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

Complex / global supply chains

Managing Cost

Speed & Agility
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

Change Management

Process

Technology
People
Cross-functional Responsibility

Change Control

- Quality
- Regulatory
- Manufacturing
- Supply Chain
- Other
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

Cross-functional

Globalization

Outsourcing
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 between $14B and $15M*.

Quality incidents are due to supplier/vendor quality issues: >40%.

FDA CDER warning letters given to manufacturing sites in India: 60%.

*One Manufacturer
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
Globalization Adds Further Complexity
## Key Change Management Challenges

<table>
<thead>
<tr>
<th>Assessing Impact</th>
<th>Executing Change</th>
<th>Inventory and Ship Decisions</th>
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</thead>
<tbody>
<tr>
<td>• Most changes require prior regulatory approval</td>
<td>• Action tracking across multiple systems</td>
<td>• Lack of timely approvals and limited visibility into approval status</td>
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<tr>
<td>• Lack of visibility into global and regulatory impact</td>
<td>• Inefficient, long cycle times, and increased potential of errors</td>
<td>• Incomplete / fragmented information impedes quick, accurate decisions</td>
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<tr>
<td>• Manual effort to collect and aggregate all site / supplier info to support decision-making</td>
<td>• Lack of global status visibility</td>
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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.
Unifying Systems Across Functional Areas

Global Visibility

Uniform Platform

QMS System
    Quality Event
    CAPA
    Change Control

Content Management System

Regulatory System

Implementation Actions

Document Change Control

Regulatory Actions
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

<table>
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<tr>
<th>Intuitive, single user interface</th>
<th>Native mobile</th>
<th>Consumer web experience</th>
<th>Built-in compliant capabilities</th>
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<tbody>
<tr>
<td>Reduces training need &amp; increases user adoption</td>
<td>Global, remote, or mobile workforce</td>
<td>Aligned with how people work / find information</td>
<td>Increased compliance</td>
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Summary
Transforming Change Management

People

Process

Technology

Culture & Executive Support

Unified Across People & Functional Areas

Enables People and Process Change
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