

**Protecting Product Integrity**



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



# Sentry BioPharma Services, Inc.

- Celebrating 20 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

Indianapolis  
location validation  
complete and first  
product arrives at  
facility

Indianapolis  
DEA CSIII-V  
import license  
approved

Indianapolis  
First Facility  
Expansion  
Completed

Danish Medical  
Authority Licensure  
Inspection for  
Sentry BioPharma  
Services ApS

2005

2008

2017

2020

2024

2006

2010

2019

2022

Establishment of  
Sentry BioPharma  
Services, Inc.  
(Sentry US)

Indianapolis  
adds Labeling  
and Secondary  
Packaging to its  
core service set

More than  
100 Clients

Danish subsidiary  
formed  
Sentry BioPharma  
Services ApS  
(Sentry EU)

Columbus Location  
constructed and  
validated as part of  
Sentry US



# 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







# IND - Facility

- State-of-the-art Facility
- Built to Factory Mutual (FM) Specifications
- Validated Systems & Environments
- 21 CFR Part 11
- Rapid Expansion Capabilities
- Redundant Systems



# IND - Storage Solutions

- 86,000 square feet
- GMP Storage

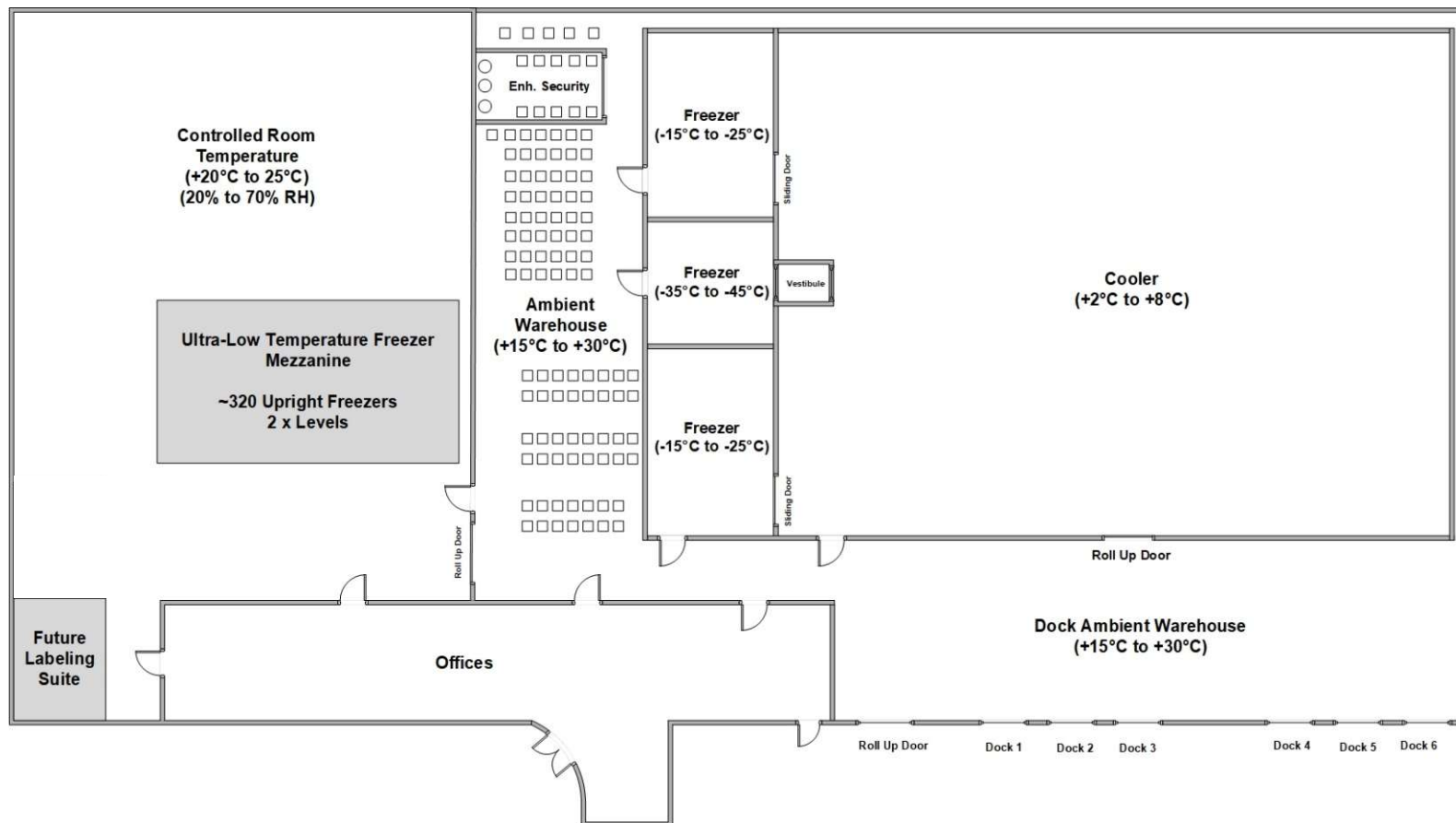
Ambient	+15°C to +30°C
Controlled Room Temp.	+20°C to +25°C
Refrigerated	+2°C to +8°C
Frozen	-15°C to -25°C
Low Temp. Frozen	-35°C to -45°C
Custom Ultra-low (50)	-40°C to -60°C
Custom Ultra-low (70)	-60°C to -80°C
Custom Ultra-low (75)	-65°C to -85°C
Ultra-low	-70°C to -90°C
VP LN2	<-135°C
Custom Solutions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

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





# IND - 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

# IND Regulatory Inspection History (2016-24)

Agency	Scope	Date
Drug Enforcement Administration (DEA)	Routine Compliance Inspection	11/21/2024
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)

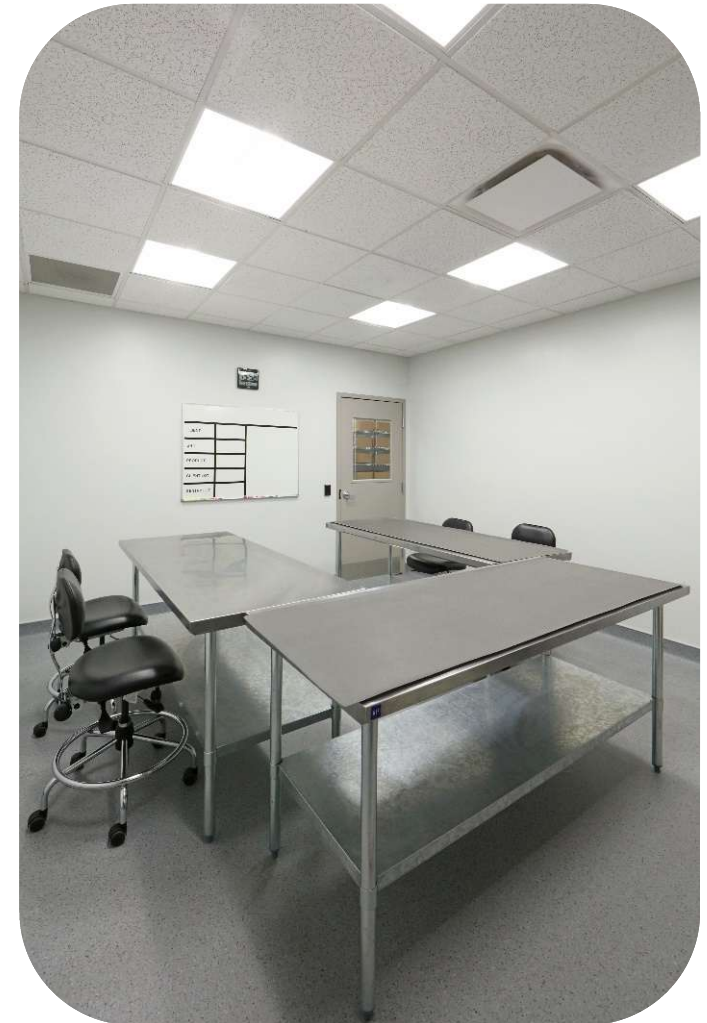
**Outside EU**  
(Norway, United Kingdom, Russia, Kazakhstan, Switzerland)

**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

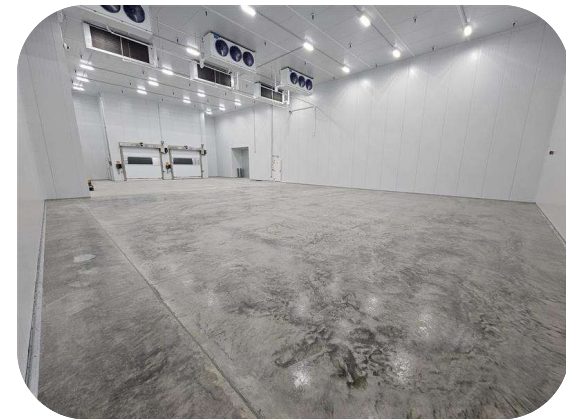
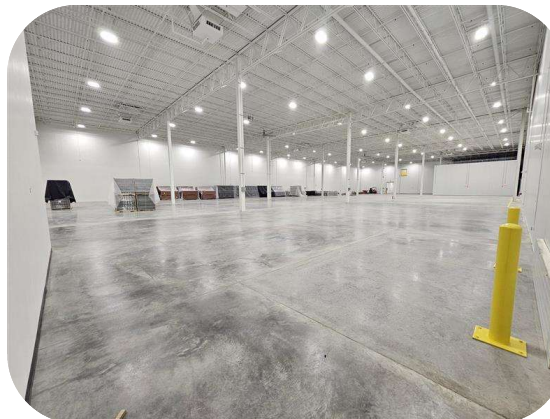




# Sentry Expansions Underway - 2025

Sentry - Indianapolis, IN - Additional 55K Square Feet - Substantially Complete

- Dedicated Refrigerated Docks
- Additional CRT/REF/FRO/ULT Capacity
- Site Process Flow Change - Overall
- Additional 3,000 Square Feet of Office and Training Space
- Infrastructure Build In Process for 161 x Additional ULT Freezers



# Sentry Expansions Underway - 2025

Sentry - Columbus, IN - New Facility 50K Square Feet

- Licensing Secured MAR2025
- Comprehensive Stability and GMP Material Storage
- Sampling and Aliquoting Suite and QC Laboratory
- Whole Facility Foreign Trade Zone





# COL - Storage Solutions

- 50,000 square feet
- GMP Storage

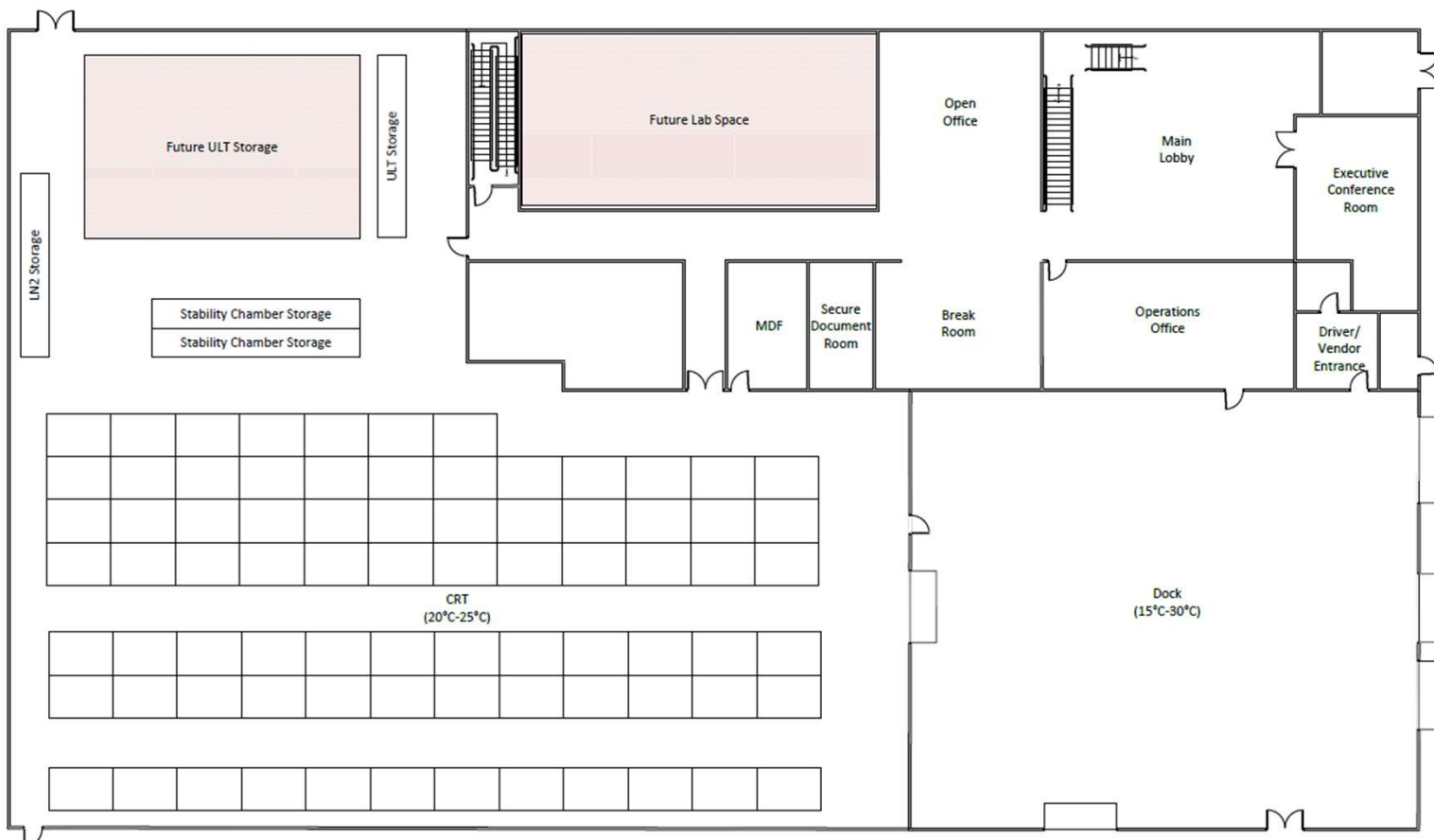
Ambient Dock	+15°C to +30°C
Controlled Room Temp.	+20°C to +25°C
Ultra-low	-70°C to -90°C
VP LN2	<-135°C
Custom Solutions	0°C to -90°C

- Foreign Trade Zone (FTZ)
- Additional ICH Stability Ranges - Q3 2025





# COL - Current Facility Layout



# Sentry COL - Upcoming Services - Stability Storage

## Environmental Conditions

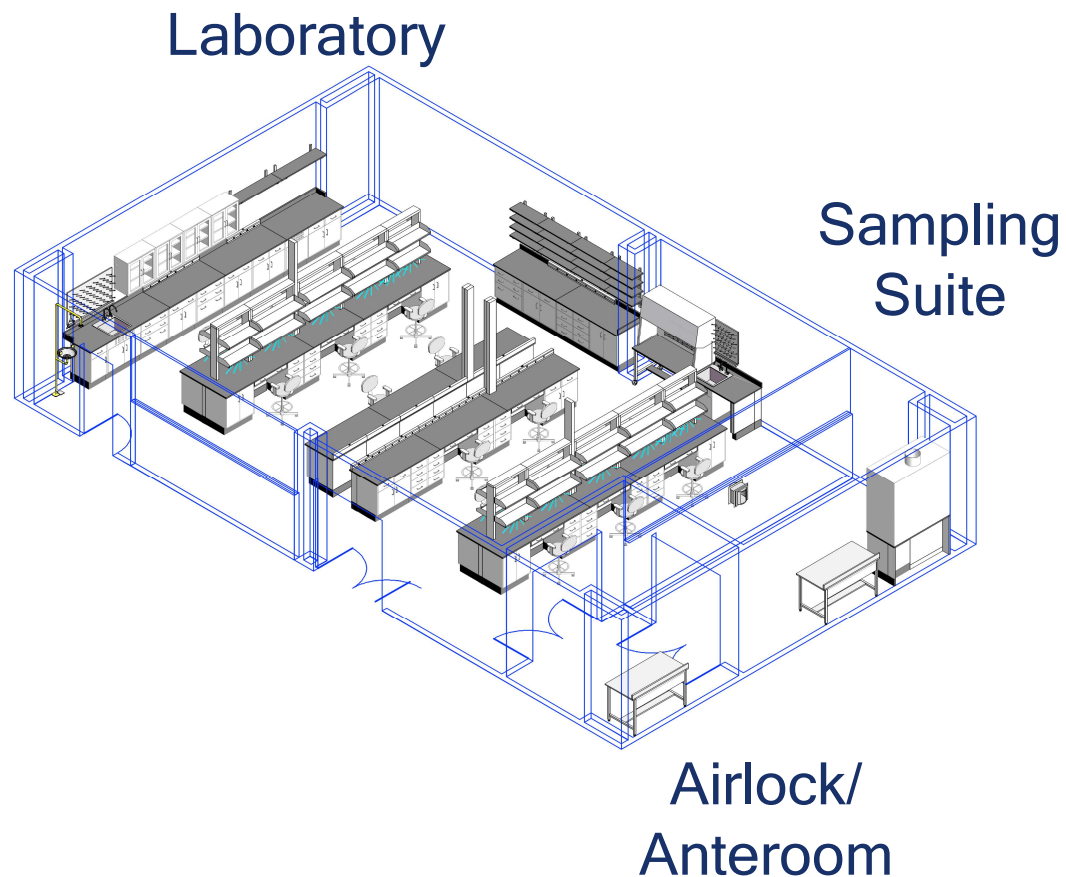
- Long Term  $25^{\circ}\text{C} \pm 2^{\circ}\text{C}/60\%$   
RH  $\pm 5\%$  RH
- Accelerated  $40^{\circ}\text{C} \pm 2^{\circ}\text{C}/75\%$   
RH  $\pm 5\%$  RH
- Refrigerated  $5^{\circ}\text{C} \pm 3^{\circ}\text{C}$
- Frozen  $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$



## Sentry COL - Upcoming Services - Analytical Laboratory

### Lab Operations

- Release Testing
- In-process Control
- Characterization
- Trace Analysis
  - Residue & Impurities
- Stability Testing
- Cleaning Verification
- Microbial Evaluation





# Sentry COL - Upcoming Services - Sampling and Dispensing

## Sampling Operations and Details - Online by End of May 2025

- Liquid Volumes - 100  $\mu$ L to 1L
- Powders/solids will be sampled at weights from 0.5g to 3000g
- Laminar Flow Hood within the Suite
  - Inert Handling in Glove Bag - Available
  - Highly Potent Capabilities
- Sampling volumes/weights may be increased or decreased, if requested
- Negative Pressure Drop - Corridor  $\rightarrow$  Lab  $\rightarrow$  Airlock  $\rightarrow$  Sampling Suite
- Badge Access Controlled w/Hands Free Egress
- Hard Ceiling w/gasketed light fixtures
- Dust Mats before lab and interlock



# Expanding Capabilities

- Formation of Sentry BioPharma ApS - EU Service Arm - Q2, 2020
- Additional Vapor Phase LN2 (<-135°C) - Q3, 2020
- Additional 250 x US Pallet Chamber (-15°C to -25°C) - Q2, 2021
- Additional Temperature Range (-60°C to -80°C) - Q2, 2022
- Electronic Quality Management System - Q1, 2024
- Additional US Site - Q3, 2024 - Licensed, validation in process
- Additional Indianapolis HQ Expansion - Q2, 2025
- Warehouse Management System Upgrade - Q2, 2025



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