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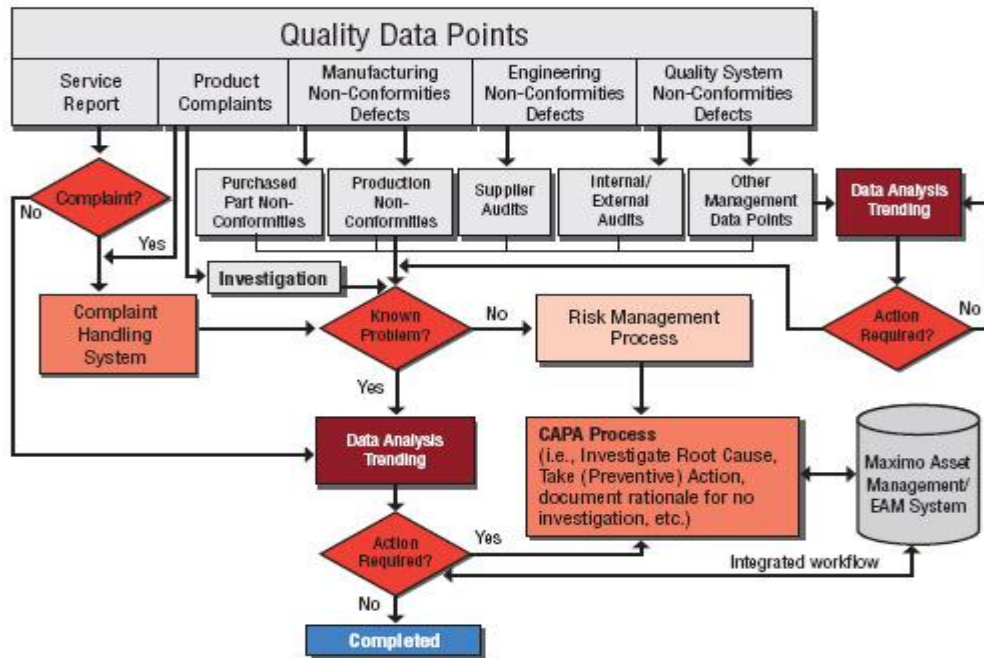
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CAPA – Inspectional Guidelines & Flow Chart



Corrective Action Preventive Action, is an Important Part of a Quality Management System

An organization's corrective action preventive action (CAPA) process is central to all control points. Corrective actions are intended to determine the cause of non-conformances that have been detected, while preventive actions are the plan put in place to stop the problem from happening again in the future.

Why is a Corrective Action Preventive Action (CAPA) System Important?

The methods for dealing with corrective and preventive actions require a high level of accuracy and flexibility. Rigorous regulatory and traceability requirements exist in industries such as aerospace, automotive, defense, life sciences or any other manufacturing operation.

Implementing a corrective preventive action (CAPA) system should be an important part of any corporate quality system, regardless of industry.

Corrective Action Preventive Action (CAPA) Software

Corrective action preventive action (CAPA) systems can serve as the cornerstone of Six Sigma, Lean and other cost reduction and process improvement efforts. FDA-regulated industries are legally mandated to comply with 21 CFR Part 11 and meet FDA GMP, GLP and GCP requirements.

Steps in a Corrective Action Procedure

A corrective action procedure is not reworking or remaking an item to bring it back into specification. Patching up a mistake doesn't address what made it happen in the first place and it won't prevent a recurrence.

A corrective action procedure can be documented using either a paper or electronic system. Either way, the process is basically the same:

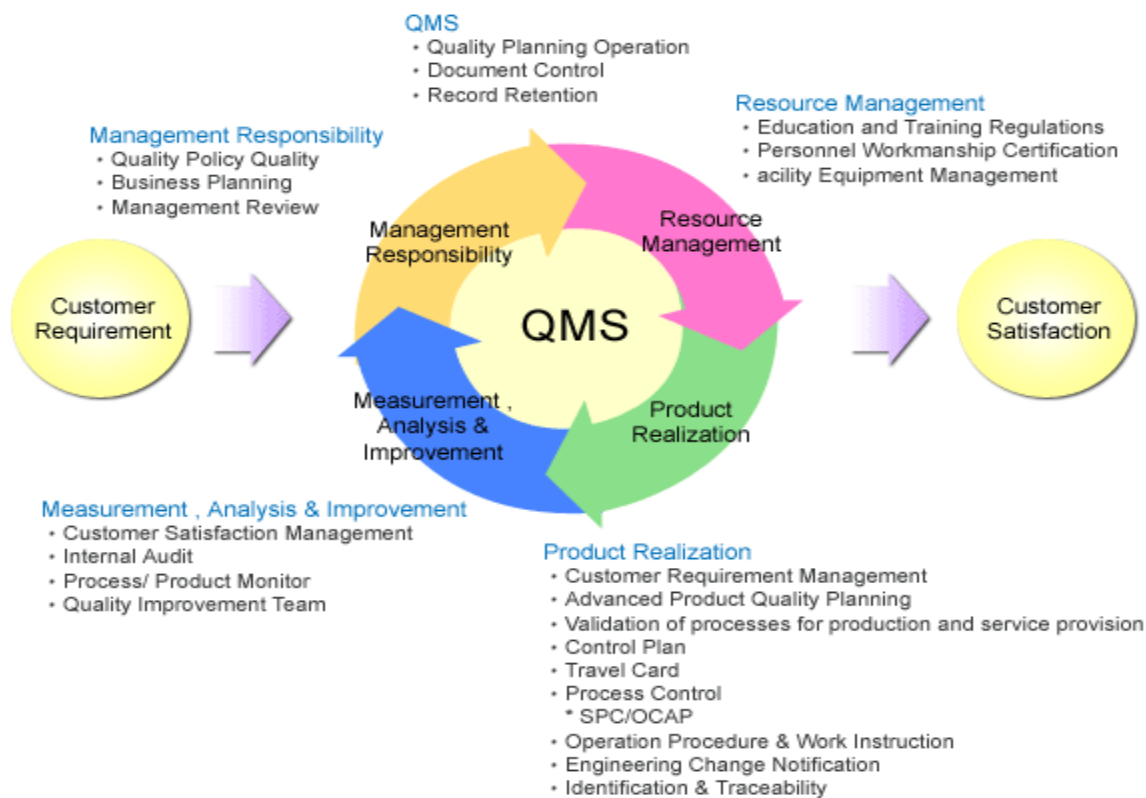
- Document that was specified versus one that was found. Check the functional specifications and any other requirements against the actual result.
- Determine how much time should be allowed for a corrective action procedure (or CAPA response).
- Decide who will investigate the problem, find a solution and perform the corrective action procedure.
- Research and document the cause of the problem.
- Plan how to keep the problem from recurring.
- Communicate the corrective action procedure to everyone involved, at each appropriate level.
- Periodically check to ensure the problem is solved and that the corrective action procedure was effective.



Corrective and Preventive Actions (CAPA)

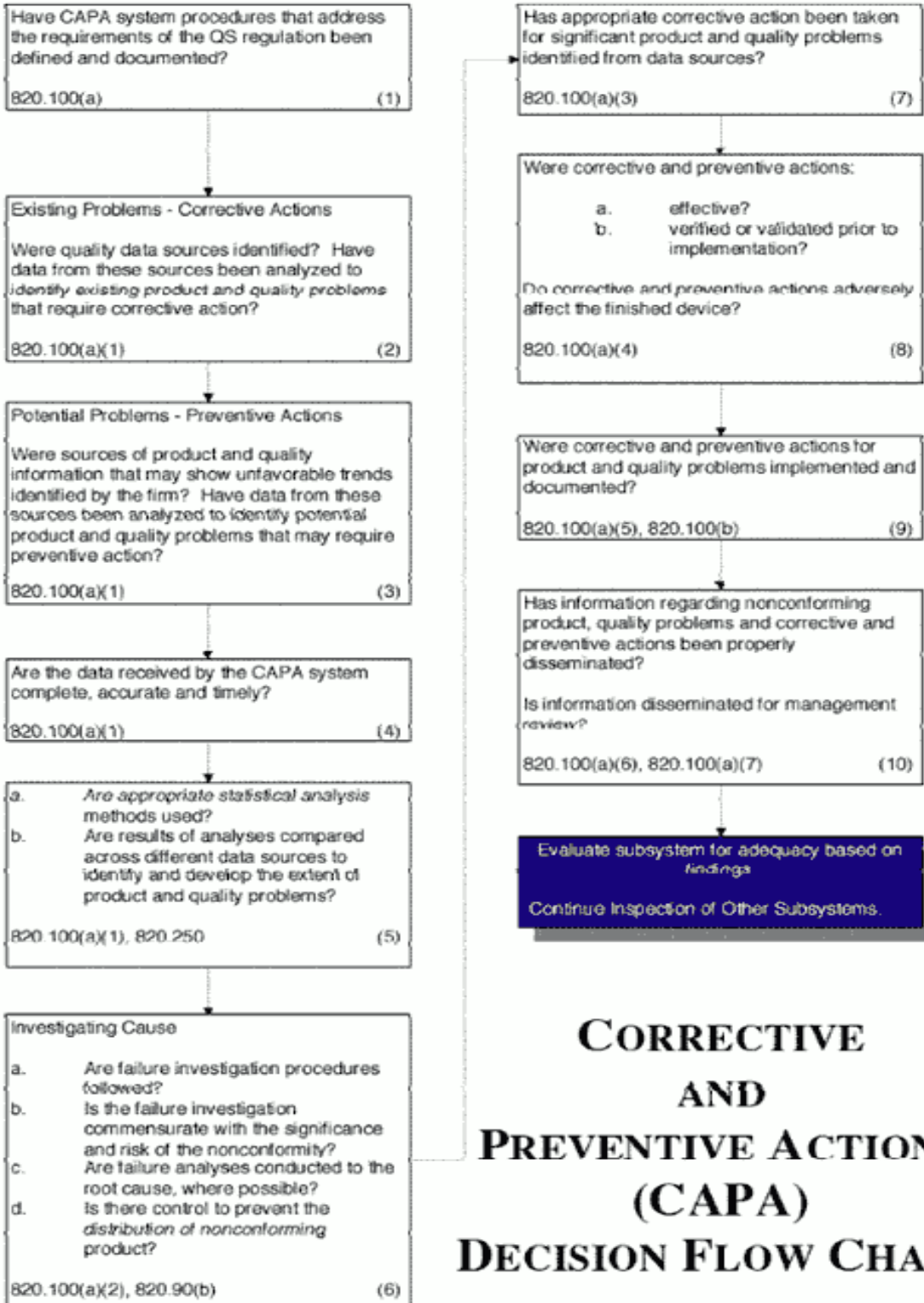
Inspectional Objectives

1. Verify that CAPA system procedure(s) that address the requirements of the quality system regulation have been defined and documented.
2. Determine if appropriate sources of product and quality problems have been identified. Confirm that data from these sources are analyzed to identify existing product and quality problems that may require corrective action.
3. Determine if sources of product and quality information that may show unfavorable trends have been identified. Confirm that data from these sources are analyzed to identify potential product and quality problems that may require preventive action.
4. Challenge the quality data information system. Verify that the data received by the CAPA system are complete, accurate and timely.
5. Verify that appropriate statistical methods are employed (where necessary) to detect recurring quality problems. Determine if results of analyses are compared across different data sources to identify and develop the extent of product and quality problems.



6. Determine if failure investigation procedures are followed. Determine if the degree to which a quality problem or nonconforming product is investigated is commensurate with the significance and risk of the nonconformity. Determine if failure investigations are conducted to determine root cause (where possible). Verify that there is control for preventing distribution of nonconforming product.
7. Determine if appropriate actions have been taken for significant product and quality problems identified from data sources.
8. Determine if corrective and preventive actions were effective and verified or validated prior to implementation. Confirm that corrective and preventive actions do not adversely affect the finished device.
9. Verify that corrective and preventive actions for product and quality problems were implemented and documented.
10. Determine if information regarding nonconforming product and quality problems and corrective and preventive actions has been properly disseminated, including dissemination for management review.






Corrective and Preventive Actions (CAPA)

Narrative

Purpose/Importance

The purpose of the corrective and preventive action subsystem is to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence. Verifying or validating corrective and preventive actions, communicating corrective and preventive action activities to responsible people, providing relevant information for management review and documenting these activities are essential in dealing effectively with product and quality problems, preventing their recurrence, and preventing or minimizing device failures.

One of the most important quality system elements is the corrective and preventive action subsystem.

-  **1. Verify that CAPA system procedure(s) that address the requirements of the quality system regulation have been defined and documented.**

Review the firm's corrective and preventive action procedure. If necessary, have management provide definitions and interpretation of words or terms such as "nonconforming product", "quality audit", "correction", "prevention", "timely", and others. It is important to gain a working knowledge of the firm's corrective and preventive action procedure before beginning the evaluation of this subsystem.




NOTE: Corrective action taken to address an existing product or quality problem should include action to:

- Correct the existing product nonconformity or quality problems and;
- Prevent the recurrence of the problem

The CAPA procedure should include procedures for how the firm will meet the requirements for all elements of the CAPA subsystem. All procedures should have been implemented.

Once you have gained a knowledge of the firm's corrective and preventive action procedure, begin with determining if the firm has a system for the identification and input of quality data into the CAPA subsystem. Such data includes information regarding product and quality problems (and potential problems) that may require corrective and/or preventive action.

-  **2. Determine if appropriate sources of product and quality problems have been identified. Confirm that data from these sources are analyzed to identify existing product and quality problems that may require corrective action.**

The firm should have methods and procedures to input product or quality problems into the CAPA subsystem. Product and quality problems should be analyzed to identify product and quality problems that may require corrective action.

The firm should routinely analyze quality data regarding product and quality problems. This analysis should include data and information from all acceptance activities, complaints, service, and returned product records. Determine if the firm is capturing and analyzing data from acceptance activities relating to component, in-process and finished device testing. Information obtained subsequent to distribution, which includes complaints, service activities and returned products, as well as information relating to concessions (quality and nonconforming products), quality records, and other sources of quality data should also be captured and analyzed. Examples of other sources of quality data include quality audits, installation reports, lawsuits, etc.



NOTE: In accordance with Agency policy (CPG 7151.02), do not request records regarding the results of internal quality audits, management reviews, third party audits (including ISO audits), or supplier audits.

However, you will be reviewing raw data that is used by the firm when conducting their quality audits, management reviews, etc. Trending information and results of analyses are generally part of evaluations under the corrective and preventive action requirements. This information is utilized in internal audits and management reviews. Information or data utilized in internal audits and management reviews are considered raw data and should be available for routine review.

✓ 3. Determine if sources of product and quality information that may show unfavorable trends have been identified. Confirm that data from these sources are analyzed to identify potential product and quality problems that may require preventive action.

Determine if the firm is identifying product and quality problems that may require a preventive action. This can be accomplished by reviewing historical records such as trending data, corrective actions, acceptance activities (component history records, process control records, finished device testing, etc.) and other quality system records for unfavorable trends. Review if preventive actions have been taken regarding unfavorable trends recognized from the analysis of product and quality information. Product and quality improvements and use of appropriate statistical process control techniques are evidence of compliance with the preventive action requirement.

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Determine if the firm is capturing and analyzing data regarding in-conformance product. Examples include capturing and analyzing component test results to detect shifts in test results that may indicate changes in vendor processes, component design or acceptance procedures. Identification of these indicators may necessitate a vendor investigation as a preventive action. Monitoring in-process and finished device test results may reveal additional indicators of potential quality problems. For devices where stability is an issue, test results of reserve samples are continually monitored. These monitoring activities may trigger process changes, additional training activities and other changes required to maintain the process within its tolerances and limits.

Determine if the firm is using statistical control techniques for process controls where statistical techniques are applicable. An example would be "Statistical Process Control" (SPC). SPC is utilized to monitor a process and initiate process correction when a process is drifting toward a specification limit. Typically, SPC activities are encountered with large volume production processes such as plastic molding and extrusion. Any continuing product improvements (in the absence of identified product problems such as non-conforming product) are also positive indicators of preventive actions.



Important linkages for this activity include 820.70 Production and Process Controls and 820.250 Statistical Techniques.

✓ 4. Challenge the quality data information system. Verify that the data received by the CAPA system are complete, accurate and timely.

Select one or two quality data sources. Using the sampling tables, review records from the chosen data sources to determine if the data were entered into the CAPA system. In addition, determine whether the data are complete, accurate and entered into the CAPA system in a timely manner.



Important linkages for this activity include 820.80 Acceptance Activities, 820.90 Nonconforming Product, 820.170 Installation, 820.198 Complaint Files and 820.200 Servicing.

✓ 5. Verify that appropriate statistical methods are employed (where necessary) to detect recurring quality problems. Determine if results of analyses are compared across different data sources to identify and develop the extent of product and quality problems.

The analysis of product and quality problems should include appropriate statistical and non-statistical techniques. Statistical techniques include Pareto analysis, spreadsheets, and pie charts. Non-statistical techniques include quality review boards, quality review committees and other methods.

The analysis of product and quality problems should also include the comparison of problems and trends across different data sources to establish a global, and not an isolated view, of a problem. For example, problems noted in service records should be compared with similar problem trends noted in complaints and acceptance activity information.

The full extent of a problem must be captured before the probability of occurrence, risk analysis and the proper course of corrective or preventive action can be determined.

✓ 6. Determine if failure investigation procedures are followed. Determine if the degree to which a quality problem or nonconforming product is investigated is commensurate with the significance and risk of the nonconformity. Determine if failure investigations are conducted to determine root cause (where possible). Verify that there is control for preventing distribution of nonconforming product.

Review the firm's CAPA procedures for conducting failure investigations. Determine if the procedures include provisions for identifying the failure modes, determining the significance of the failure modes (using tools such as risk analysis), the rationale for determining if a failure analysis should be conducted as part of the investigation, and the depth of the failure analysis.

Discuss with the firm their rationale for determining if a corrective or preventive action is necessary for an identified trend regarding product or quality problems. The decision process may be linked to the results of a risk analysis and essential device outputs.

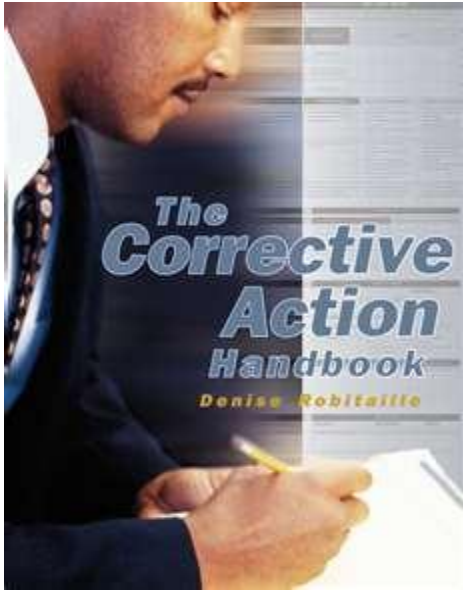
Using the sampling tables, select failure investigation records regarding more than one failure mode (if possible) and determine if the firm is following their failure investigation procedures.

Confirm that all of the failure modes from your selected sample of failure investigations have been captured within data summaries such as reports, pie charts, spreadsheets, Pareto charts, etc.

Determine whether the depth of the investigation (where possible) is sufficient (root cause) to determine the corrective action necessary to correct the problem. Select one significant failure investigation that resulted in a corrective action and determine if the root cause had been identified so that verification or validation of the corrective action could be accomplished.

Using the sampling tables, review a number of incomplete failure investigations for potential unresolved product non-conformances and potential distribution of nonconforming product. Unresolved problems that could be of significant risk to the patient or user may require product recall if the problem cannot be resolved.

Using the sampling tables, review records regarding nonconforming product where the firm concluded corrective or preventive action was not necessary. As noted above, verify that the firm is not continuing to distribute nonconforming product. This may be an important deficiency based on the class of, and the risk associated with, the product.



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Important linkages for these activities include 820.20 Management Responsibility, 820.25 Training, 820.30 Design Controls, 820.90 Nonconforming Product and possibly 820.250 Statistical Techniques.

Using the sampling tables, review nonconforming product and quality concessions. Review controls for preventing distribution of nonconforming products. Product and quality concessions should be reviewed to verify that the concessions have been made appropriate to product risk, within the requirements of the quality system and not solely to fulfill marketing needs.



Important linkages regarding these activities include 820.20 Management Responsibility and 820.90 Nonconforming Product.

✓ 7. Determine if appropriate actions have been taken for significant product and quality problems identified from data sources.

Where appropriate, this may include recall actions, changes in acceptance activities for components, in-process and finished devices, etc.

Using the sampling tables, select and review significant corrective actions and determine if the change or changes could have extended beyond the action taken. A significant action would be a product or process change to correct a reliability problem or to bring the product into conformance with product specifications. Discuss with the firm their rationale for not extending the action to include additional actions such as changes in component supplier, training, changes to acceptance activities, field action or other applicable actions. Investigators should discuss and evaluate these issues but be careful not to say anything that could be construed as requesting a product recall.

✓ 8. Determine if corrective and preventive actions were effective and verified or validated prior to implementation. Confirm that corrective and preventive actions do not adversely affect the finished device.

Using the selected sample of significant corrective and preventive actions, determine the effectiveness of these corrective or preventive actions. This can be accomplished by reviewing product and quality problem trend results. Determine if there are any similar product or quality problems after the implementation of the corrective or preventive actions. Determine if the firm has verified or validated the corrective or preventive actions to ensure that such actions are effective and do not adversely affect the finished device.

Corrective actions must be verified and (if applicable) validated. Corrective actions must include the application of design controls if appropriate.

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Good engineering principles should include: establishing a verification or validation protocol; verification of product output against documented product requirements and specifications; ensuring test instruments are maintained and calibrated; and that test results are maintained, available and readable.



Important linkages regarding this CAPA element include 820.30 Design Control and 820.70(b) Production and Process Control.

✓ 9. Verify that corrective and preventive actions for product and quality problems were implemented and documented.

Using the sampling tables, select and review records of the most recent corrective or preventive actions (this sample may consist of or include records from the previously selected sample of significant corrective actions). To determine if corrective and preventive actions for product and quality problems and changes have been documented and implemented it may be necessary to view actual processes, equipment, facilities or documentation.

✓ 10. Determine if information regarding nonconforming product and quality problems and corrective and preventive actions has been properly disseminated, including dissemination for management review.

Determine that the relevant information regarding quality problems, as well as corrective and preventive actions, has been submitted for management review. This can be accomplished by determining which records in a recent CAPA event were submitted for management review. Review the raw data submitted for management review and not the actual results of a management review.

Review the CAPA (and other procedures if necessary) and confirm that there is a mechanism to disseminate relevant CAPA information to those individuals directly responsible for assuring product quality and the prevention of quality problems.

Review information related to product and quality problems that have been disseminated to those individuals directly responsible for assuring product quality and the prevention of quality problems. Using the sample of records from Objective 9 above, confirm that information related to product and quality problems is disseminated to individuals directly responsible for assuring product quality and the prevention of quality problems.

Business Intelligence Solutions offers very practical steps on how to implement some of the sweeping regulatory changes in the mindsets of executives working in FDA regulated industries, in bite-sized steps.



Our client approach allows you to immediately access the technology resources and talent you need to run your project, without having to create a stand-alone unit. Our capabilities add leverage to your technology investments and reduce cost to create sustainability in a climate of reduced resources.



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Business Intelligence Solutions provides innovative quality system and regulatory compliance solutions that improve performance, eliminate inefficiencies, and increase compliance.

Customized, Practical Solutions

Quality and compliance do not come sold in a box. Companies need real world guidance, not textbook answers. Advice must be practical for the specific situation. MBC & Associates provides real world answers that come from our breadth and depth of experience.

Our extensive list of Quality System and Regulatory Compliance services provides just the start for designing a custom solution for your business needs.

Our Services

- [Quality Assessments & Auditing](#)
- [Quality System Design & Implementation](#)
- [Software Configuration, Validation & Implementation](#)
- [Project Management](#)
- [Regulatory Affairs and Training](#)

Quality Assessments & Auditing

We provide complete assessment and audit reports including detailed recommendations for system improvement, ways to reduce regulatory risk, and increase business efficiency based on industry best practices.

Some of the services we offer are:

- Quality System & compliance assessments
- Development and management of Internal Quality Audit programs
- Development and management of Supplier Quality Audit programs
- FDA QSIT, ISO 13485, ISO 14971, and ISO 9001 assessments & audit preparation
- MDD, IVDD, CMDR, and FDA Part 11 assessments & audit preparation
- Mock FDA Inspections



Quality System Design & Implementation

We offer comprehensive quality system and regulatory compliance leadership for the creation or re-design of quality systems. We work closely with your team to develop and author individualized quality system policies and procedures to enhance your compliance efforts and support your specific business needs.

Some of the services we offer are:

- Quality System design & deployment
- Quality System gap analysis & re-engineering
- Document and Change Control business systems
- Data & Records Management business systems
- Design Control strategies & process development
- Development and implementation of CAPA programs
- Development and implementation of Complaint Handling systems
- Nonconforming Material programs & management
- Process Validation programs & assistance
- FDA Facility Registration assistance
- Recall & Field Correction assistance

Project Management

Effective project management is critical to the success of any quality system implementation or re-engineering effort. We offer comprehensive project management services for the complete life-cycle of the implementation or re-engineering effort, including PM support for any software application configuration, validation, and implementation efforts. We work closely with your implementation team to ensure the project is completed with the highest quality, on time, and within budget.

Project management professional services include:

- The Project Manager assigned to the project will work closely with the client's implementation team to define and document major tasks, milestones, deliverables, timelines, and resources needed to successfully complete the project.
- S/he will act as liaison between implementation personnel, management, and vendors by conducting meetings to review project details and obtain necessary reviews and approvals.

- S/he will monitor all phases of the project, review status reports, and modify schedules or plans as required. The Project Manager will also prepare regular project reports for the client and other defined stakeholders.
- The Project Manager will confer with project personnel to provide technical advice to resolve issues.

Regulatory Affairs Consulting

Business Intelligence Solutions provides comprehensive assistance to FDA regulated companies attempting to get their medical device or pharmaceutical product through the regulatory process.

No matter what phase you're in, we can provide direction and hands-on support to help you:

- **Develop a regulatory road map.** A clear path through the regulatory hurdles that will face your business including documentation and testing requirements and risk and obstacle assessments. Our experience with low and high risk devices has given us the ability to anticipate exactly what the FDA will be looking for.
- **Identify Design Control deliverables.** We will assist with ensuring that all Design Control deliverables required by the FDA are completed before you file with the FDA.
- **Write and deliver your submission to the FDA.**
- **Secure FDA approval for the first time.** We will defend your submission during the review process with the FDA and assist with securing approval for your device or IVD.
- **Audit and manage critical contract suppliers.**
- **Establish your first Quality System.** We create procedures; provide training, support and stabilization.

Regulatory Affairs Services

We provide full-service regulatory affairs assistance to support your product development pipeline and emerging technologies including:

- Strategic planning
- Clinical study protocols & IRB approvals
- Bio-Informatics and statistical analysis
- 510(k) and PMA submissions
- Project Management
- Regulatory Assessments
- Regulatory strategies & submissions
- Design Control Process assistance

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Regulatory Training

We will assist you in developing an efficient and compliant training system that works for your business. Additionally, we can create customized training courses designed specifically for audiences ranging from the executive board room to manufacturing operators/technicians to field service personnel.

Some of the customized training services include:

- Instructional design
- Content development
- Expert delivery in a variety of class formats
- Testing and/or evaluation of effectiveness
- Certificates of completion or training records, as appropriate

