

Document Control Information

Product Name:

Dosage Form / Strength(s):

Market(s):

Manufacturer / Site:

Review Period:

APQR Number / ID:

Previous APQR Reference:

Date of Issue:

Table of contents

Objective

Describe the objective of this Annual Product Quality Review (APQR)

Abbreviations

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Introduction

Product Details

Product name(s) and code(s)

Dosage form and strength(s)

Packaging configuration(s)

Markets where the product is commercialized

Regulatory status per market (approved, pending, etc.)

Process Flow Overview

Review of Manufacturing-Related Information

Batch Overview

Step-by-Step and Global Yield Review

Rejections, Reworks, and Scrap

Review of Critical Quality Parameters

In-Process and Intermediate Testing Results

Finished Product Testing Results

Out-of-Specification (OOS) / Out-of-Trend (OOT) Results

List of OOS/OOT events

Root cause summaries

Effectiveness of corrective actions

Quality Tools Review

Deviations and Events

CAPAs

Change Controls

Table of contents

Market Feedback

Complaints
Returns and Recalls

Stability Data Review

Stability studies included
Trend analysis

Validation and Qualification Status

Process validation status
Equipment qualification
Cleaning validation
Analytical method validation

Supplier and Material Quality Review

API quality and traceability
Key raw materials and packaging components
Supplier performance and issues
Technical and quality agreements status

Review Against Previous APQR

Comparison with prior APQR findings
Status of previous recommendations and actions

Conclusions

Product quality
Process performance
Compliance status
Emerging risks
Recommendations and Action Plan

Annexes

Approval

Introduction

Brief overview of the product and its manufacturing context.

Include a short description of:

- Product use and lifecycle stage
- Manufacturing site(s)
- Scope of this APQR (all strengths, formats, and markets covered)

Review of manufacturing-related information

1. Batch Overview

- Total batches manufactured (approved and rejected)
- Batch disposition summary

Include tables covering:

- Batch numbers
- Manufacturing dates
- Batch status

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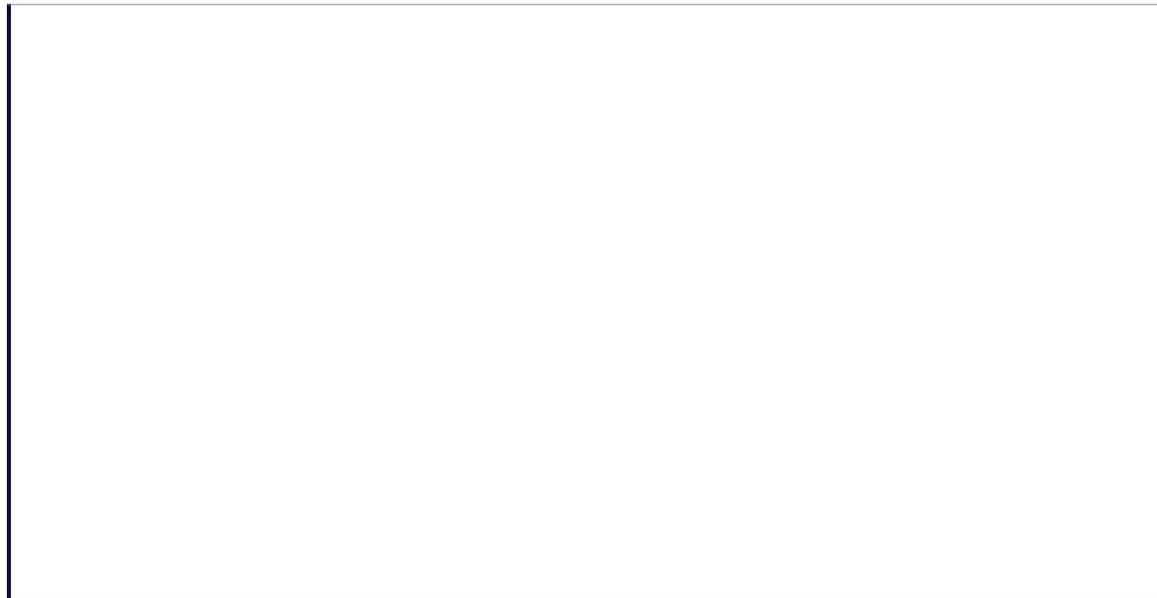
2. Step-by-step and Global Yield Review

- Yield trends and variability
- Significant yield deviations

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Out-of-Specification (OOS) / Out-of-Trend (OOT) Results

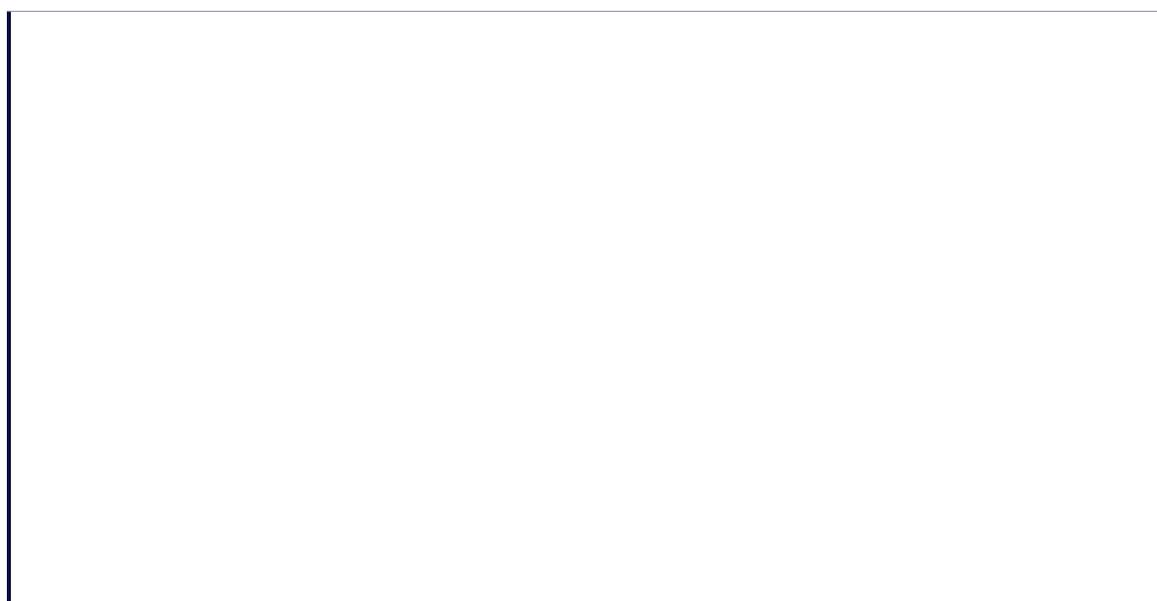
- List of OOS/OOT events
- Root cause summaries
- Effectiveness of corrective actions



Quality Tools Review

1. Deviations and Events

- Number and classification of deviations
- Key trends and recurring issues



2. CAPAs

- CAPAs initiated and closed during the period
- Effectiveness review

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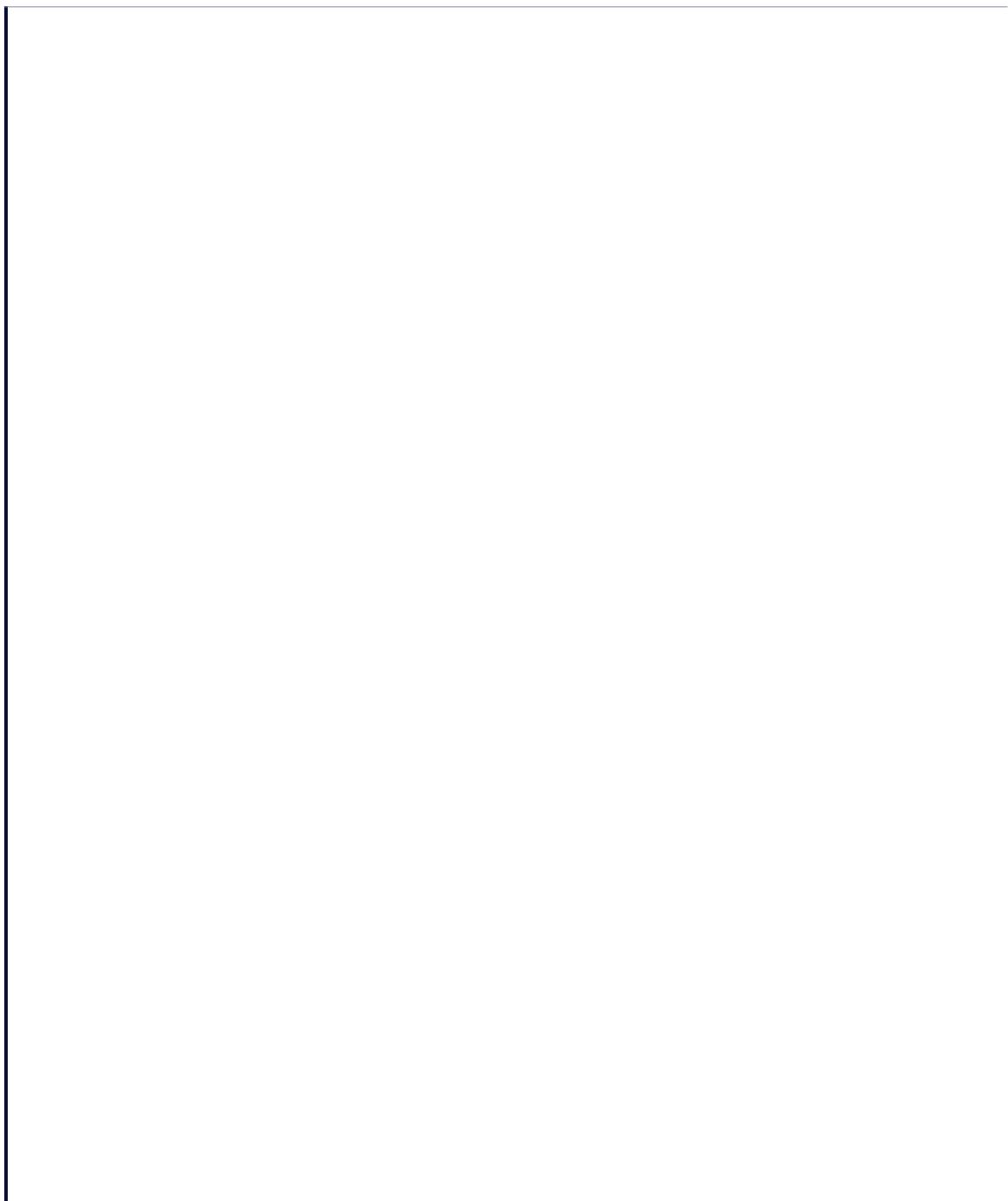
3. Change Controls

- Summary of process, method, or material changes
- Impact assessment on product quality

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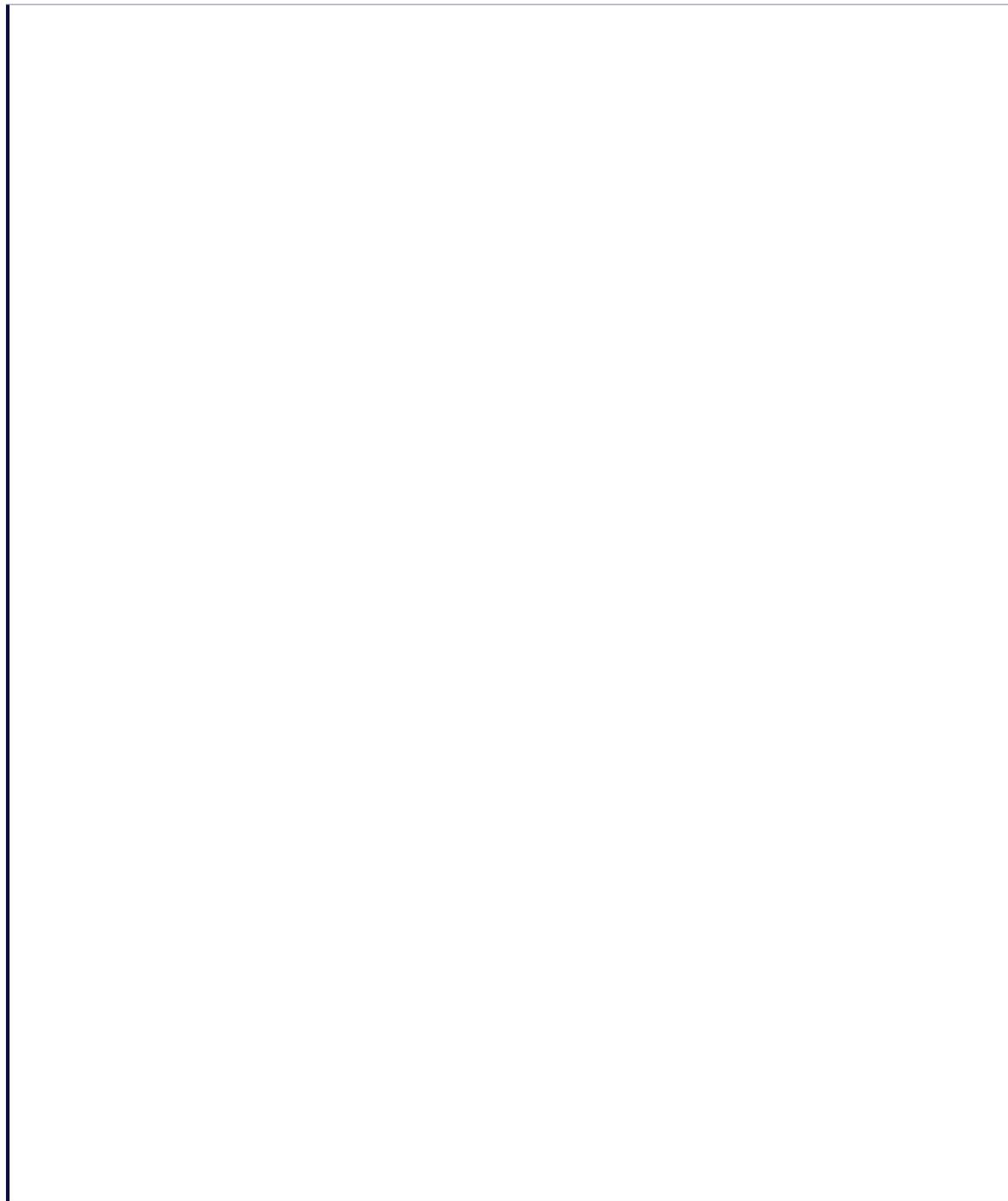
Stability Data Review

- Stability studies included
- Trend analysis



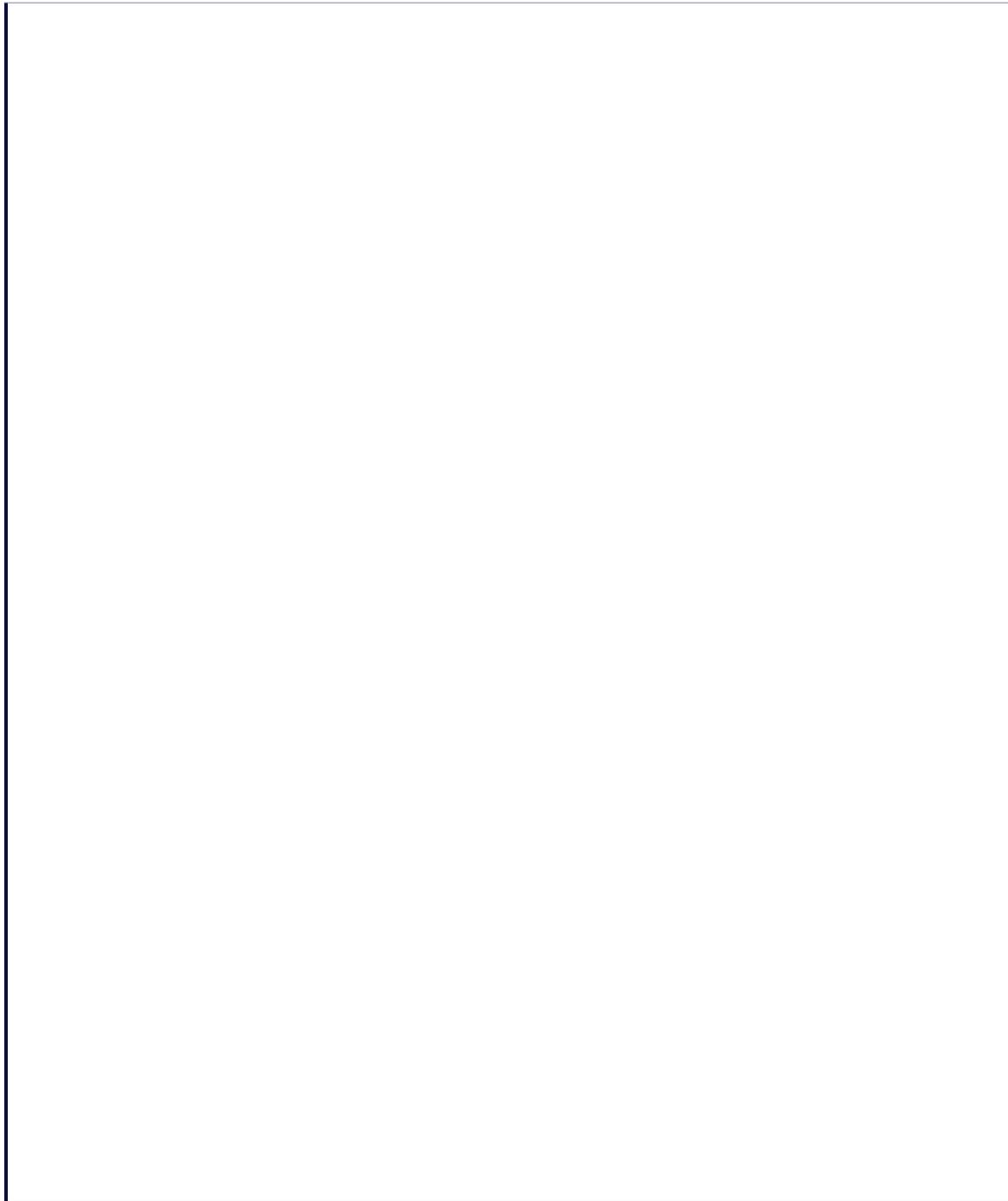
Validation and Qualification Status

- Process validation status
- Equipment qualification
- Cleaning validation
- Analytical method validation



Supplier and Material Quality Review

- API quality and traceability
- Key raw materials and packaging components
- Supplier performance and issues
- Technical and quality agreements status

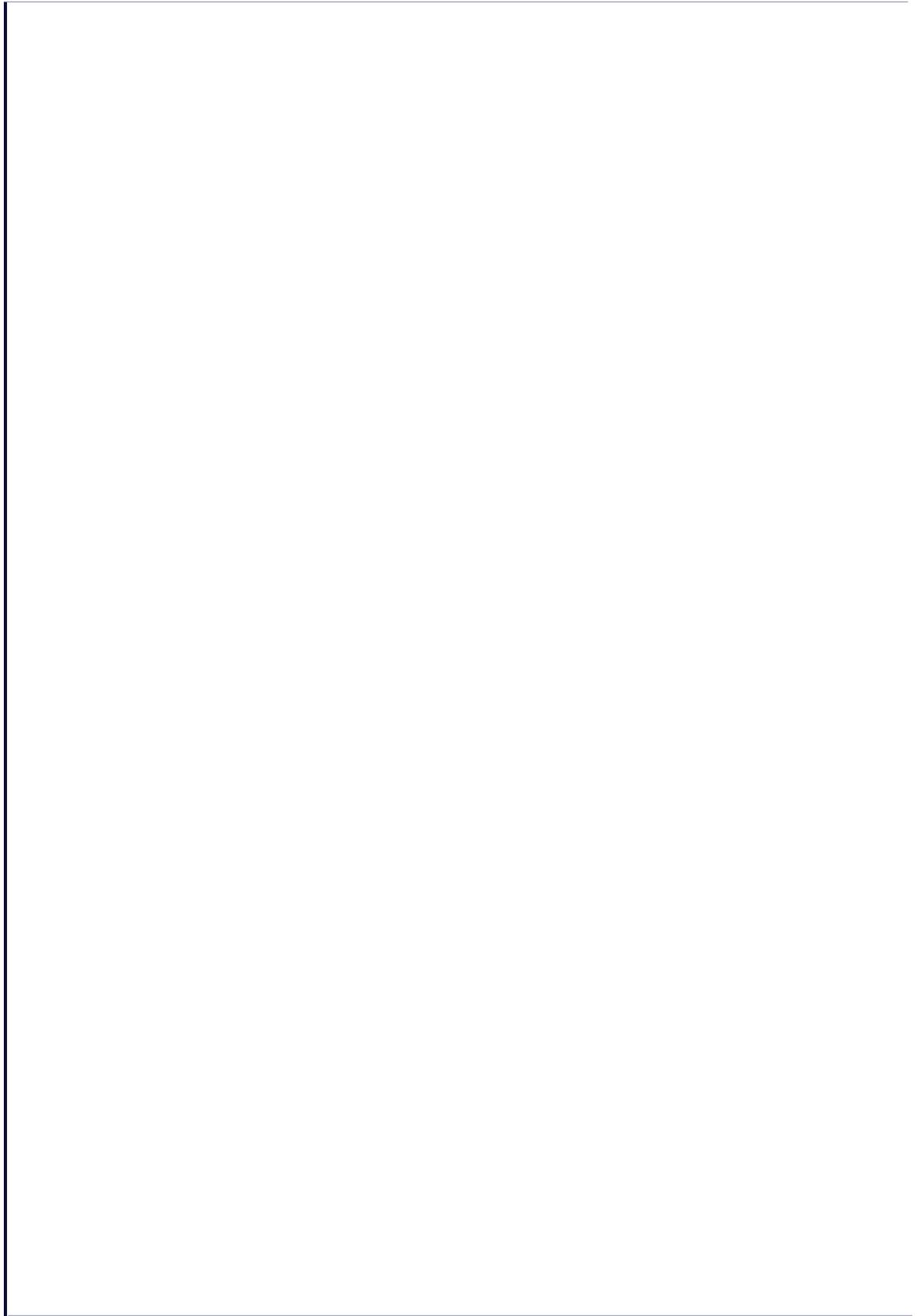


Review Against Previous APQR

- Comparison with prior APQR findings
- Status of previous recommendations and actions

Annexes

Supporting tables, charts, graphs, and raw data.



Annexes

Supporting tables, charts, graphs, and raw data.

Approval

	Name	Role	Signature	Date
Prepared by				
Reviewed by				
Approved by				

Scilife