EQUIPMENT QUALIFICATION DOCUMENT

Pharma Division Cold Storage Robotics Systems

Polar Dynamics Robotics, Inc.

Document No. EQD-2024-PH-001

Effective Date: January 15, 2024

1. PURPOSE AND SCOPE

1. This Equipment Qualification Document ("EQD") establishes the qualification requirements and validation protocols for Polar Dynamics Robotics, Inc.'s ("Company") autonomous mobile robot systems deployed in pharmaceutical cold storage environments.

2. This EQD applies to the IceNav(TM) Series 3000 Autonomous Mobile Robot platform and associated control systems operating in GMP-regulated pharmaceutical storage facilities at temperatures ranging from -30 C to +25 C.

2. DEFINITIONS

1. "Equipment" refers to the IceNav(TM) Series 3000 autonomous mobile robot system, including all integrated hardware components, control systems, and thermal management modules.

2. "Qualification" means the documented verification that the Equipment consistently operates within established parameters under specified environmental conditions.

3. "GMP" refers to Good Manufacturing Practice as defined by FDA 21 CFR Part 211 and applicable EU GMP guidelines.

3. EQUIPMENT SPECIFICATIONS

1. Physical Specifications

- Dimensions: 1200mm x 800mm x 450mm
- Operating Weight: 185kg
- Payload Capacity: 500kg
- Power Source: Lithium Iron Phosphate Battery System (24V)

2. Environmental Operating Parameters

- Temperature Range: -30 C to +25 C
- Humidity: 10% to 95% non-condensing
- Floor Surface: Sealed concrete, epoxy coating
- Air Quality: Class 100,000 (ISO 8) or better

4. QUALIFICATION REQUIREMENTS

1. Installation Qualification (IQ)
- Verification of proper mechanical installation
- Confirmation of electrical systems compliance
- Documentation of control system configuration
- Verification of safety systems installation
- Network connectivity validation

2. Operational Qualification (OQ)
- Navigation system accuracy testing
- Temperature management system verification
- Battery performance validation
- Emergency stop system testing
- Obstacle detection system validation

3. Performance Qualification (PQ)
- Extended operation testing (minimum 168 hours)
- Load capacity verification
- Environmental stress testing
- Navigation accuracy under load
- System recovery testing

5. VALIDATION PROTOCOLS

1. Temperature Management
- Continuous monitoring of internal component temperatures
- Verification of thermal protection systems
- Documentation of temperature mapping

- Thermal cycling stress tests

2. Navigation System

- Path accuracy validation (5mm)
- Obstacle avoidance verification
- Emergency routing validation
- Multi-unit coordination testing

3. Data Integrity

- Verification of audit trail functionality
- Data backup system validation
- Access control testing
- Electronic records compliance (21 CFR Part 11)

6. MAINTENANCE AND CALIBRATION

1. Preventive Maintenance Schedule

- Daily operational checks
- Weekly system diagnostics
- Monthly mechanical inspection
- Quarterly software updates
- Annual comprehensive review

2. Calibration Requirements

- Navigation sensors: Every 3 months
- Temperature sensors: Every 6 months
- Load cells: Every 6 months
- Safety systems: Monthly

7. DOCUMENTATION REQUIREMENTS

1. Required Records

- Installation qualification reports
- Operational qualification data

- Performance qualification results
- Calibration certificates
- Maintenance logs
- Training records
- Change control documentation

2. Record Retention

- All qualification documents shall be maintained for a minimum of 5 years
- Electronic records shall be backed up daily
- Access controls shall be maintained per SOP-SEC-001

8. COMPLIANCE STATEMENT

This Equipment Qualification Document complies with:

- FDA 21 CFR Part 211
- EU GMP Annex 11
- ISO 13485:2016
- Company SOP-EQ-001 through SOP-EQ-005

9. APPROVAL AND AUTHORIZATION

APPROVED BY:

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Date:

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Date:

10. REVISION HISTORY

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Prepared by: Technical Documentation Team

Reviewed by: Quality Assurance Department

Approved by: Executive Leadership Team