

Use Cases for Life Sciences: Regulatory Information Management

How can we be sure we are compliant with all regulations when there are so many to manage?

Appian Customer

- Large multi-national pharmaceutical company.
- Global presence across 150+ countries.
- Focus on regulatory compliance.

Challenges

- Heavy reliance on manual processes, SharePoint, and Excel files.
- Current solutions in place do not provide comprehensive awareness of global portfolio.
- Internal audits uncover significant gaps in compliance.
- Silos of data across many systems creates a lack of visibility to the latest information.
- This lack of full awareness and visibility puts company at global risk.

Goals

- Unify data from across many different systems and geographies.
- Ensure compliance across hundreds of global regulations to reduce global risk.
- Eliminate manual, mistake-prone SharePoint sites and Excel tracking sheets.
- Bring new drugs to market faster.

Sample app: Regulatory submission management platform.

Business Case

- Compliance regulations for >1000 products across 150+ countries.
- Challenge to balance quality and compliance with the need to take each new drug to market as quickly as possible.
- Information captured and stored in a multitude of silos across the global business.

Approach

- Simplify end-to-end business processes focused on planning, regulatory compliance, and productivity.
- Eliminate existing silos by creating a “single authoritative truth,” converging all data from across systems.
- Create a single, intuitive platform for use across multiple global departments.

Results

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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

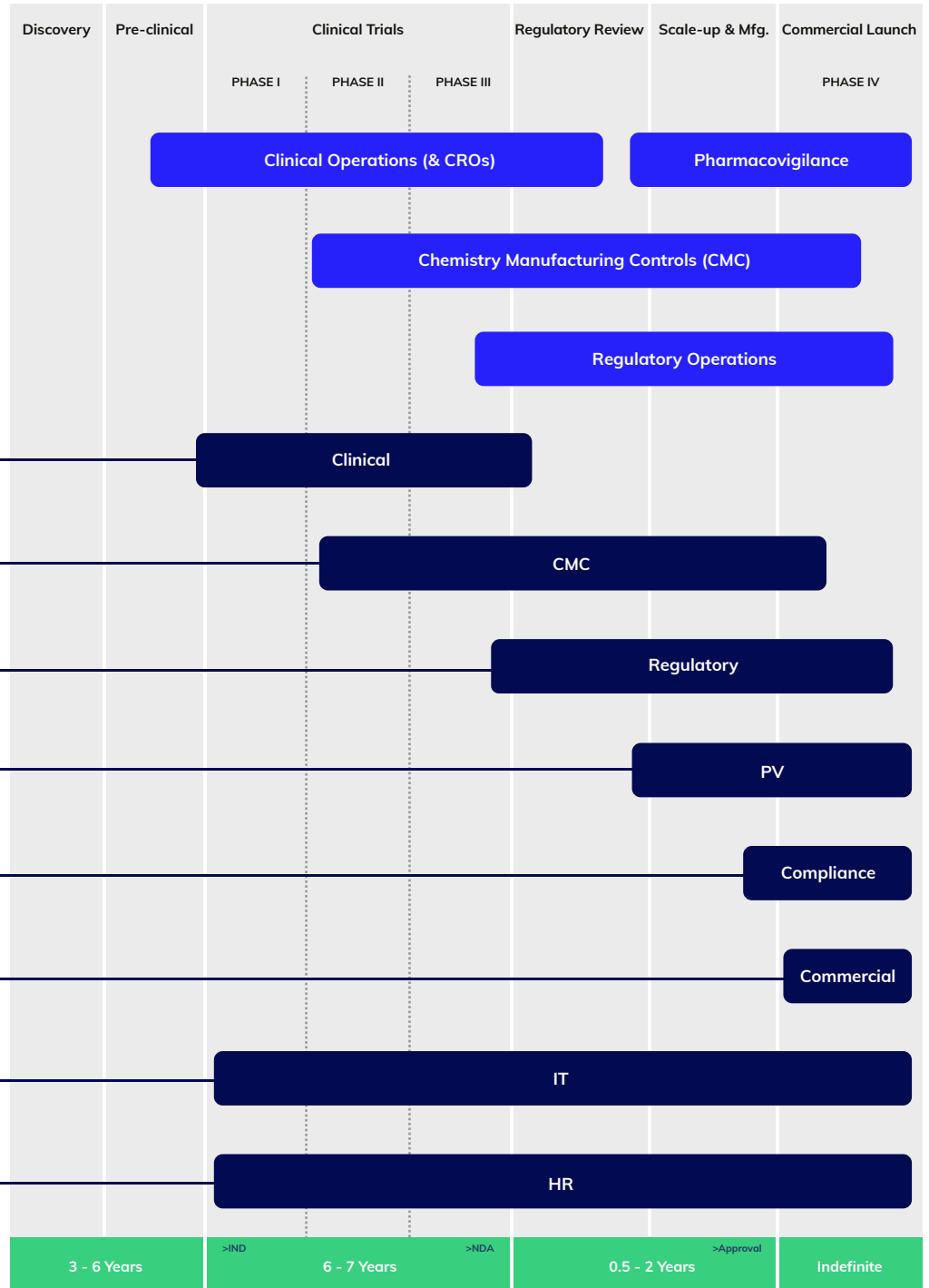
PV: Safety Information Management, Safety Signal Tracking

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



Appian provides a low-code automation platform that accelerates the creation of high-impact business applications. Many of the world's largest organizations use Appian applications to improve customer experience, achieve operational excellence, and simplify global risk management and compliance.

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