



Transforming Change Management
with Modern Systems

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Abstract

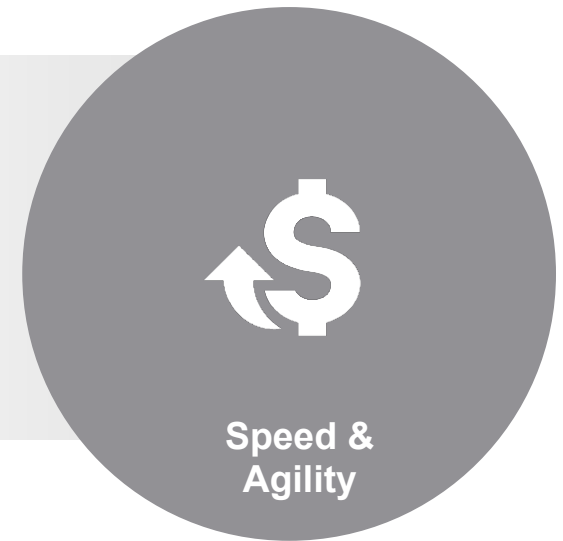
Transforming Change Management with Modern Systems

Assessing impact, and creating and executing a change plan are difficult with global stakeholders and multitude of systems. Extensive coordination is often needed between different functional areas such as quality, manufacturing, and regulatory. Join us and hear how modern systems break down organizational silos – transforming change management. In this session, we will discuss:

- Providing a framework to systematically assess global operational and regulatory impact
- How to gain greater visibility between quality and regulatory departments, and how to work together
- Structuring change releases and putting into effect in a global environment
- Gaining better intelligence and efficient changes for greater agility and better decision-making



Importance of Change Management



The Challenge

200+

Changes a year for a single product

Evaluated changes in a year for a top 20
Implemented 15,000 of the requests

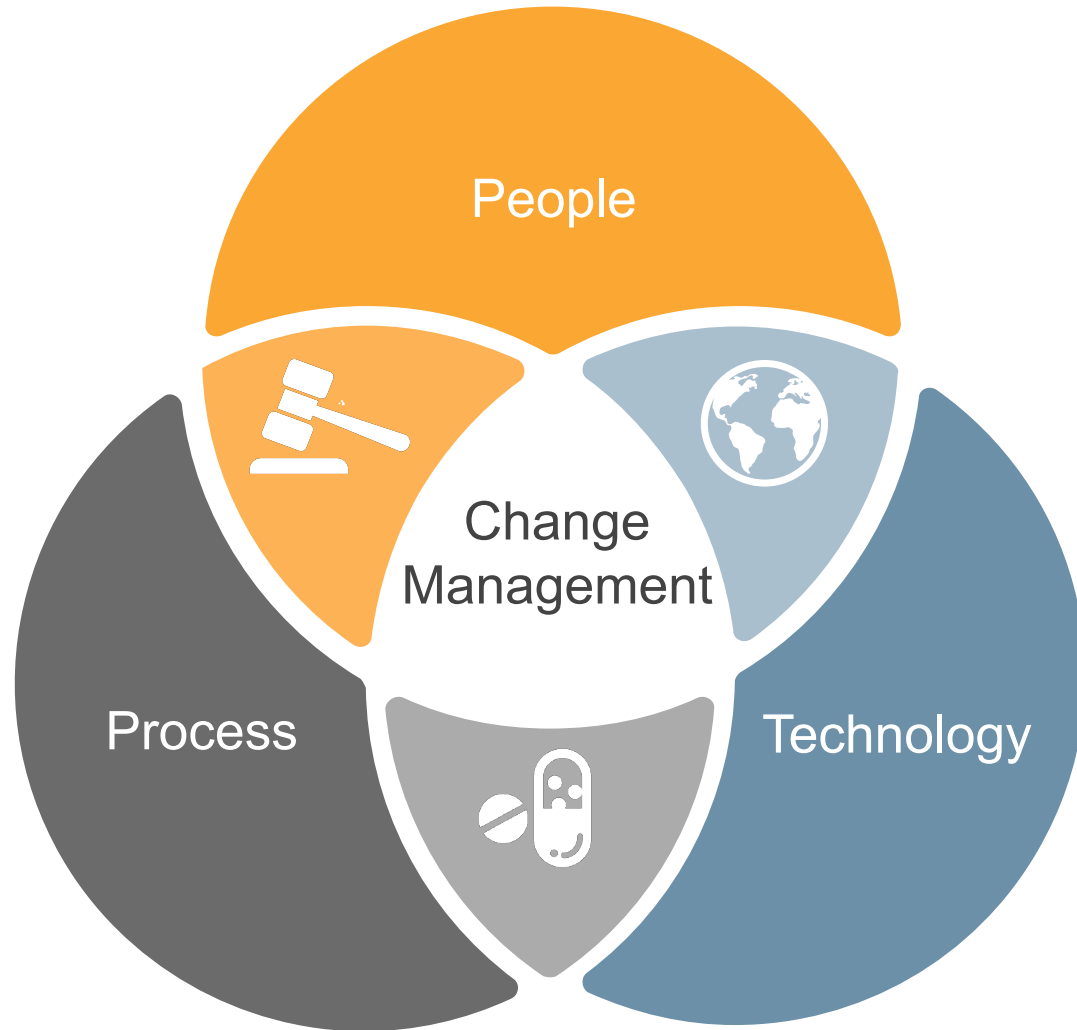
40,000

**Months
to Years**

From initial assessment to final regulatory
approval and implementation



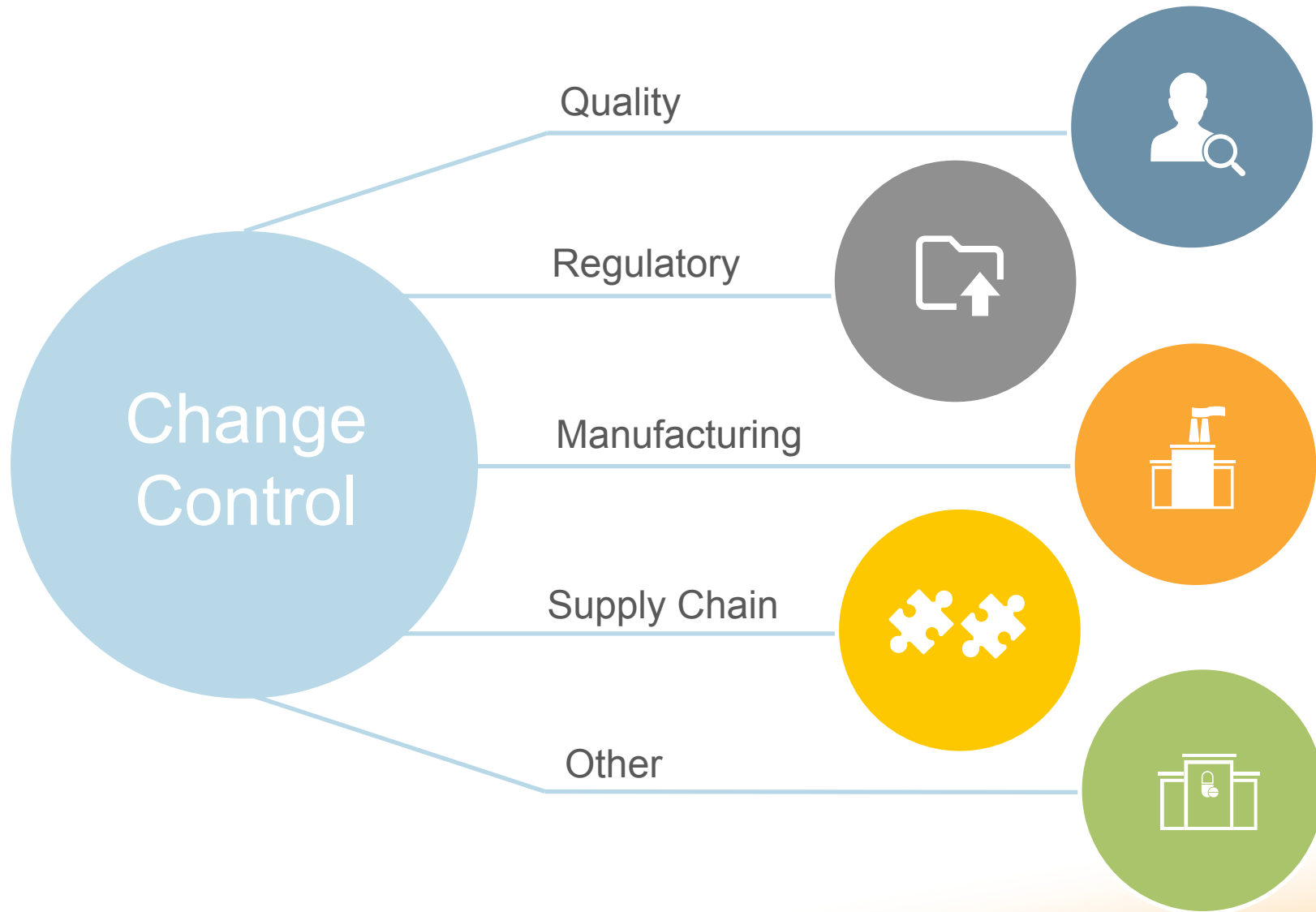
Transforming Change Management



People



Cross-functional Responsibility



People

Culture Change

- Breaking down silos between groups
- Changing people's mindset to embrace new ways of doing things

Empowerment

- Empower people to make decisions with accessible information

Behavior Shift

- Drive behavior change to collaborate across functional areas

Executive Support

- With significant changes across the organization, support from executives is essential for success



Process



Increasing Process Complexity



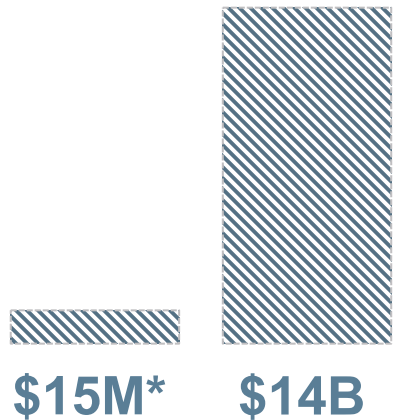
Key Questions to Ask

Is the current process working?

Can we make changes at the right speed?

Do we involve critical external parties?

Product recall can cost an organization between¹

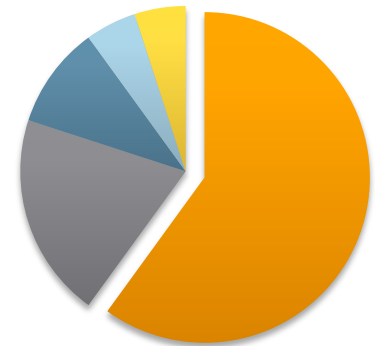


*One Manufacturer

>40% Quality incidents are due to supplier/vendor quality issues²



60% FDA CDER warning letters given to manufacturing sites in India³



Changing the Process

Better Intelligence

- Cross-functional processes that enable information access to all relevant parties for faster and more informed decision-making

Impact-based Triaging

- Over-engineering processes hinders agility and scalability
- Amount of effort and control should reflect impact
- Enables consistent, scalable processes

End-to-End

- Seamlessly incorporate all parties into a single process
- Process should easily work across functional areas

Transparency

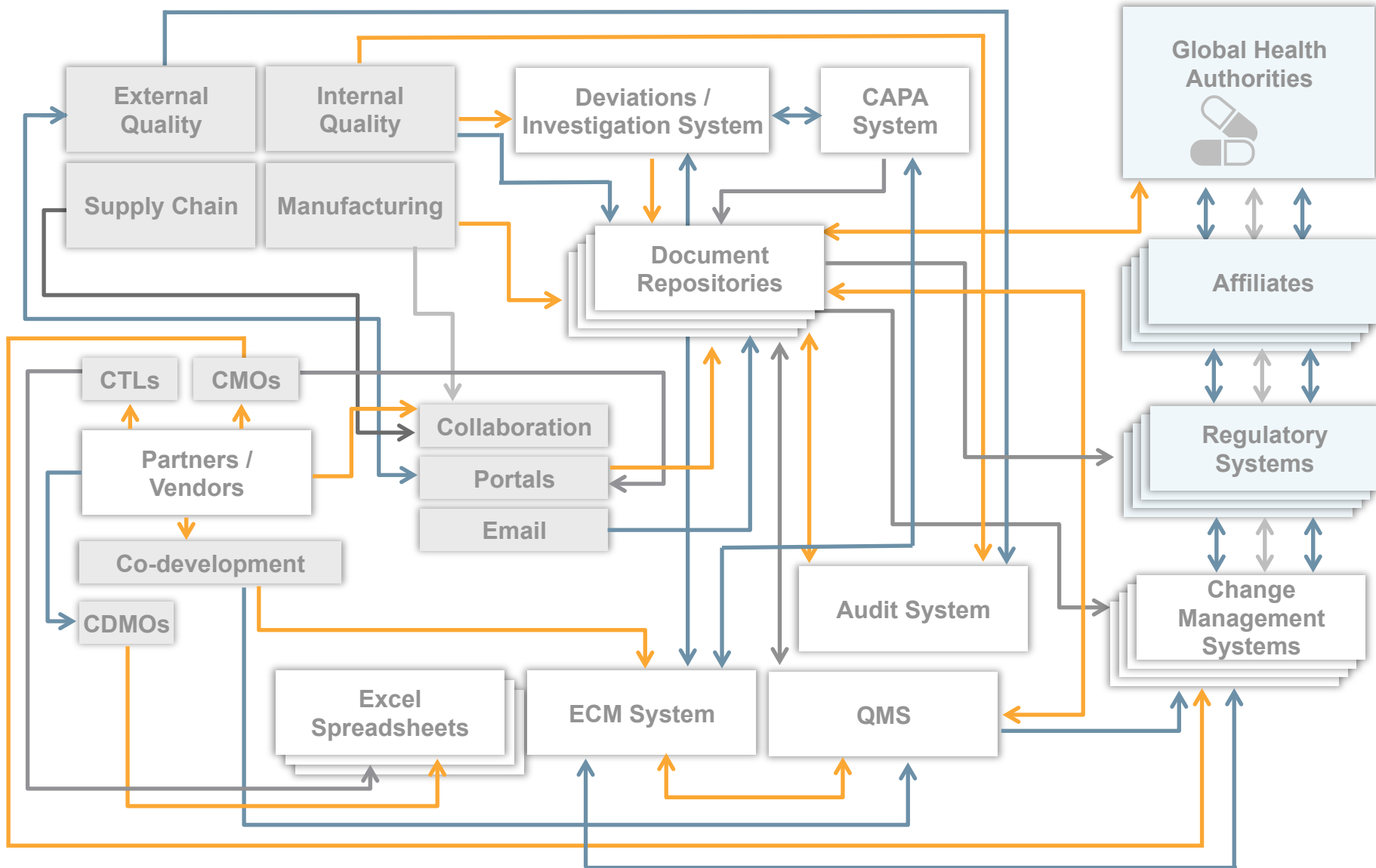
- See who is responsible for each part of the process
- Providing status and process visibility allows everyone to be part of the process and help drive change



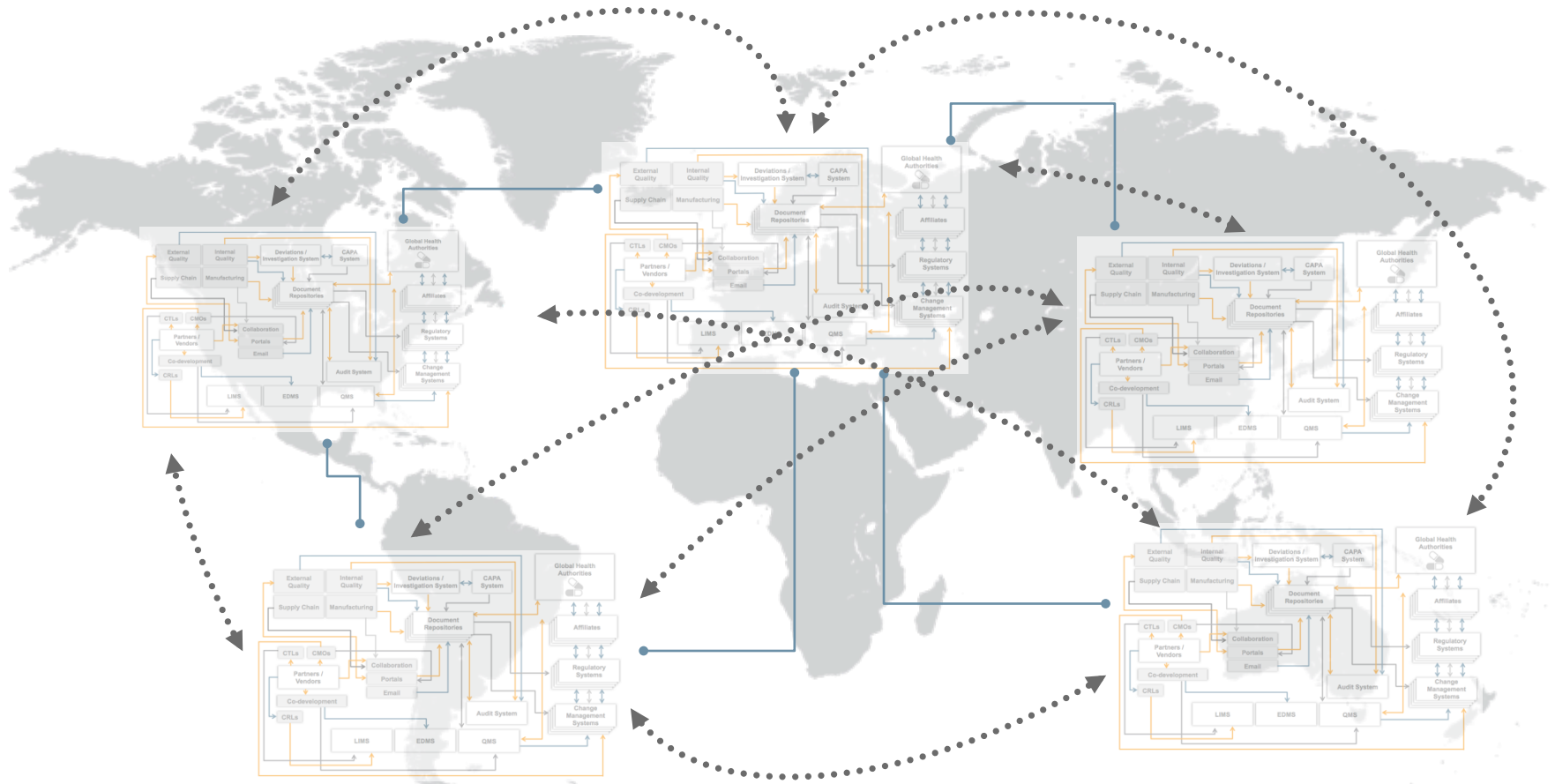
Technology



Fragmented Solutions



Globalization Adds Further Complexity



Key Change Management Challenges

Assessing Impact

- Most changes require prior regulatory approval
- Lack of visibility into global and regulatory impact
- Manual effort to collect and aggregate all site / supplier info to support decision-making

Executing Change

- Action tracking across multiple systems
- Inefficient, long cycle times, and increased potential of errors
- Lack of global status visibility

Inventory and Ship Decisions

- Lack of timely approvals and limited visibility into approval status
- Incomplete / fragmented information impedes quick, accurate decisions



Can You Have Better Intelligence?

How are global sites impacted?

When should the change be implemented?

How should changes be bundled?

Which countries have regulatory approval for change?

Which changes require regulatory filings, in which markets?

Which documents require updating?

How do we optimize inventory?



Unified System

Single place to ensure all change control and quality issues are resolved and regulatory approvals are in place before shipping

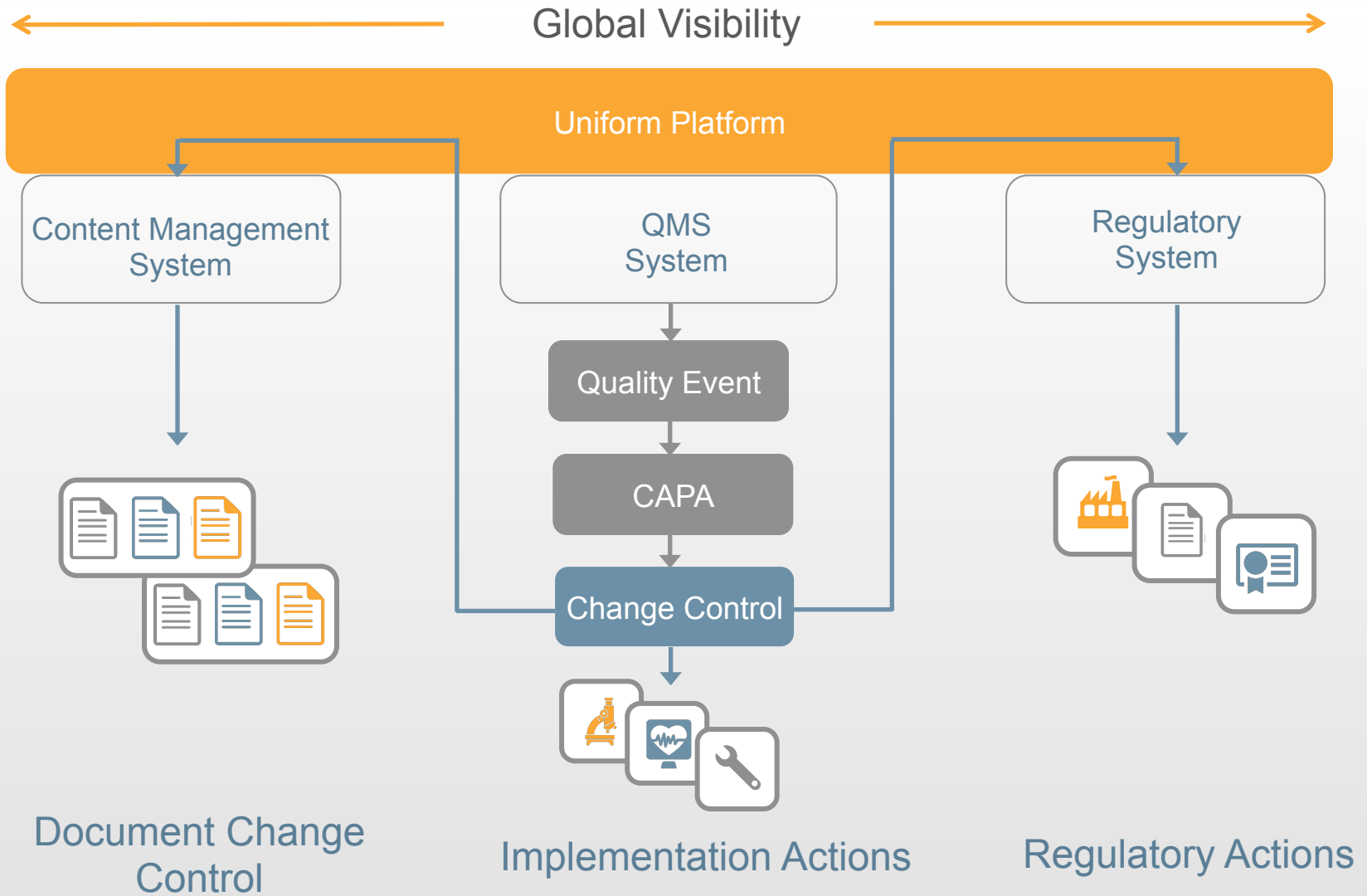
Unified System Across Functional Areas

Unified Quality System

Change Management	CAPA	Document Management
Deviations	Audits	Complaints
Document Training	Supplier Quality	Investigations

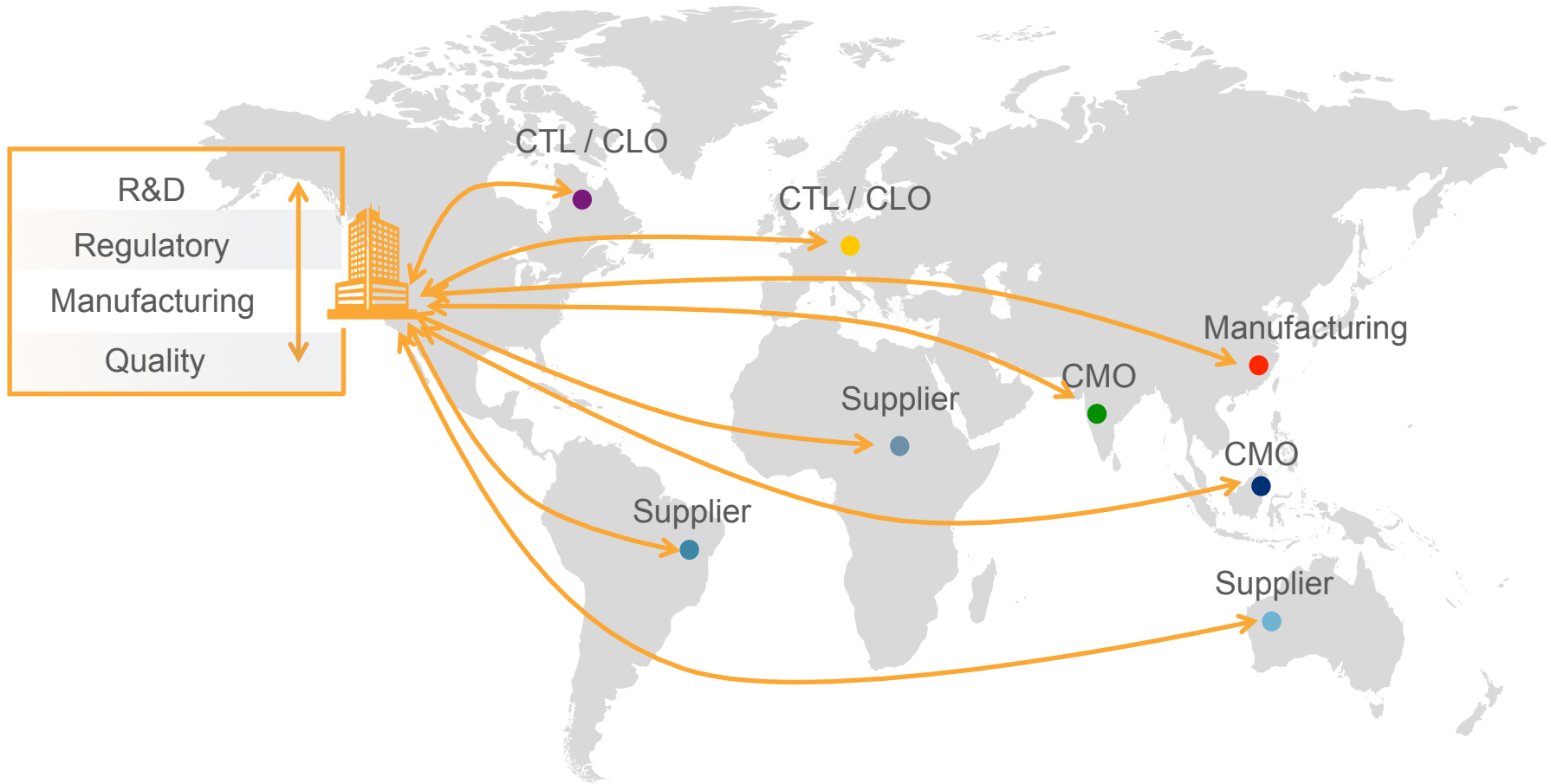
Regulatory Information Management System

Unifying Systems Across Functional Areas



Incorporating Internal and External Parties

Bidirectional communication with all critical stakeholders



Ease of Adoption Across All Employees

Modern solution support a changing workforce and environment

Intuitive, single user interface



Reduces training need & increases user adoption

Native mobile



Global, remote, or mobile workforce

Consumer web experience



Aligned with how people work / find information

Built-in compliant capabilities



Increased compliance



Summary



Transforming Change Management

People



Culture &
Executive Support

Process



Unified Across People
& Functional Areas

Technology



Enables People and
Process Change



Transforming Change Management with Modern Technology

A Unified Global Solution

Raw Material (Excipient)

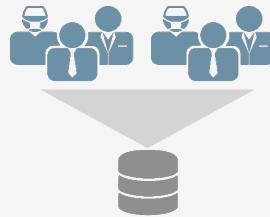
Drug Product

Labeling

Packaged Item

Drug Substance

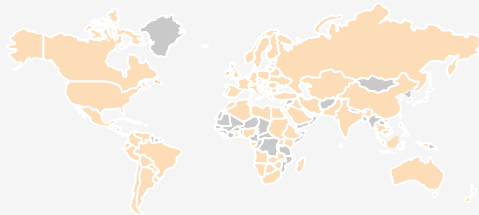
Improved visibility to
in-flight changes



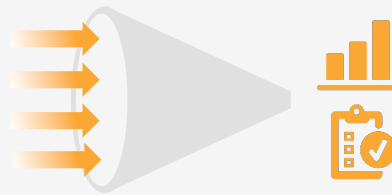
Reduced time spent
searching for information



Effective specification and
material management



Full visibility to
registration impacts



Improved product supply
planning and compliance



Reduced
regulatory risk

Enabling with Cloud Technology

Easily Incorporate External Parties

- Real-time visibility into quality processes and data
- More collaborative vendor relationships
- Directly engage partners anywhere in the world

Bring Together Quality, Regulatory, & Manufacturing Data

- Complete quality view for greater insights
- Resource allocation based on performance

Seamless Quality & Document Management Processes

- Accelerate event identification to correction
- Streamline change management process

Supports a Changing Workforce

- Find information quickly
- Native mobile capabilities, work from anywhere
- Easy to use, train, and administer

