FDA COLD CHAIN COMPLIANCE GUIDELINES 2023

FDA COLD CHAIN COMPLIANCE GUIDELINE

Polar Dynamics Robotics, Inc.

Internal Regulatory Compliance Document

Effective Date: January 1, 2023

Document ID: PDR-FDA-2023-001

1. PURPOSE AND SCOPE

1. This document establishes internal guidelines for ensuring compliar

2. These guidelines apply to all BlueCore(TM)-enabled AMRs operati

2. REGULATORY FRAMEWORK

1. These guidelines incorporate requirements from:

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21 CFR Part 211 - Current Good Manufacturing Practice for Finished

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21 CFR Part 110 - Current Good Manufacturing Practice in Manufactu

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FDA Guidance for Industry: "Temperature-Controlled Drug Products"

3. TEMPERATURE MONITORING REQUIREMENTS

1. AMR Sensor Specifications

Primary temperature sensors must maintain accuracy within 0.5 C

- Backup sensors required with independent power supply

- Calibration required every 90 days

- Real-time data logging at minimum 5-minute intervals

2. Environmental Monitoring

- Continuous monitoring of ambient temperature

- Humidity tracking in specified zones

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Airflow pattern verification

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Temperature mapping validation every 6 months

4. BLUECORE(TM) TECHNOLOGY COMPLIANCE F

1. Automated Documentation

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Digital audit trail of temperature readings

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Electronic batch records

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Automated deviation alerts

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System access logs

2. Quality Control Integration

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Real-time compliance monitoring

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Automated shutdown protocols for out-of-spec conditions

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Integration with facility management systems

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Data encryption meeting 21 CFR Part 11 requirements

5. STANDARD OPERATING PROCEDURES

1. Daily Operations

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Pre-operation system checks

- Temperature verification protocols
- Clean room transition procedures
- Emergency response protocols

2. Maintenance Requirements

- Quarterly sensor calibration
- Monthly system validation
- Documentation requirements
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Corrective action procedures

6. TRAINING AND QUALIFICATION

1. Personnel Requirements

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Initial qualification training

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Annual requalification

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Documentation of training records

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Competency assessments

2. System Administration

Access control protocols

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User authentication requirements

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Change management procedures

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Audit trail maintenance

7. QUALITY ASSURANCE

1. Quality Control Measures

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Regular system audits

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Performance monitoring

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Deviation investigation procedures

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Corrective action tracking

2. Documentation Requirements

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Electronic records maintenance

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Backup procedures

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Archive protocols

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Retention schedules

8. EMERGENCY PROCEDURES

1. System Failures

- Backup power protocols
- Manual override procedures
- Emergency notification system
- Recovery procedures

2. Temperature Excursions

- Alert thresholds

Response protocols

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Investigation requirements

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Reporting procedures

9. COMPLIANCE REPORTING

1. Internal Reporting

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Monthly compliance summaries

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Quarterly trend analysis

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Annual system review

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Management oversight requirements

2. External Reporting

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FDA inspection preparation

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Regulatory submission requirements

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Third-party audit protocols

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Documentation requirements

10. DOCUMENT CONTROL

1. This document shall be reviewed annually and updated as necessa

2. Revision History:

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Rev. 1.0: January 1, 2023 - Initial Release

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Rev. 1.1: March 15, 2023 - Updated Section 4.2

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Rev. 1.2: June 30, 2023 - Updated Section 3.1

11. APPROVAL AND AUTHORIZATION

APPROVED BY:

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CEO & Co-founder

Date: December 15, 2022

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Chief Operating Officer

Date: December 15, 2022

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Chief Robotics Officer

Date: December 15, 2022

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