

Protecting Product Integrity

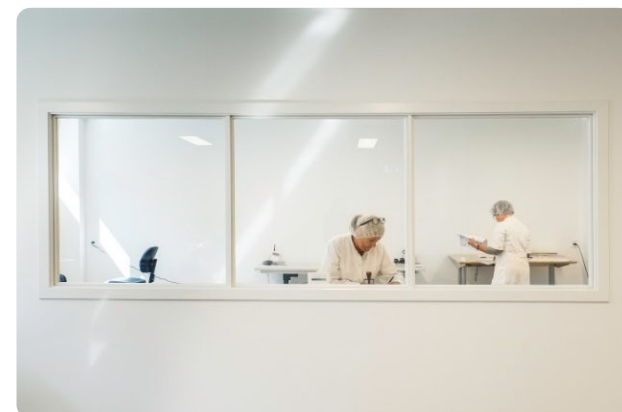


COLD CHAIN • PACKAGING • DISTRIBUTION • CLINICAL TRIALS • CUSTOM SOLUTIONS



Sentry BioPharma Services ApS

- Founded in 2020
- Wholly owned Sentry US subsidiary
- Integrated Sentry services in cooperation with KLIFO A/S
- Contract management by Sentry US, contract operation by KLIFO
- Integrated GDP & GMP QMS
- QP Declarations and Certification of IMP



EU Location

- Copenhagen, Denmark
- Central European Location with Global Reach
 - Direct Flights between ORD to CPH - (Supplies between Copenhagen and Indianapolis)
- Close proximity to Copenhagen Airport (Kastrup)



EU Facility

- Warehouse Management System
- Building Management System
 - ELPRO Temperature Monitoring
 - Remote and Local Alarming
- Redundant Systems
 - Critical Systems Backup Generator(s)
- Access Restriction



EU Storage Solutions

GMP Temperature Controlled Environments

Controlled Room Temp.	+15°C to +25°C
Refrigerated	+2°C to +8°C
Frozen	-15°C to -25°C
Ultra-low	-70°C to -90°C
Custom Solutions	0°C to -90°C



Plantegning – Produktion og lager

On the Mezzanine

Below Mezzanine

Backup generator (KLI-0047)

Backup generator (KLI-0027)

NOT KLIFO

WH1 PORTSLUZE

WH2

WH3

WH4

WH5

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WH100

PRODUKTIONSGANG

SLUZE P

SLUZE S

LABEL KONTR

P.1

S.1

S.2

S.3

S.4

PRODUKTIONSKONTOR

WH5 Kontor

WH6

WH7

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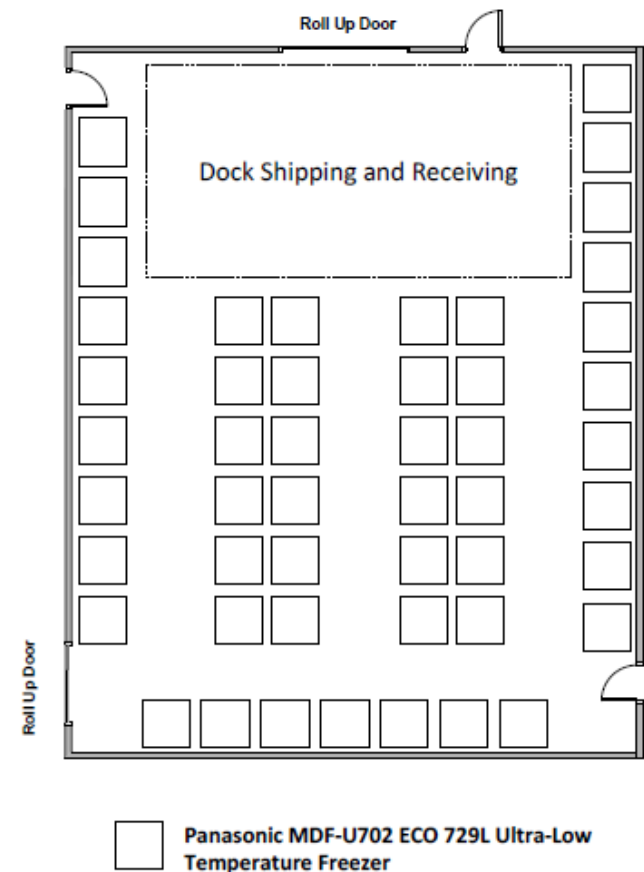
WH100

Legend:

- ELPRO
- Airpressure
- Klimaaniæg
- Temperaturføler
- Air Con

EU ULT Freezer Space (-70°C to -90°C)

- Infrastructure for ~50 Upright ULTs
- Dedicated Dock Shipping and Receiving Area
- Emphasis on High Value Biologic BDS/API/DP/Reference Standard and Intermediate Storage



EU Quality and Regulatory

- Quality Management System
- Validated Systems & Environments
- EU GMP Standards
- GCP, GVP and QP Audits
- QP Declarations and Certification of IMP
- Danish Medical Authority (DMA) - March 2022



Global Manufacturing Support

- Labeling/Relabeling
 - Clinical/Commercial Supplies
 - Label Translation and Regulatory Checks
 - Temperature-Sensitive Products
 - Open and Blinded
 - Serialized
 - Randomization
 - Multilingual



Sentry Managed Batch Record
Operations in US and EU

Global Manufacturing Support

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



EU Additional Services

- Regulatory Assistance/Consulting
- Label Translation and Regulatory Checks
- Qualified Person Release and Import/Export
- IRT Setup and Clinical Study Management
- Logistics Management
- Rapid Expansion Capabilities



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)

If you have questions:



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US Depot

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