to end management of their Product Licenses/Registration.

Solution Profile

Birlasoft's GPR platform will receive the Finished Good as an input and generate the submission documentation based on pre-configured templates. The documentation is managed within an Agile workflow and upon approval submitted to the regulatory bodies. The GPR platform processes the regulatory body's response within Oracle Agile PLM, taking actions based on their feedback and input from workflow owners. Once released, GPR will automatically track the expiration of registrations and initiate the renewal process for approved Finished Goods.

Global Product Registration Platform



GPR consolidates the regulatory requirements into a uniform process across the enterprise and enables the systematic tracking of the regulatory requirements by building a seamless integration with the Product Lifecycle Management process.

Benefit

Evolving from disparate source systems, divisional and region unique business processes, and manual processes to an automated, enterprise product registration platform eliminated cumbersome time-sinks and prevailed a transparent, uniform, and efficient process. GPR has provided the ability to leverage where-registered reporting, enabled tracking and notification of all product registration, and installed a globally accessible repository for product registration.

RESOURCES plm@birlasoft.com | birlasoft.com

Enterprise to the Power of Digital™

Birlasoft combines the power of domain, enterprise and digital technologies to reimagine business processes for customers and their ecosystem. Its consultative and design thinking approach makes societies more productive by helping customers run businesses. As part of the multibillion diversified CK Birla Group, Birlasoft with its 10,000 engineers, is committed to continuing our 150 year heritage of building sustainable communities.