

Use Cases for Life Sciences: Medical Device Regulatory Information Management

COMPANY PROFILE

- A top global life sciences and medical devices organization
- One of the most diverse medical device and diagnostics manufacturers
- Over 100,000 employees operating in over 60 countries worldwide

CHALLENGES

This company was struggling with their regulatory operations in the medical device space. Information and critical documents were maintained in various systems, and accessing templates and reference documents was challenging for lack of standardization and clear processes.

The time it took to gather important information and documents in support of regulatory projects and associated submission was delaying regulatory approvals and patient access to important and critical devices and treatments.

SOLUTION GOALS

To obtain successful end-to-end regulatory affairs management, the company sought a powerful and agile solution. They needed a system that could drive business value and accelerate innovation through the creation of harmonized processes, and provide traceability and detailed audit trails to maintain compliance.

They needed something that could be flexible enough to adapt as regulations shifted and improve as more and more information was inputted. They chose Appian to answer all of these requirements.

RESULTS

The MDRIM solution created on Appian's platform is a GxP-compliant, validated application running on Appian Cloud, serving thousands of users and managing hundreds of millions of data records. The breadth and depth of the system are extensive, contributing to organizational success, including:

- Management of approximately 20,000/annual Regulatory Affairs assessments for changes to product, process, and regulations
- A compendium of regulatory requirements in approximately 100 countries
- The ability to generate real-time regulatory portfolio reports and regulatory risk metrics
- 50+ Interactive Reports with the ability to interactively filter data to the user's needs
- Transition from 67% paper to 100% automated electronic process
- Successful handling of 150,000 licenses and millions of document transactions so far



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Existing Applications

CLINICAL: Site Initiation – Readiness – Effectiveness Study Start Up, “1572”, IP (Green Light), Global CRO Contracts, Pre-approval Inspection

CMC: High Throughput Experiment Tracking, Global Compound Ordering, LIMS

REGULATORY: Regulatory Operations, IDMP, e-Submissions & Publishing, Online 510K FDA Review

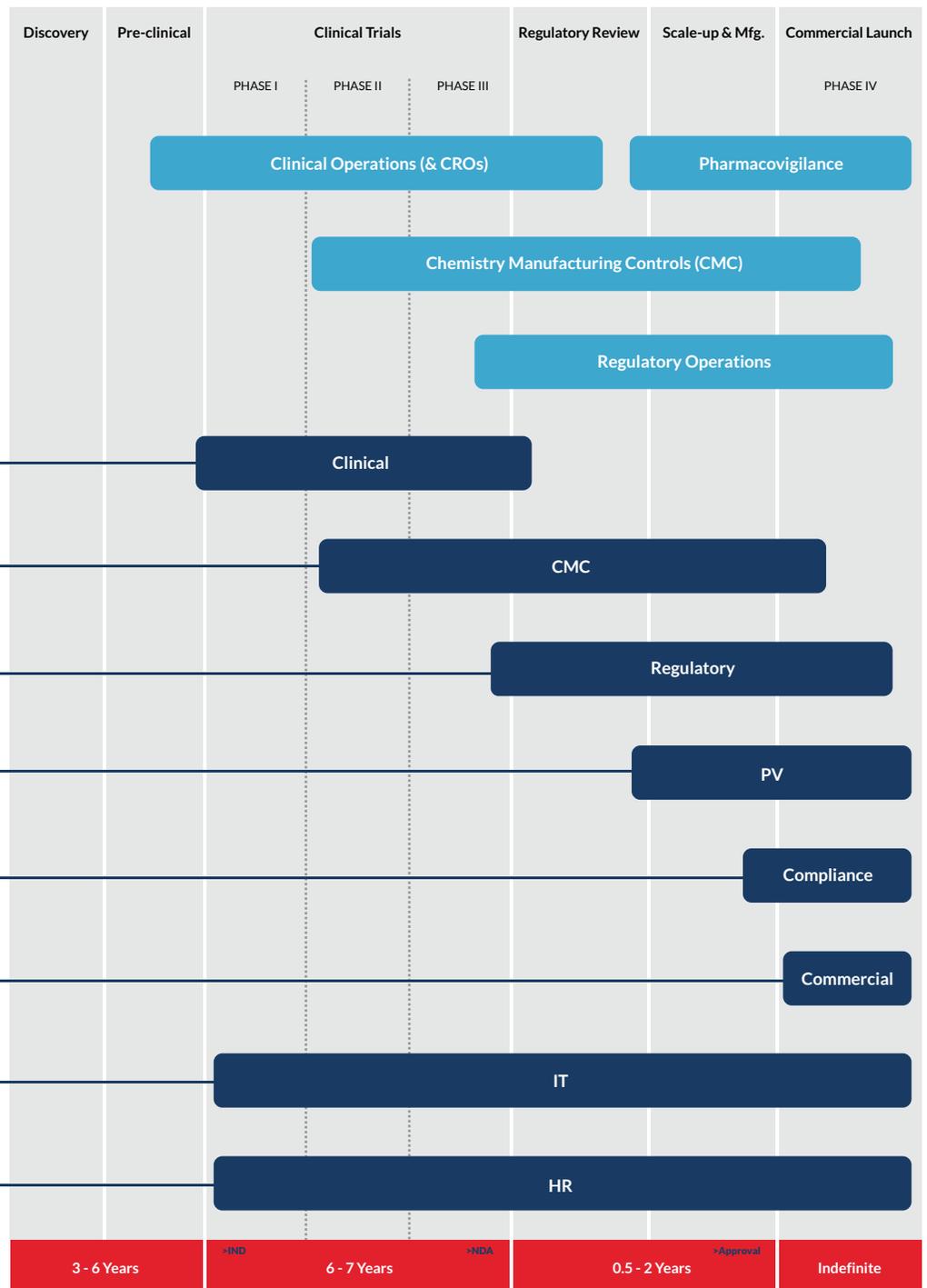
PV: Safety Information Management, Safety Signal Tracking

COMPLIANCE: Anti Bribery and Corruption (FCPA), Third Party Intermediaries, Sunshine Act

COMMERCIAL: Sales Force Automation, Contracts

IT: Asset Management v. Resources, Statements of Work Management

HR: On Boarding, Recruiting



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Appian provides a software development platform that combines intelligent automation and low-code development to rapidly deliver powerful business applications. Many of the world’s largest organizations use Appian applications to improve customer experience, achieve operational excellence, and simplify global risk and compliance.

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