Effectively Employing Change Control in CAPA
Agenda

CAPA and Change Control are both systematic approaches to becoming a self-correcting organization

- FDA’s perspective
- Change Control’s role in CAPA processes
- CAPA’s role in Change Control processes
- Interactive exercise – becoming a self-correcting organization
FDA on CAPA

21 CFR Part 820 Subpart J Sec. 820.100

- CAPA processes shall include:
  - Identifying and investigating existing and potential causes of quality problems
  - Identifying the actions needed to correct and prevent recurrence of quality problems
  - Verifying the corrective actions are effective
  - Implementing changes in procedures
  - Disseminating information about quality problems
  - Submitting this information for management review
FDA on Change Control

**Change Control:** The processes, authorities for, and procedures to be used for all changes that are made to the computerized system and/or the system's data. Change control is a vital subset of the Quality Assurance [QA] program within an establishment and should be clearly described in the establishment's SOPs.

– *Glossary of Computer Systems Software Development Terminology*
FDA on Change Control

- **Design Control (21 CFR Part 820 Subpart C Sec. 820.30(i))**
  - Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review and approval of design changes before their implementation.

- **Document Control (21 CFR Part 820 Subpart D Sec. 820.40(b))**
  - Changes to documents shall be reviewed and approved.
Production and Process Controls: Process Validation (21 CFR Part 820 Subpart G Sec. 820.70(b))

Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or where appropriate validated...before implementation and these activities shall be documented. Changes shall be approved....
FDA on Change Control

- Production and Process Controls: Software Validation (21 CFR Part 820 Subpart G Sec. 820.70(i))
  - All software changes shall be validated before approval and issuance
- Electronic Records; Electronic Signatures (21 CFR Part 11 Subpart B Sec. 11.10(k2))
  - Use of appropriate controls over systems documentation including revision and change control procedures...
FDA on Change Control

General Principles of Software Validation

- Once a software product has been baselined (approved), any change to that product should have its own "mini life cycle," including testing
FDA on Change Control

General Principles of Software Validation

- The FDA's analysis of 3140 medical device recalls conducted between 1992 and 1998 reveals that 242 of them (7.7%) are attributable to software failures. Of those software related recalls, 192 (or 79%) were caused by software defects that were introduced when changes were made to the software after its initial production and distribution.
The CAPA Process

- Initiate CAPA
- Investigate CAPA
- Plan corrective and preventive activities
- Implement corrective and preventive activities
- Verify CAPA effectiveness
- Approve and close CAPA
Change Control and the CAPA Process

- Initiate CAPA
  - A CAPA record is itself a quality record and therefore subject to change control
  - This is usually provided as a capability within the CAPA computerized system as a part of overall configuration management functionality
- Review and approval
- Versioning
- Audit trail
Change Control and the CAPA Process

- Investigate CAPA
  - Containment actions may involve change control
    - Changing batch status to “On Hold”
  - Corrections may involve change control
    - Obtaining authorization to make a change that implements a correction
Change Control and the CAPA Process

- Plan and implement corrective and preventive activities
  - Potentially any item subject to configuration management might undergo controlled change
    - Specifications
    - Methods
    - Processes/procedures
    - Documentation
    - Computerized systems
      - Hardware, software, data
Change Control and the CAPA Process

- Verify effectiveness; approve and close CAPA
- If CAPA was in any way ineffective, additional controlled changes may need to be made
- Approving and closing the CAPA record is done via change control
The Change Control Process

- Change request
  - Describe and justify the change
- Change assessment
  - Impact analysis
  - Risk analysis
  - Business considerations
- Change review and approval
- Implement change
  - Verification
  - Documentation updates
CAPA and the Change Control Process

- CAPA is one of several triggers used to correct deficiencies in the Change Control process itself
- Other triggers include:
  - Business process improvement initiatives
  - Audits and inspections
- A CAPA could be initiated as a result of failure to follow the change control process
CAPA and the Change Control Process

- A CAPA could be initiated as the result of executing a change request
  - Impact analysis
  - Risk analysis
  - Change implementation
  - Verification
- Systemic quality issues and opportunities to prevent them could be discovered at any time!
CAPA and Change Control: Commonality

- CAPA and Change Control are both systematic approaches to becoming a self-correcting organization
- CAPA allows identification, correction, and prevention of recurrence of quality issues
- Change Control allows maintenance of validations during corrective and preventive actions
- So just what is this “self-correcting organization” anyway?
Behaviors of the Self-Correcting Organization

- Finds and fixes its own quality issues
- Celebrates defect discovery
- Rewards defect prevention
- What else?
The Self-Correcting Organization: a Poll

- Hardly ever (  )
- Occasionally (  )
- Fairly regularly (  )
- Frequently (  )
- Almost always (  )
Becoming a Self-Correcting Organization: Roadblocks

What are the impediments to becoming a self-correcting organization?

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Becoming a Self-Correcting Organization: A Roadmap

Building a robust Quality System engenders self-correction

1. Management review
2. Quality audits
3. Validation
4. Acceptance activities
5. Complaint handling
6. CAPA
7. Change control
Interactive Exercise: Becoming a Self-Correcting Organization

- Session attendees will divide into five groups.
- Each group will be assigned a QS area.
- Work together to tell a story for your QS area that shows how it helps an organization become self-correcting.
- Stories can be real or theoretical.
- A spokesperson from each group will debrief the session-at-large.
- Example: Change control activities revealed a systemic non-use of document templates. A CAPA was initiated to address this issue.
Conclusion

Questions?

Thank you!