

**Protecting Product Integrity**



**COLD CHAIN • PACKAGING • DISTRIBUTION • CLINICAL TRIALS • CUSTOM SOLUTIONS**



# Sentry BioPharma Services, Inc.

- Celebrating 19 Years of Service
- Contract Service Provider
- Privately held company
- Extensive Industry Experience
- Exclusively serves life science industry
- Commitment to grow with the needs of our clients



## Presentation Summary

- History and Location
- Facility - Management and Storage
- Security, Quality and Regulatory
- Additional Capabilities - FTZ,  
Labeling, Kitting and Packaging
- Expanding Services



# History





## Location

- Central Location with Global Reach
- Close proximity to Indianapolis International Airport (IND)
- Adjacent to FedEx ground and air hubs (2<sup>nd</sup> Largest Worldwide)
- Extensive Interstate Access
  - I-65, I-69, I-70 and I-74
- 75-85% U.S. within 1 day truck drive







# Facility

- State-of-the-art Facility
- Built to Factory Mutual (FM) Specifications
- Validated Systems & Environments
- Rapid Expansion Capabilities
- Redundant Systems



# Storage Solutions

- 86,000 square feet
- GMP Storage

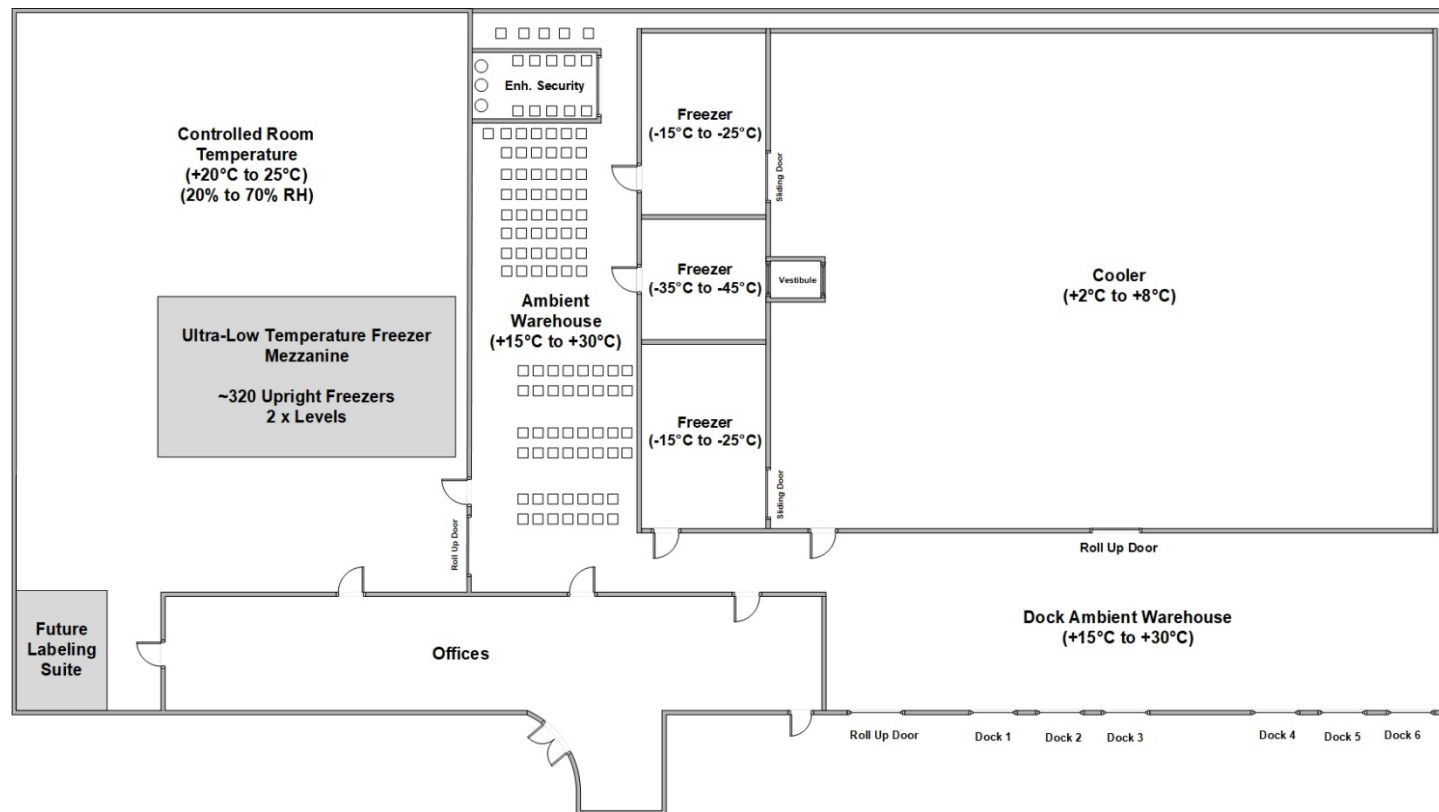
Ambient	+15°C to +30°C
Controlled Room Temp.	+20°C to +25°C
Refrigerated	+2°C to +8°C
Frozen	-15°C to -25°C
Low Temp. Frozen	-35°C to -45°C
Custom Ultra-low (50)	-40°C to -60°C
Custom Ultra-low (70)	-60°C to -80°C
Custom Ultra-low (75)	-65°C to -85°C
Ultra-low	-70°C to -90°C
VP LN2	<-135°C
Custom Solutions	0°C to -90°C

- DEA Controlled Substance (CSIII - V)
- Foreign Trade Zone (FTZ)





# Current Facility Layout



# Facility Management

- Robust PM Program
  - Walk-In Environments, Upright Freezers, Generator, General Facility
- Weekly, Monthly and Quarterly Walkthroughs
- Monthly and Quarterly Temperature Trending
- Backup Calibrated Temperature Monitoring
- Requalification Program





# Facility Risk Management and Mitigation

- 2 x 1000 kW Cummins Diesel Generators
  - Automatic Transfer Switches with Redundancy
  - Full Facility Backup Power
  - Automatic Failover to Primary Systems
  - Additional Generator Connection Cabinet



## Facility Risk Management and Mitigation - Cont'd

- Third Party Oversight
  - Factory Mutual
  - Client Audits - Quality Assurance, Security, HSE
  - Government Defense Audits - Quality Assurance and Security
  - QP Audits - Most Recent 7/2022
  - Clients - 15 of Top 20 Pharma





# Security and Transparency

- 24/7 Central Security Monitoring System
- Access Restriction
- Closed Circuit TV system
- Cyber Security / System Backup
- Building Management System
  - Local and remote building alerts
- Perimeter fence and gate
- Encrypted Client Inventory Access
- Automated Activity Notifications



# Quality and Regulatory

- eQMS - Dot Compliance
- 21 CFR, Part 210 & 211 Compliant
- FDA Labeler Code - 32405
- Robust Regulatory History
- Destruction Management Program
- Returns Management Program
- NABP® Accredited
- Licensed in all 50 states and U.S. Territories





# Regulatory Snapshot

Inspected regularly by:

- FDA - Food and Drug Administration
- USDA - United States Department of Agriculture
- PMDA - Pharmaceuticals and Medical Devices Agency (Japan)
- DEA - Drug Enforcement Administration
- FAA - Federal Aviation Administration
- NABP - National Association of Boards of Pharmacy
- CBP - U.S. Customs and Border Protection

## US Regulatory Inspection History (2016-24)

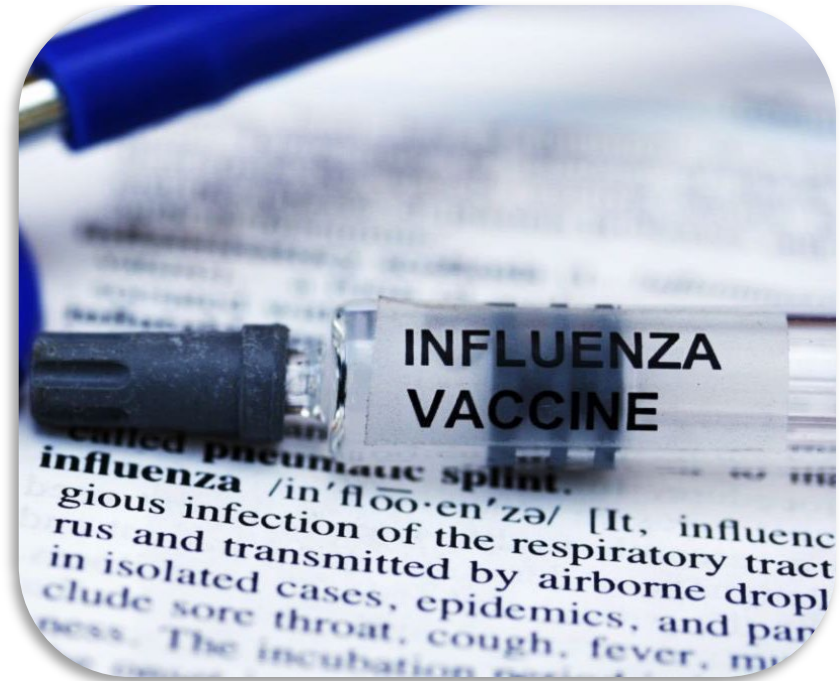
Agency	Scope	Date
Pharmaceuticals and Medical Devices Agency, (PMDA), Japan	Registration Renewal	05/30/2024
Drug Enforcement Administration (DEA)	Routine Compliance Inspection	12/05/2023
National Association of Boards of Pharmacy® (NABP®)	Triennial Reaccreditation Site Survey	05/13/2022
Food and Drug Administration (FDA)	Routine Surveillance Inspection	06/29/2021
US Customs and Border Protection (CBP)	General	06/15/2021
Drug Enforcement Administration (DEA)	Routine Compliance Inspection	05/20/2020
National Association of Boards of Pharmacy® (NABP®)	Triennial Reaccreditation Site Survey	01/10/2020
Pharmaceuticals and Medical Devices Agency, (PMDA), Japan	Registration Renewal	05/30/2019
Drug Enforcement Administration (DEA)	Routine Compliance Inspection	01/28/2019
US Customs and Border Protection (CBP)	General	06/29/2018
Food and Drug Administration (FDA)	Routine Surveillance Inspection	06/07/2018
United States Department of Agriculture (USDA)	Client-specific	07/20/2017
Drug Enforcement Administration (DEA)	Routine Compliance Inspection	12/12/2016
National Association of Boards of Pharmacy® (NABP®)	Triennial Reaccreditation Site Survey	10/06/2016
Food and Drug Administration (FDA)	Routine Surveillance Inspection	06/30/2016

\*Qualified Person (QP) GMP Facility Audit performed July 08, 2022



# Vaccine Management Solutions

- Seasonal/Pandemic Solutions
- Diverse Material Management Capabilities
  - Vaccine and bio-defense product storage and rotation
  - Executable plans for Emergency Response distribution
  - Multiple U.S. Government Awards with the CDC and HHS



# Supply Chain Management

- Cold Chain Management
- Domestic and Global Distribution
- Cross-docking
- End-to-End Logistics Management
- Channel Qualification
- Import Optimization
- Foreign Trade Zone (FTZ)
- Direct Fulfillment



# Global Logistics Coordination



## Limited Agency-Driven Logistics

- US/EU Storage Hubs
- Qualified Freight Forwarders, Brokers, & Shipping Systems
- Shipping Lane Identification & Validation
- Risk Mitigation Considerations
- Export/Import Facilitation
- Paperwork Generation
- White Glove Temperature Sensitive Transit
- Updates Throughout Movement Process



## Sentry's Global Distribution Map

**North America**  
(Canada, Mexico, Puerto Rico, United States)

**South America**  
(Argentina, Brazil, Chile, Columbia, Paraguay, Peru, Uruguay, Venezuela)

**European Union**  
(Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Poland, Portugal, Romania, Spain, Sweden)

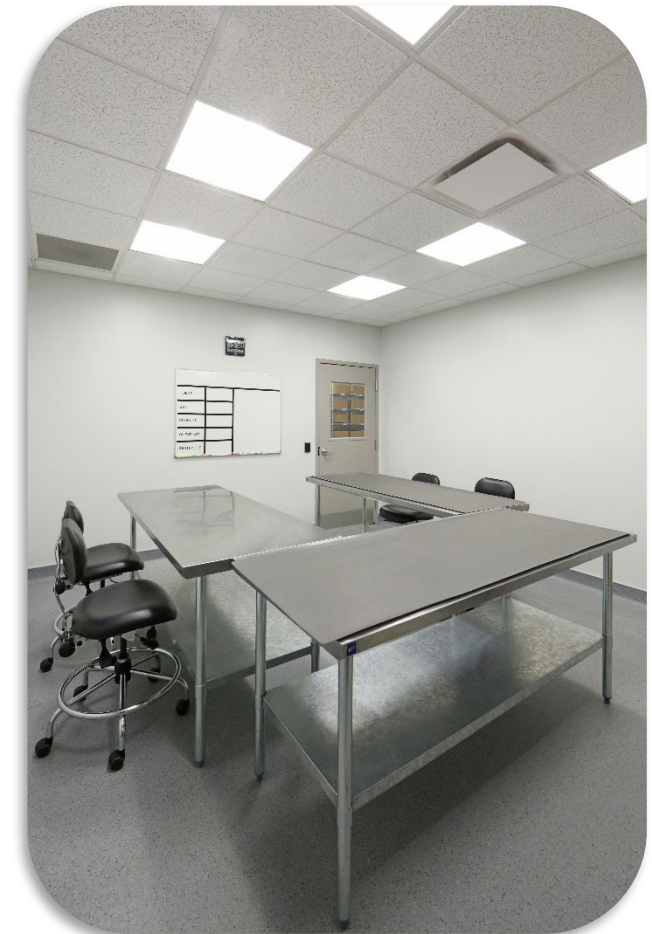
**Outside EU**  
(Norway, United Kingdom, Russia, Kazakhstan, Switzerland)

**Middle East**  
(Georgia, Israel, Jordan, Lebanon, Saudi Arabia, Turkey, UAE)

**Asia**  
(Australia, Bangladesh, Cambodia, China, India, Indonesia, Japan, Malaysia, Myanmar, Nepal, New Zealand, Pakistan, Philippines, South Korea, Taiwan, Singapore, Thailand, Vietnam)

# Manufacturing Support

- Labeling
  - Clinical and Small-Scale Commercial
  - Temperature-Sensitive Products
  - Open and Blinded
  - Serialized
  - Randomization
  - Multilingual
  - Peel-off / Perforated



# Manufacturing Support

- Secondary Packaging
  - Bulk packaging
  - Single- / Multi-dose cartons
  - Package Inserts
  - Kits
  - Double-blind Packaging
  - Tamper-evident





# Expanding Capabilities

- Formation of Sentry BioPharma ApS - EU Service Arm - Q2, 2020
- Additional Vapor Phase LN2 ( $<-135^{\circ}\text{C}$ ) - Q3, 2020
- Additional 250 x US Pallet Chamber ( $-15^{\circ}\text{C}$  to  $-25^{\circ}\text{C}$ ) - Q2, 2021
- Additional Temperature Range ( $-60^{\circ}\text{C}$  to  $-80^{\circ}\text{C}$ ) - Q2, 2022
- Electronic Quality Management System - Q1, 2024
- Warehouse Management System Upgrade - Q3, 2024
- Additional US Site - Q3, 2024 - Validation in Process
- Additional Indianapolis HQ Expansion - EOY 2024



US Depot - Indianapolis, IN  
Sentry BioPharma Services, Inc.

EU Depot  
Sentry BioPharma Services ApS



US Depot - Columbus, IN  
Sentry BioPharma Services, Inc.



If you have questions:  
email [BD@sentrybps.com](mailto:BD@sentrybps.com) or call 1-866-757-7400