TAKING THE BURDEN OUT OF CORRECTIVE AND PREVENTIVE ACTION

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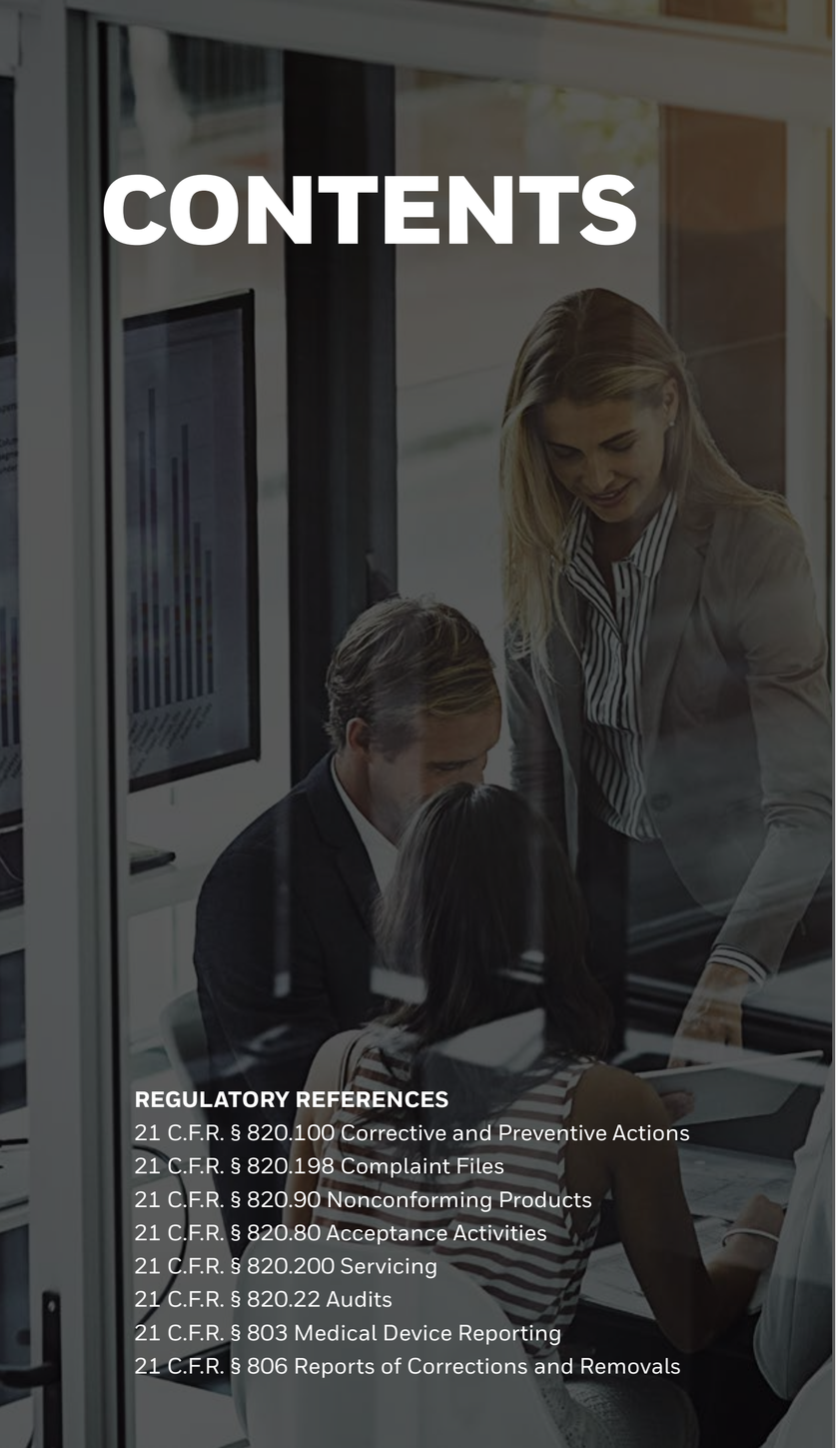

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REGULATORY REFERENCES

21 C.F.R. § 820.100 Corrective and Preventive Actions
21 C.F.R. § 820.198 Complaint Files
21 C.F.R. § 820.90 Nonconforming Products
21 C.F.R. § 820.80 Acceptance Activities
21 C.F.R. § 820.200 Servicing
21 C.F.R. § 820.22 Audits
21 C.F.R. § 803 Medical Device Reporting
21 C.F.R. § 806 Reports of Corrections and Removals

INTRODUCTION

Fast-paced technology and innovations are taking the life sciences industry by storm at the center of the fourth industrial revolution transformation.

Quality 4.0 does not replace the traditional methods; it harmonizes people, culture, technology and processes to achieve organizational goals. Systems considered burdensome, such as CAPA, are now a powerful, proactive tool helping shape the future of quality.

A successful corrective and preventive action (CAPA) system is not a one-size-fits-all, reactive, overburdensome process. The CAPA system is an effective, efficient, user-friendly process that should increase product quality, safety, customer satisfaction and meet regulatory compliance.

This eBook will provide an overview of obtaining a holistic, predictive and proactive CAPA system to foster improvements continuously.

CAPA MANAGEMENT

Insufficient corrective and preventive action procedures continue to top the most common FDA inspection observations. A strong CAPA structure embedded into the lifecycle process provides an organized method to identify concerns or potential concerns, solve them and prevent them from recurring.

An efficient CAPA process is critical for a successful quality management system (QMS). ISO and the FDA provide the framework for the CAPA process, but it is ultimately each organization's responsibility to determine and maintain a systematic and practical system.

CORRECTIVE (REACTIVE) ACTION

- It is a reaction to the issue
- Performed to correct the quality incident and keep it from recurring

PREVENTIVE (PROACTIVE) ACTION

- Identifying the issue can prevent recurrence in products and processes
- Continuous improvement to prevent the same or similar problem from happening at any location within the organization that may have the same or similar processes in place
- Involves cross-functional teams

THREE CAPA BUILDING BLOCKS

A proper CAPA system can aid in reducing costs that would be spent on supporting quality initiatives within other organizational departments. Implementing a closed-loop CAPA management system is critical in reducing organizations' quality issues and improving the overall cost of quality.

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CREATE, STRUCTURE AND DOCUMENT A HOLISTIC CAPA SYSTEM

ESTABLISH A CAPA FOUNDATION

USING CAPA FOR CONTINUOUS IMPROVEMENT

1 | CREATE, STRUCTURE AND DOCUMENT A HOLISTIC CAPA SYSTEM

Clear policies on the CAPA process should be documented and staff should be trained per their job matrix. Ensure that your CAPA system is centralized and controlled, thereby consolidating operations and eliminating overlap between departments. Have an effective method for tracking all incidents and events, ensuring visibility, and providing one truth source.

THE BENEFITS OF A HOLISTIC AUTOMATED CAPA SYSTEM

- Provide a centralized database for improved visibility and efficiency
- Recognize and initiate CAPAs
- Provide seamless traceability to related quality processes, such as change control and training
- Create an automated workflow to ensure consistency, reducing investigation cycle time while improving root cause analysis
- Capture quality process data to improve quality trends and management reports
- Describe action plans for improvement
- Decrease risk
- Root cause analysis
- Verify effectiveness checks

2 | CAPA FOUNDATION

CAPA PROCESS | HINTS

INTAKE OF ISSUE OR POSSIBLE ISSUE

Provide the basic concept around the issue or potential issue

- Issues can come from internal and external sources

NOTIFICATION REQUESTS FOR CAPA REVIEW

- High-risk cross-function team (harmed or potentially harmed a patient)
- Low risk directly involved (continuous improvement methods)

A key part of the CAPA process is reviewing data on quantity and severity to find out if a CAPA is necessary

- Conducting a risk assessment
- Patient involved
- Nonconforming product sent out
- Recurring event
- Impacting regulations, product design, or performance

RISK REVIEW

- Historical data determining attributes, frequency and impact
- Qualify risk and impact
- Utilizing a 2x2 matrix to focus on high risk and high impact

ACCEPT OR REJECT CAPA REQUEST

- Accept and initiate a CAPA
- Reject and continue with a nonconformance or complaint

If a CAPA is not required, then it will move to a nonconformance or complaint

- Document the justification for no CAPA
- If CAPA is initiated notify the appropriate people

DETERMINE CAPA TEAM

- If the CAPA is high-risk a cross-functional team should be used
- If the CAPA is low–risk, areas that are directly affected should be involved

IDENTIFY ANY IMMEDIATE ACTIONS WHICH ARE REQUIRED

- If the CAPA is high-risk a cross-functional team should be used
- If the CAPA is low–risk, areas that are directly affected should be involved

ANALYZE DATA, INVESTIGATE THE CAUSE

Five common root cause analysis tools:

- The 5 Whys
- Flowcharts
- The Fishbone Diagrams
- Failure Mode and Effects Analysts (FMEA)
- Scatter Diagrams

IMPLEMENTATION OF ACTIONS (CHANGES)

Prediction based actions help prevent or monitor an event before it escalates, examples:

- Reviewing suppliers
- Monitoring and analyzing negative trends
- Risk analysis
- Calibration control programs
- Disaster recovery plans
- Internal audits

DISSEMINATE INFORMATION

Notifying management team on actions

VERIFICATION AND EFFECTIVENESS

Is a way to ensure that the actions have resolved any issue and stopped recurrence

- Set clear, impartial measurements providing date ranges, where data will come from and acceptable limits
- Provide details on how the verification is conducted

Effectiveness failures usually occur when actions were not clear or a lack of an adequate metrics

CLOSURE

Submit for review and closure

3 | IT'S ALL ABOUT CONTINUOUS IMPROVEMENT

With all the confusion on when a CAPA should be open, companies spend less time problem solving and making improvements. Using a closed-loop risk-based CAPA process with the Plan, Do, Check, Act process can reduce cost and increase customer satisfaction. Continuous improvement is an ongoing effort to improve products, processes, and services continually. Ensure the following are part of your CAPA continuous improvement process:

- Cross-functional review of the root cause(s) and agreement on the appropriate actions
- Promoting a strong quality culture that prioritizes improvement and growth
- Involvement of the right stakeholders
- Utilizing the CAPA system for gains, not just flaws
- Retooling where appropriate
- Dissemination of CAPA outcome, which included risk remediation, procedure or process changes, documented training with appropriate staff members and effectiveness of training
- Modifying responsibilities

THE CAPA JOURNEY

With these building blocks in place, organizations can empower the CAPA process and use it as a continuous improvement method to drive product quality and patient safety.

A consolidated CAPA management system has been proven time and again as the most efficient system for preventing future occurrences, which will result in a minimal drain on the time and resources that companies view as impediments to profitability. Systems considered burdensome, such as CAPA, are now a powerful, proactive tool shaping the future of quality.

Contact us to learn more:
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