GMP COMPLIANCE DOCUMENTATION - ROBOTIC SYSTEMS

Polar Dynamics Robotics, Inc.

Document Reference: GMP-2024-001

Effective Date: January 15, 2024

Version: 3.0

1. PURPOSE AND SCOPE

1. This Good Manufacturing Practice (GMP) Compliance Documentation establishes the quality management system and manufacturing controls for autonomous mobile robots (AMRs) produced by Polar Dynamics Robotics, Inc. ("Company"), specifically addressing the IceNav(TM) platform and associated cold-environment robotic systems.

2. This documentation applies to all manufacturing operations at Company facilities located at:

- Primary Manufacturing Facility: 2850 Arctic Way, Dover, Delaware 19901
- R&D Center: 375 Frost Innovation Park, Cambridge, Massachusetts 02142

2. REGULATORY COMPLIANCE FRAMEWORK

1. The Company's manufacturing processes adhere to:

- ISO 9001:2015 Quality Management Systems
- ISO/TS 15066:2016 Robotics Safety Standards
- FDA 21 CFR Part 11 (for pharmaceutical facility deployments)
- ANSI/RIA R15.06-2012 Industrial Robot Safety Standards

2. Validation protocols are maintained in accordance with GAMP 5 guidelines for automated systems in regulated environments.

3. MANUFACTURING PROCESS CONTROLS

1. Environmental Controls

- Temperature monitoring systems: -40 C to +50 C range
- Humidity control: 15-85% RH
- Clean room specifications: ISO Class 7 (Class 10,000)
- ESD protection protocols per ANSI/ESD S20.20-2014

2. Component Qualification

- Thermal stress testing for cold-resistant actuators
- Accelerated life testing at -30 C
- IP65 rating verification for sealed components
- Battery performance validation at extreme temperatures

3. Assembly Process Controls

- Automated torque verification systems
- Digital work instructions with real-time verification
- Component traceability through RFID tracking
- Calibrated testing equipment with NIST traceability

4. QUALITY CONTROL PROCEDURES

1. Incoming Material Inspection

- Component verification against approved vendor list
- Material certification documentation
- Non-conforming material quarantine procedures
- Supplier audit program requirements

2. In-Process Quality Controls

- Critical control point monitoring
- Statistical process control (SPC) implementation
- Digital signature requirements for quality gates
- Automated visual inspection systems

3. Final Product Testing

- Full-system functional testing at -30 C
- Navigation accuracy verification
- Safety system validation
- Battery cycle testing
- EMC compliance verification

5. DOCUMENTATION AND RECORD KEEPING

1. Required Documentation

- Device History Records (DHR)
- Equipment qualification protocols
- Calibration records
- Training records
- Change control documentation
- Non-conformance reports

2. Electronic Records Management

- 21 CFR Part 11 compliant systems
- Backup and disaster recovery procedures
- Access control and audit trail requirements
- Document retention schedule (minimum 7 years)

6. TRAINING REQUIREMENTS

1. Manufacturing Personnel

- Initial GMP training
- Product-specific assembly training
- Safety system programming
- Quality system requirements
- Annual refresher training

2. Quality Personnel

- Advanced GMP certification
- Internal auditor qualification
- Statistical analysis training
- Risk management procedures

7. CHANGE CONTROL AND VALIDATION

1. Change Management

- Engineering change request procedures
- Impact assessment requirements

- Validation protocol development
- Implementation planning
- Post-implementation monitoring

2. Software Validation

- IceNav(TM) platform validation protocol
- Algorithm verification procedures
- Security testing requirements
- Version control procedures

8. CERTIFICATION AND AUTHORITY

This GMP Compliance Documentation has been reviewed and approved by:

/s/ Sarah Nordstrom

Sarah Nordstrom

Chief Operating Officer

Date: January 15, 2024

/s/ Dr. James Barrett

Dr. James Barrett

Chief Robotics Officer

Date: January 15, 2024

/s/ Katherine Wells

Katherine Wells

Chief Financial Officer

Date: January 15, 2024

9. REVISION HISTORY

Version | Date | Description | Approved By

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0 | 2024-01-15 | Updated for IceNav(TM) 2.0 platform | S. Nordstrom

1 | 2023-06-20 | Added pharmaceutical compliance | J. Barrett

0 | 2023-01-10 | Major revision - ISO updates | K. Wells

0 | 2022-03-15 | Initial release | E. Frost