Data Analysis Policy

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[Company Name], Inc.

Revision History

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Table of Contents

1. Purpose

2. Scope

3. Normative References

4. Definitions

5. Data Collection and Analysis

  5.1 Data to be Collected

  5.2 Data Analysis

6. Review of Analysis Results

7. Reporting of Analysis Results

8. Record Retention

9. References

10. Supplementary Provisions

1. Purpose

The purpose of this policy is to establish requirements for the collection and analysis of data from appropriate sources to demonstrate the suitability, adequacy, and effectiveness of the quality management system (QMS), and to identify opportunities for improvement. This policy ensures that [Company Name], Inc. (hereinafter referred to as "the Company") systematically collects, analyzes, and utilizes quality data to support timely and appropriate decision-making for QMS changes and improvements for all medical device products handled by the Company.

2. Scope

This policy applies to all data collection and analysis activities related to medical device products handled by the Company, including but not limited to:

- a) Customer feedback and complaint data
- b) Product conformity to requirements
- c) Process and product characteristics and trends
- d) Supplier performance data
- e) Internal and external audit results
- f) Service records (where applicable)
- g) Other data relevant to QMS performance and effectiveness

3. Normative References

This policy is based on the following normative references:

- a) 21 CFR Part 820 (Quality Management System Regulation - QMSR), specifically:

  - §820.100 Corrective and preventive actions

  - §820.250 Statistical techniques

- b) ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes, specifically:

  - Clause 8.4 Analysis of data

  - Clause 8.5 Improvement

4. Definitions

Term	Definition
Quality Management System (QMS)	Management system to direct and control an organization with regard to quality. (ISO 9000:2015, 3.5.4)
Process Parameters	Characteristics to be monitored and measured in a process, including production conditions, operating conditions of equipment and machinery, and test conditions of test equipment.
Deviation	Departure from established procedures or specifications.

SCAR	Supplier Corrective Action Request - A formal request issued to a supplier to implement corrective actions.
Receiving Inspection	Inspection performed to determine whether purchased items conform to specified requirements.
In-Process Inspection	Inspection performed during manufacturing to determine whether work-in-process meets specified requirements. Control of in-process products until required inspections, tests, or other verification activities are completed, or necessary approvals are received and documented.
Final Inspection	Inspection performed on finished products to determine whether they meet product requirements.
Statistical Techniques	Mathematical procedures used in the collection, analysis, presentation, and interpretation of numerical data. (21 CFR 820.250)
CAPA	Corrective and Preventive Action - Actions to eliminate the cause of detected or potential nonconformities.
FTTF	First Time to Failure - The time from initial use until the first failure occurs.

5. Data Collection and Analysis

5.1 Data to be Collected

The following table identifies data sources, analysis items, and applicable analysis methods. The Company shall collect and analyze data from these sources to evaluate QMS performance and identify improvement opportunities.

Category	Data Source	Analysis Items	Analysis Methods
Customer Feedback	Complaint Data	Complaint count and content	Trend graphs Pareto charts Stratification (by product, phenomenon)
Product Conformity to Requirements	Complaint Data	Complaint count and content	Trend graphs Pareto charts Stratification (by product, phenomenon)
Product Conformity to Requirements	Post-Market Safety Data	Safety information count and content Safety corrective measures count and content	Safety information trend graphs Pareto charts Stratification (by product, phenomenon, safety measures)
Product Conformity to Requirements	Regulatory Authority/External Certification Bodies	Regulatory authority observations	Stratification (by observation document)
Process and Product Characteristics and Trends	Quality Objectives	Achievement of quality objectives	Measurement of achievement against targets
Process and Product Characteristics and Trends	Corrective and Preventive Actions	Effectiveness of CAPA CAPA count Days to close CAPA Percentage of closed	Pareto charts (by product, nonconformity event) Trend graphs