Production & Cleaning Governance Procedure

Document Approval

	Prepared By	Reviewed By	Authorised By
Name:			
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Date:			

Contents

Document Preparation & Adaptation Notes (To Be Removed Before Use)

- All instructional text (e.g. red text) should be removed or replaced before final issue.
- Example content should be reviewed and tailored to reflect actual processes and system design.
- This document should be adapted to align with the organisation's quality management system and documented practices.
- Document identifiers, revision details, and approval sections should be updated in accordance with the organisation's document control requirements.
- Any referenced procedures, records, or systems should be verified and aligned with current site documentation.
- Terminology should remain consistent across all related documents within the quality system.
- Formatting and presentation may be adjusted to align with internal standards where required.

1 Purpose & Scope

This procedure establishes a structured framework for governing **production and cleaning activities** within a quality management system.

The purpose of this procedure is to:

- Define governance expectations for production and cleaning processes
- Ensure activities are subject to appropriate review and control
- Support identification and management of risks and deviations
- Maintain traceability and oversight across manufacturing and cleaning operations

This procedure applies to:

- production processes and activities
- equipment and area cleaning
- line clearance and changeover
- associated records and documentation

The depth and formality of application shall be proportionate to:

- product risk
- process complexity
- contamination potential
- regulatory expectations

2 Regulatory & Guidance Context

This procedure is designed to align with commonly adopted frameworks, including:

- ISO 9001 / ISO 13485
- EU GMP (as applicable)
- FDA 21 CFR (as applicable)
- ICH Q10 Quality Systems
- Applicable data integrity expectations (ALCOA+)

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9 Appendix A- Production & Cleaning Risk Considerations

Purpose

This appendix provides illustrative guidance for identifying and evaluating risks associated with production and cleaning activities, including contamination, process variability, and control effectiveness.

Example Risk Factors

Risk assessment may consider:

- Potential for cross-contamination between products or materials
- Effectiveness of cleaning processes and verification methods
- Complexity of production processes and manual interventions
- Equipment design, condition, and cleanability
- Frequency of product changeover or shared equipment use
- Sensitivity of product to contamination or variability
- Adequacy of documentation, record completion, and review
- Human factors impacting execution of production or cleaning activities

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Example Risk Categorization (Illustrative)

Risk Level	Example Characteristics
High	High contamination risk, complex cleaning, shared equipment, critical product
Medium	Moderate process variability, routine cleaning with defined controls
Low	Simple processes, low contamination potential, dedicated equipment

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Example Control Approach (Illustrative)