AUTOMATED SYSTEM VALIDATION PROTOCOL

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Polar Dynamics Robotics, Inc.

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1. PURPOSE AND SCOPE

1. This Automated System Validation Protocol ("Protocol") establishes

2. This Protocol applies to all automated systems operating in temper

2. DEFINITIONS

1. "Validation" means the documented process of establishing and co

2. "System" refers to any combination of hardware, software, and mec

3. "Test Environment" means a controlled facility meeting the specifica

4. "Validation Master Plan" or "VMP" refers to the high-level documen

3. REGULATORY COMPLIANCE

1. This Protocol adheres to:

a) ISO/IEC 25051:2014 Software Engineering requirements

b) ANSI/RIA R15.06-2012 Industrial Robot Safety standards

c) IEC 61508-3:2010 Functional Safety requirements

d) 21 CFR Part 11 (where applicable for pharmaceutical applications)

4. VALIDATION METHODOLOGY

1. Test Environment Requirements

a) Temperature-controlled testing chamber capable of -40 C to +25 C

b) Humidity control (20% to 80% RH)

c) Calibrated measurement instruments

d) Simulated operating environment matching customer specifications

2. Validation Phases

2.1. Installation Qualification (IQ)

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- Hardware component verification
- Software installation verification
- Network connectivity confirmation
- Environmental monitoring system validation

2.2. Operational Qualification (OQ)

- Navigation system accuracy testing
- Power system performance validation
- Emergency stop functionality

Sensor calibration verification

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Communication protocol testing

2.3. Performance Qualification (PQ)

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Extended runtime testing (minimum 168 hours)

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Load capacity verification

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Environmental stress testing

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System recovery procedures

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User interface validation

5. TEST PROCEDURES

1. Each validation phase requires:

a) Detailed test scripts

b) Acceptance criteria

c) Data collection methods

d) Deviation reporting procedures

e) Documentation requirements

2. Critical Parameters

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Navigation accuracy: 5mm at -30 C

Battery performance: minimum 8 hours continuous operation

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System response time: <100ms

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Error recovery: <30 seconds

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Safety system activation: <50ms

6. DOCUMENTATION REQUIREMENTS

1. Required Documentation:

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Validation Master Plan

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Test scripts and protocols

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Raw data records

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Deviation reports

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Change control records

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Final validation report

2. Record Retention

All validation documentation shall be maintained for a minimum of sev

years from the date of system retirement.

7. ROLES AND RESPONSIBILITIES

1. Validation Team

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Validation Lead

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Quality Assurance Representative

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Technical Subject Matter Expert

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Safety Systems Engineer

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Documentation Specialist

2. Review and Approval Requirements

All validation documentation requires review and approval by:

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Quality Assurance Manager

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Chief Technology Officer

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Chief Robotics Officer

8. DEVIATIONS AND CHANGES

1. Any deviation from this Protocol must be documented and approve

2. Critical deviations requiring immediate attention shall be escalated

9. ACCEPTANCE CRITERIA

1. System validation is considered complete when:

a) All test cases achieve passing results

b) Deviations are documented and resolved

c) Final documentation is complete and approved

d) Quality Assurance issues formal approval

10. LEGAL DISCLAIMER

This Protocol is confidential and proprietary to Polar Dynamics Roboti

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the right to modify this Protocol at any time to maintain compliance wi

applicable regulations and industry standards.

APPROVAL

APPROVED BY:

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