

# PREVALIDATION SUMMARY REPORT

For Medical Devices Used in Pharmaceuticals Manufacturing

## 1. Device Overview

**Purpose and Intended Use:** The medical device is intended to automate the filling, sealing, and packaging of pharmaceutical containers while maintaining stringent sterility standards. Its application ensures consistent product quality and compliance in high-volume production environments.

### Function:

- The device supports the sterile handling and processing of liquid and solid pharmaceuticals.
- It integrates automated quality checks to detect anomalies during production.
- Its use reduces manual handling, mitigating risks of contamination and human error.

### Design and Components:

- **Conveyor System:** A stainless steel conveyor for smooth transport of containers.
- **Filling Mechanism:** A precision nozzle system with sterility sensors for accurate dosage delivery.
- **Sealing Unit:** Automated sealers designed to maintain airtight closures while identifying defects using high-speed cameras.
- **Temperature Control:** Integrated climate system to preserve environmental conditions essential for sterility.

### Risk Assessment:

- **Potential Risks Identified:**
  - Misalignment of nozzles leading to dosage inconsistencies.
  - Mechanical wear causing device failure over extended use.
  - Power fluctuations impacting temperature control and sterility.
- **Mitigation Measures:**
  - Routine calibration of nozzles and quality inspection cameras.
  - Implementation of scheduled preventive maintenance checks.

- Installation of a secondary power backup system to ensure uninterrupted operation.

## 2. Validation Approach

**Scope of Validation:** The validation encompasses Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ). It addresses all critical parameters, including sterility, precision, and operational efficiency.

### Validation Strategy:

- Risk-based validation combining design analysis and performance testing.
- Execution of simulated production conditions to test operational reliability.
- Integration of environmental control assessments within qualification protocols.

### Planned Validation Activities:

- Development of detailed testing protocols for sterility and quality assurance.
- Installation verification, ensuring the device meets manufacturing requirements.
- Operational validation through repeated production scenarios, testing precision and consistency.
- Performance validation using long-term reliability tests under maximum load conditions.

### Acceptance Criteria:

- Precision of dosage delivery within  $\pm 1\%$ .
- Environmental conditions maintained within GMP-required thresholds.
- No detected contaminants during sterility tests.
- Operational reliability demonstrated over 100 continuous production cycles.

## 3. Regulatory and Compliance

**GMP Compliance:** The validation activities adhere to GMP guidelines specified in EU Annex 15, addressing risk management, documentation standards, and control measures.

**Regulatory Compliance:** Validation efforts align with MHRA regulations and EU MDR standards for medical devices, ensuring full conformity to applicable laws and industry requirements.

## 4. Documentation

**Validation Master Plan:** A comprehensive document detailing:

- Objectives and methodology for validation.
- Resource allocation and projected timelines.
- Risk analysis and mitigation strategies.

**Validation Protocols:** Each validation activity is supported by detailed protocols outlining:

- Test methods, expected outcomes, and procedures.
- Acceptance criteria to evaluate results.
- Corrective actions for non-compliance or irregularities.

**Documentation Standards:**

- All validation records are structured according to MHRA guidelines.
- Records include electronic logs, operator notes, and analytical test results.
- Final documentation is archived for inspection readiness.