Sparta Systems

Three Best Practices for Effective Change Control

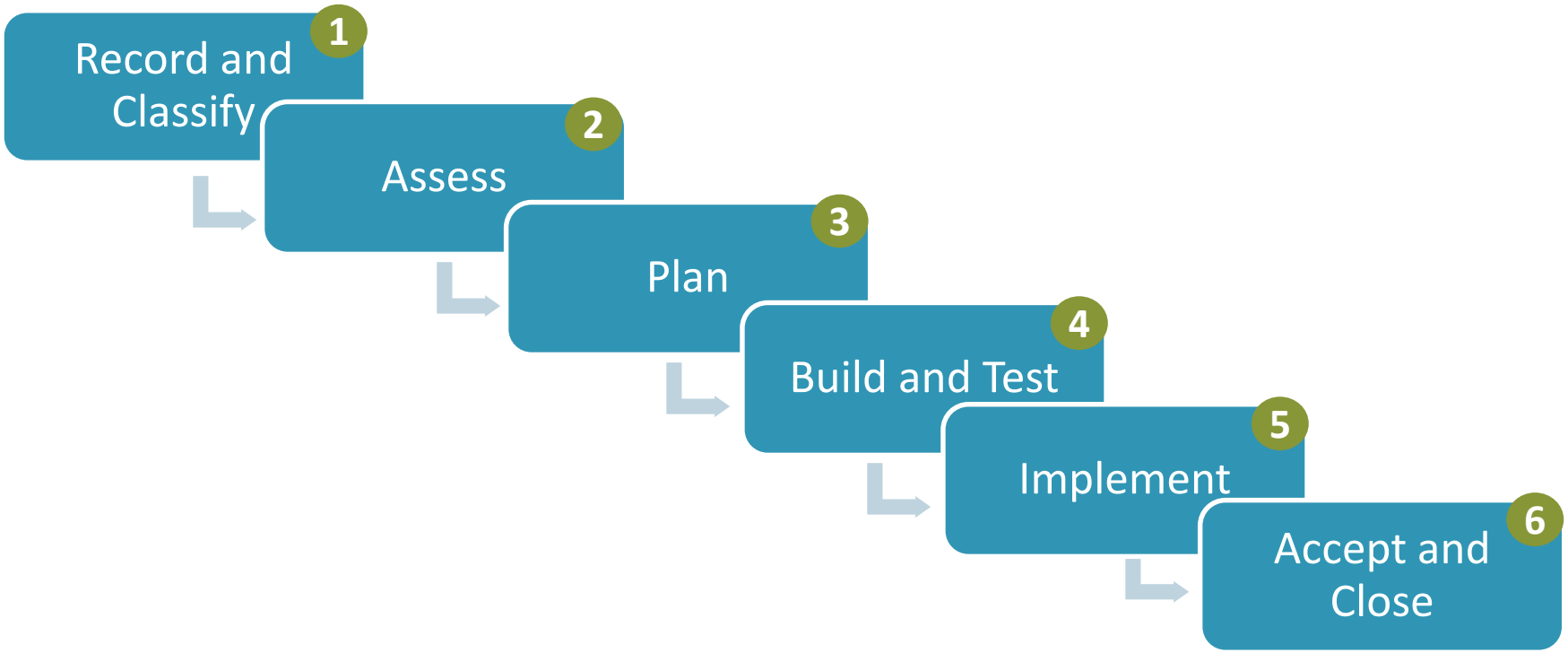
Change Control Guide for the Pharmaceutical Industry

Introduction

Defining Change Control :

Change control is a process that is applied to make certain that changes in a system or product are controlled, coordinated and approved before their implementation.

The change control process includes the following steps:



Introduction

Why is Change Control Management Important?

Every modification to a process, material or equipment needs to be properly recorded and authorized

Ensures proper coordination across stakeholders through automated workflows and alerts

Ensures compliance with industry and government regulations and standards

Changes that occur in these systems involve many areas of a company because a change can be made by practically anyone which can consequently impact any department

Introduction

In order to stave off any issues associated with changes to production and processes and procedures, systematic controls must be put in place.

- For any company with a complex manufacturing process, systems must be in place to evaluate changes and to track them, to ensure adequate control.
- Change control ensures the safety, quality, purity and potency of medicines are not compromised by production and process changes.

The lives of consumers and the manufacturer's reputation can be at stake, and product irregularities simply cannot occur.

According to the FDA, "Inadequate change control exposes a company to product liability actions, results in product recalls, causes internal confusion, and is a serious violation of the Quality System (QS) regulation."

Introduction

Types of Change that can Trigger a Change Control

The vast and complex nature of change control procedures has caused many companies to struggle with implementing a global change management system.

As a result, many of these manufacturers instead utilize a collection of disparate manual systems, spreadsheets and databases. These manual, disconnected mechanisms can lead to:

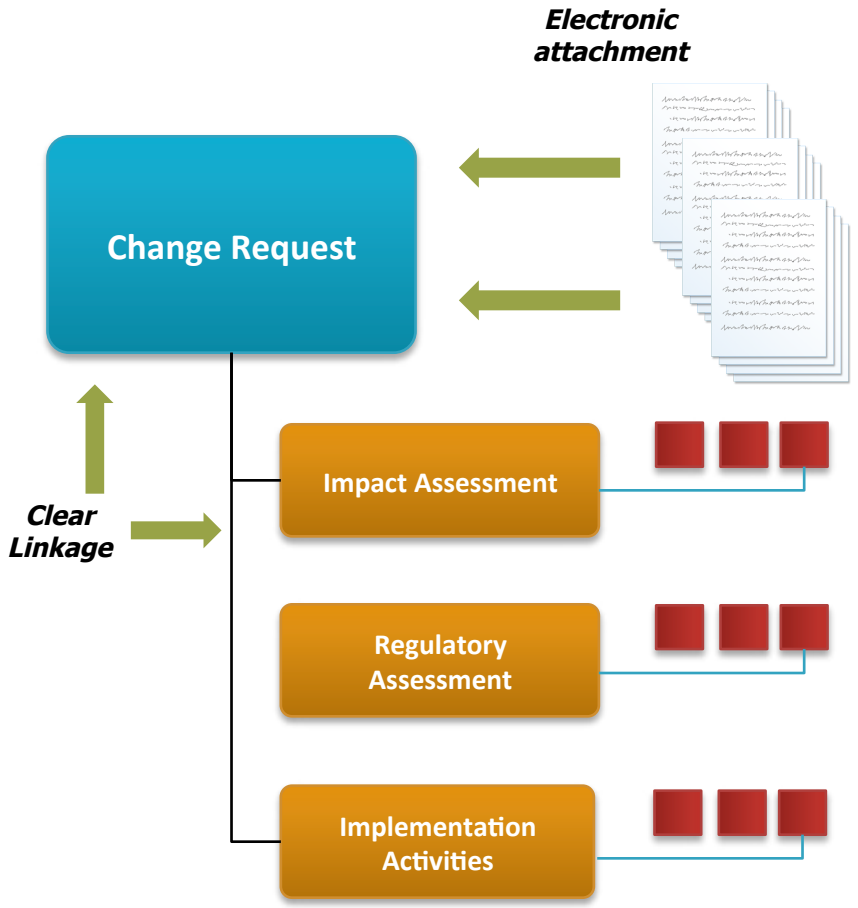
- Delays
- Input Errors
- Inconsistencies
- Duplicate data
- Loss of Productivity

Current State: Prevalent Issues

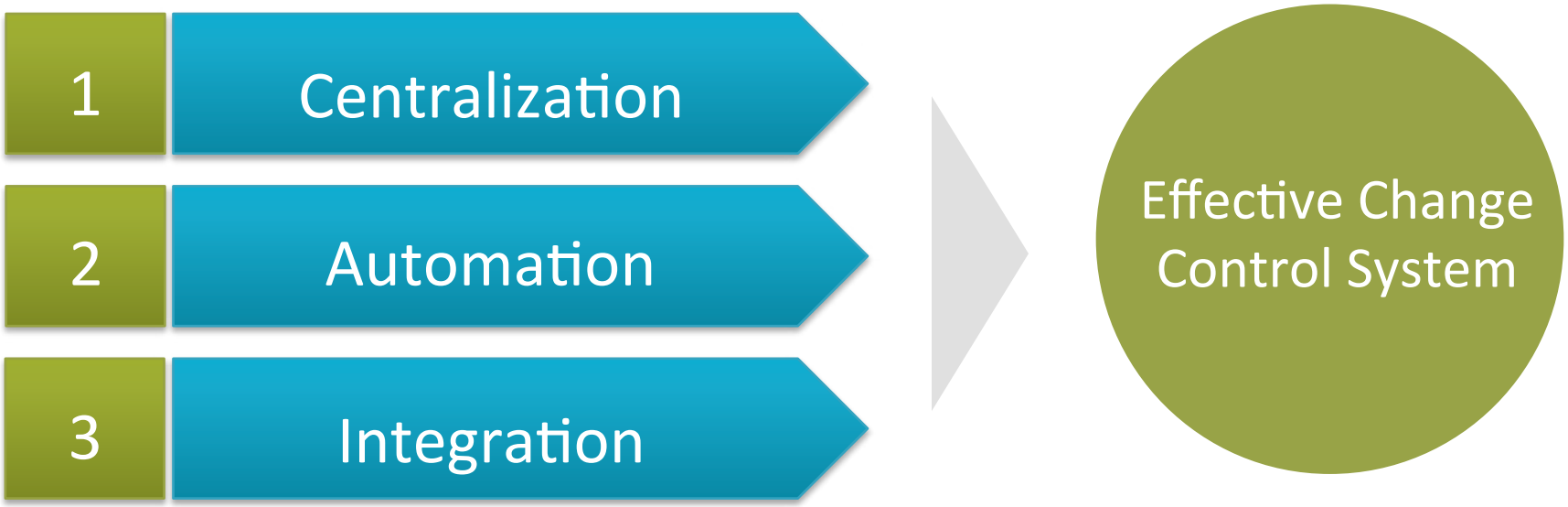
1. Decentralization of change control data
   - Little or no sharing of information
   - Redundant change controls
   - Difficult to assess risk
2. Cumbersome processes that disrupt production and delay change control resolution
3. Inconsistent change control solutions which result in compliance risks
4. Ineffective utilization of data for trending and reporting to understand how to avoid such risks
5. Inefficient and ineffective mechanisms for managing action items associated with change control

Desired State: Enterprise Change Control

- Hierarchical relationship of one change request and its associated activities.
- Electronic attachment and organization of supporting documentation.
- Logical association of supporting information directly to change request.
- Automated, consistent, and efficient change control process.
- Clear visibility to all levels of the organization through centralization of information and dashboards.
- Accommodation of both proactive and reactive change activity.



Three Best Practices



Three Best Practices

1: Centralization

- Electronically and securely manage all information in a centralized, scalable, and reliable system to eliminate the potential of lost information.
- Centralize management of all change control items onto an enterprise quality management software platform to eliminate redundant systems and decrease production costs.
- Enforce consistent and harmonized processes and procedures across the organization to reduce liability and patient risk.
- Automatically assign investigations to responsible parties across the organization.

2: Automation

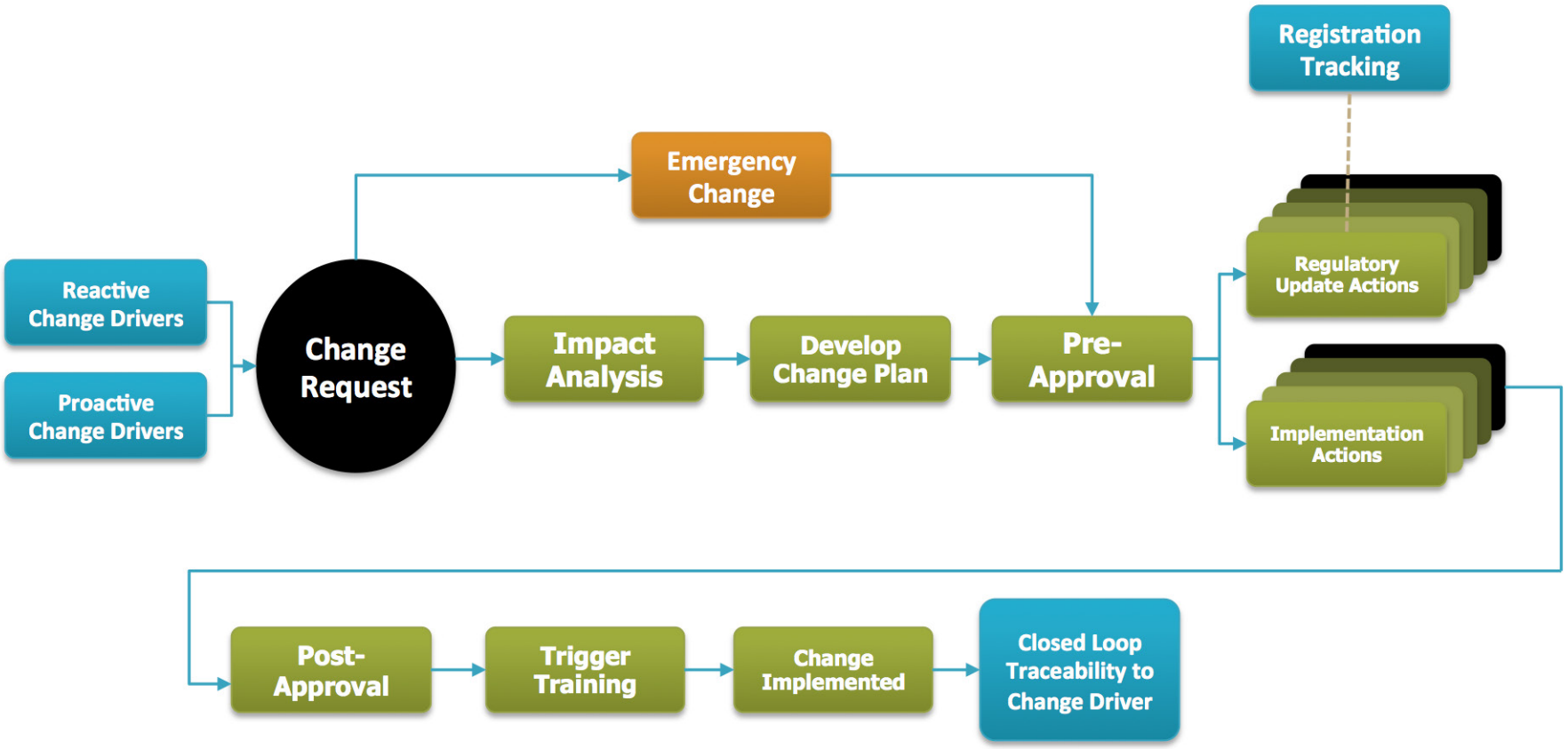
- Automate required impact assessments based on the change type, impact, and other criteria to advance the impact assessment process.
- Automatically notify other departments and sites when problems occur to increase visibility and reduce product impact.
- Automate workflow and implement fully electronic parallel review and approval processes to improve efficiency and reduce change control closure time.
- Automate and enforce specific actions to comply with ISO and other industry regulations.

3: Integration

- Link change controls to CAPAs to ensure an effective and closed-loop CAPA process.
- Integrate reporting and escalation to accelerate cycle time and batch release.
- Integrate change control workflow with document management systems for enhanced collaboration and productivity.

Result: Effective Change Control System

Full lifecycle including seamless integration to other quality systems processes.



Benefits of an Effective Change Control System

Manages all action items associated with a change including impact assessments, implementation items, regulatory notifications, approvals and effectiveness checks.

Reduces risk by enforcing a consistent and harmonized change control process that is compliant with industry regulations.

Improves efficiency and reduces change control closure time by automating workflows and implementing an electronic parallel review and approval process.

Reduces risk of lost or duplicated data by enforcing a consistent and harmonized change control process.

Conclusion

Change control in life sciences organizations is a critical business issue in terms of risk, safety and business performance, and it cannot be short-changed.

Change control systems that are not managed correctly can:

- Severely damage your bottom line
- Put customers at risk
- Damage brand reputation

Successful implementation of an enterprise-wide global change control program can:

- Improve cycle time and time to market
- Enhance production
- Increase product quality
- Increased flexibility to adapt to changing regulations

Sparta Systems, an industry pioneer and global leading provider of enterprise quality management software (EQMS) solutions, enables businesses to safely and efficiently deliver their products to market. Its TrackWise® EQMS, a trusted standard among highly regulated industries, is used by quality, manufacturing and regulatory affairs professionals to manage compliance, reduce risk and improve safety across the global enterprise. Headquartered in New Jersey and with locations across Europe and Asia, Sparta Systems maintains an extensive install base in the pharmaceutical and biotechnology, medical device, electronics manufacturing and consumer products markets.

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