PHARMACEUTICAL STORAGE COMPLIANCE AUDIT REPORT

PHARMACEUTICAL STORAGE COMPLIANC

Polar Dynamics Robotics, Inc.

Report Date: January 11, 2024

Reference: PDR-PSCAR-2024-001

1. EXECUTIVE SUMMARY

This Pharmaceutical Storage Compliance Audit Report evaluates Pola
Robotics, Inc.'s ("PDR") BlueCore(TM)-enabled autonomous mobile r
compliance with pharmaceutical storage regulations and industry stan

automated cold chain operations. The audit was conducted between M
2023, and December 31, 2023, by Independent Pharmaceutical Comp
Associates, LLC ("IPCA").

2. AUDIT SCOPE AND METHODOLOGY

2.1 Scope of Review

-

Temperature maintenance capabilities (-40 C to +25 C)

-

GMP compliance for automated handling systems

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21 CFR Part 11 compliance for electronic systems

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USP <1079> compliance for shipping and storage

GDP (Good Distribution Practice) adherence

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FDA regulatory requirements for pharmaceutical storage automation

2.2 Audit Methodology

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Physical inspection of BlueCore(TM) AMR units

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Review of system documentation and validation protocols

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Temperature mapping studies in controlled environments

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Performance testing under various load conditions

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Review of electronic monitoring systems

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Assessment of fail-safe mechanisms

-

Evaluation of data logging and reporting capabilities

3. FINDINGS AND OBSERVATIONS

3.1 Temperature Control Systems

-

BlueCore(TM) navigation system maintains operational stability at -40

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Temperature variance within 0.5 C during transport

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Successful completion of 168-hour continuous operation test

Compliant with USP <1079> requirements for temperature excursion

3.2 Electronic Systems Compliance

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Electronic monitoring systems meet 21 CFR Part 11 requirements

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Audit trail functionality properly implemented

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Electronic signatures compliant with regulatory requirements

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Data integrity controls adequately maintained

3.3 GMP Compliance

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Clean room compatible materials used in construction

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Sanitization protocols validated for pharmaceutical environments

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Proper documentation of cleaning procedures

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Material contact surfaces meet FDA requirements

4. RISK ASSESSMENT

4.1 Identified Risks

Battery performance degradation in extreme cold conditions

Potential for communication interruptions in metal-walled freezer envi

Condensation management during temperature transitions

4.2 Risk Mitigation Measures

Implementation of redundant power systems

Enhanced signal boosting technology

Proprietary condensation prevention system

Automated fail-safe protocols

5. COMPLIANCE STATUS

5.1 Regulatory Compliance

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FDA 21 CFR Part 211 (Current Good Manufacturing Practice): COMP

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EU GMP Annex 11 (Computerized Systems): COMPLIANT

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WHO GDP Guidelines: COMPLIANT

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ISO 13485:2016 Medical Devices: COMPLIANT

5.2 Industry Standards Compliance

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ISTA 7E Temperature Test: PASSED

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GAMP 5 Software Validation: VALIDATED

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IEC 60068-2-1 Cold Test: PASSED

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IEC 60068-2-14 Temperature Cycling: PASSED

6. RECOMMENDATIONS

6.1 Immediate Actions

Implement enhanced temperature monitoring redundancy

Update standard operating procedures for multi-zone operations

Strengthen battery performance documentation

6.2 Long-term Improvements

Develop automated cleaning validation protocols

Enhance data integration capabilities with warehouse management sy

Implement predictive maintenance algorithms

7. VALIDATION SUMMARY

7.1 Performance Qualification

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- 500 operational hours completed
- 1,000 temperature cycles tested
- 100% success rate in maintaining temperature stability
- Zero critical deviations recorded

7.2 Documentation Review

- Installation qualification protocols: COMPLETE
- Operational qualification protocols: COMPLETE
- Performance qualification protocols: COMPLETE

Standard operating procedures: APPROVED

8. CERTIFICATION

Based on the comprehensive audit findings, Polar Dynamics Robotics
BlueCore(TM)-enabled autonomous mobile robots are certified compl
pharmaceutical storage requirements and applicable regulations as o
2024.

9. DISCLAIMERS AND LIMITATIONS

This report represents findings as of the audit date and is subject to c
based on regulatory updates or system modifications. The audit was
using currently available information and testing protocols. Future reg
changes may impact compliance status.

10. AUTHENTICATION

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11. APPENDICES

A. Temperature Mapping Data

B. Validation Protocols

C. Test Results Documentation

D. Regulatory Compliance Certificates

E. Standard Operating Procedures

F. Risk Assessment Matrices

[END OF REPORT]