



Use Case for Life Sciences: Medical Device Regulatory Information Management

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 harmonized processes, traceability, and detailed audit trails.

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 fulfill all of these requirements.

Results.

The MDRIM solution created on the Appian platform is a GxP compliant and supports 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 the following:

- 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.

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.



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 and Publishing, Online 510K FDA Review

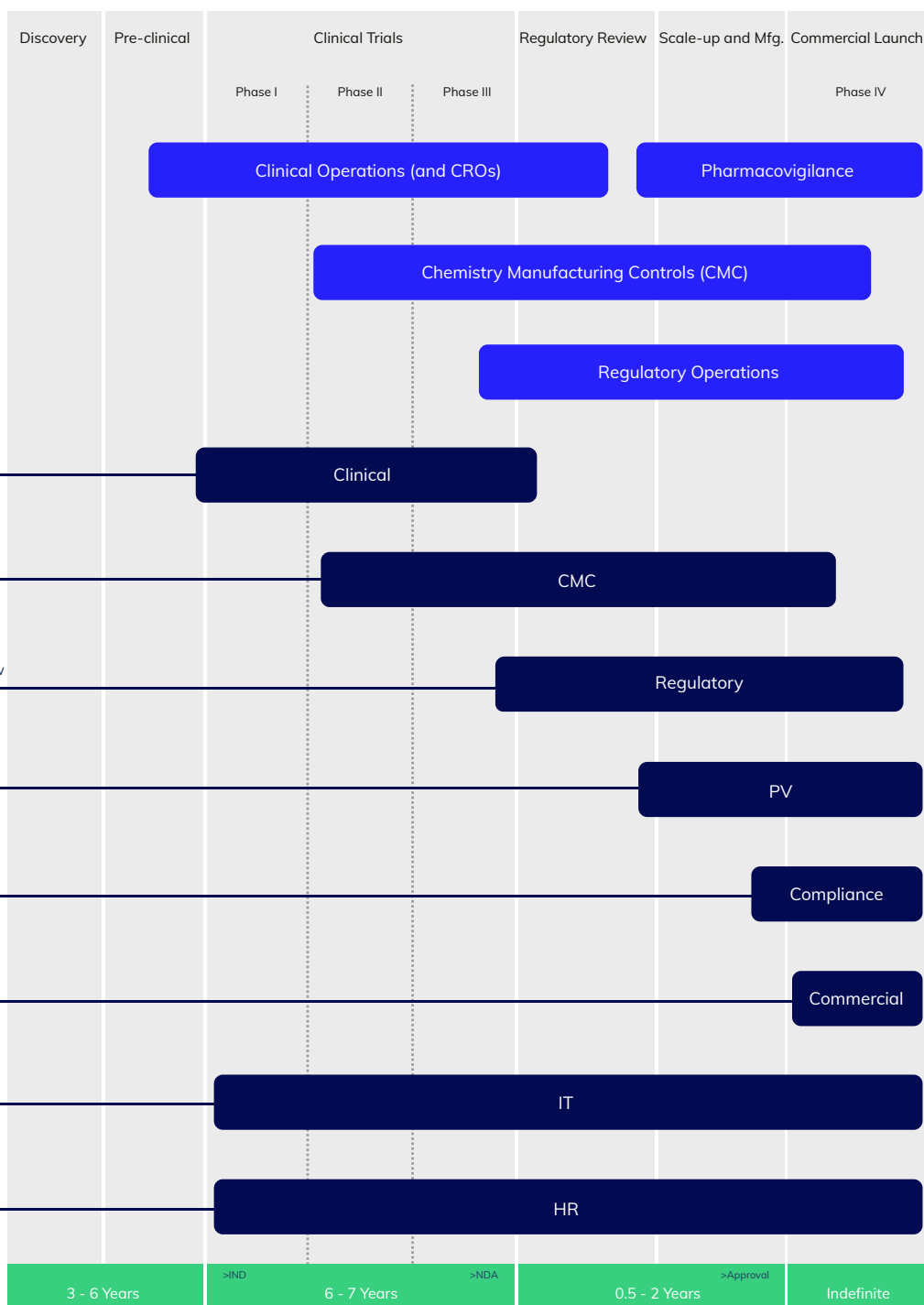
PV: Safety Information Management,
Safety Signal Tracking

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

COMMERCIAL: Sales Force Automation, Contracts

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

HR: Onboarding, Recruiting



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