

[Organization logo]

[Organization name]

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PROCEDURE FOR DATA ANALYSIS

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| Code: | |
| Version: | 0.1 |
| Created by: | |
| Approved by: | |
| Date of version: | |
| Signature: | |

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Change history

| Date | Version | Created by | Description of change |
|------|---------|------------|------------------------|
| | 0.1 | Advisera | Basic document outline |
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Table of contents

| | |
|--|---|
| 1. PURPOSE, SCOPE AND USERS | 3 |
| 2. REFERENCE DOCUMENTS | 3 |
| 3. DATA ANALYSIS | 3 |
| 3.1. COLLECTING DATA..... | 3 |
| 3.2. REVIEW AND DATA ANALYSIS..... | 3 |
| 3.3. DECISION AND ACTIONS | 3 |
| 4. MANAGING RECORDS KEPT ON THE BASIS OF THIS DOCUMENT | 4 |
| 5. APPENDICES | 4 |

[organization name]

1. Purpose, scope and users

The purpose of this Procedure is to describe the method for collecting and analyzing data generated by monitoring and measurement processes to demonstrate the suitability, adequacy and effectiveness of the Quality Management System (QMS).

This Procedure applies to the collecting and analyzing of data generated by monitoring and measurement of QMS processes of [organization name].

Users of this document are [job title(s)] in [organization name].

Commented [AES4]: Include the name of your organization.

Commented [AES5]: E.g., department managers

Commented [AES6]: Include the name of your organization.

2. Reference documents

- ISO 13485:2016 standard, clause 8.4
- MDR 2017/745, articles 10(9), 88 and Annex IX – Chapter I
- Quality Manual

Commented [AES7]: Delete this if your organization does not need to be compliant with MDR.

You can find the full text of the MDR on the following link:
<https://advisera.com/13485academy/mdr/>

Commented [AES8]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "03_Quality_Manual".

Commented [AES9]: E.g., Management Representative

3. Data analysis

[Job title] must gather data of monitoring and measuring conducted in QMS processes and interpret

3.1. Collecting data

All data generated from monitoring and measurements of the quality management system processes, including, internal and external audits, customer satisfaction data, customer complaints

Commented [AES10]: E.g., Management Representative

3.2. Review and data analysis

[Job titles] are responsible for preliminary observation of acquired data is done through trend analysis to determine that the data represents the measured quality parameter.

Commented [AES11]: E.g., Management Representative,

Commented [AES12]: E.g., CEO, Management Representative

Commented [AES13]: E.g., histograms, Control chart, Process

The data analyses generate information related to customer satisfaction, product conformity to requirements, product and process trends and supplier information.

Commented [AES14]: Adapt to the organization's practice.

3.3. Decision and actions

[organization name]

The information obtained from data analysis is verified for accuracy and reliability before any recommendation for improvement action is given.

Documented on the appropriate improvement action, following the [redacted] [redacted] [redacted] information that supports management consideration and is provided to [redacted] to ensure being managed under an [redacted] Management System.

Commented [AES15]: E.g., QA, Production, Sales, [redacted]

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Commented [AES17]: Adapt to the organization's practice. [redacted]

Commented [AES18]: You can find a template for this [redacted]

4. Managing records kept on the basis of this document

| Record name | Code | Storage | | Responsibility |
|----------------------|--------|-------------------|---------------------------------------|----------------|
| | | Retention Time | Location | |
| Data Analysis Report | PR26.1 | 1 year | Office Management System/Server | [redacted] |

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5. Appendices

- Appendix 1 – Data Analysis Report

[job title]

[name]

[signature]

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