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Global Pharma Supply Chain & Logistics Innovation Forum, Berlin Germany

19 October 2023

Topic: Innovation in Pharmaceutical Quality Assurance: Enhancing Compliance and Efficiency

Introduction

- Over 30 experience within the GMDP sector across Healthcare, Pharma and Biotech.
- Worked from grass roots to corporate level, globally, cross functionally and with respect to GxP oversight
- Eligible as a Responsible Person since 2008; Good working relationships with the MHRA and other regulators
- Conceived, developed and realised corporate strategy within the Logistics and Pharmaceutical sectors
- Expansive experience working with WHO, IATA, MHRA, GDP Association and companies such as McKinsey
- Strong experience in managing and supporting teams, partners, suppliers and affiliates
- Developed corporate strategy ref- Pharmaceutical Logistics at 3PL's
- Supply Chain Optimisation e.g's: Astra Zeneca, Reckitt Benckiser, Baxter Healthcare and Lupin Labs

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Prevailing Regulations (EMA)

- Good distribution practice (GDP) describes the minimum standards that a wholesale distributor must meet to ensure that the quality and integrity of medicines is maintained throughout the supply chain

- Compliance with GDP ensures that:
  - medicines in the supply chain are authorised in accordance with the European Union (EU) legislation;
  - medicines are always stored in the right conditions, including during transportation;
  - contamination by or of other products is avoided;
  - an adequate turnover of stored medicines takes place;
  - the right products reach the right addressee within a satisfactory time period

- The distributor should also put in place a tracing system to enable finding faulty products and have an effective recall procedure

- GDP also applies to the sourcing, storing, and transportation of active pharmaceutical ingredients and other ingredients used in the production of the medicines

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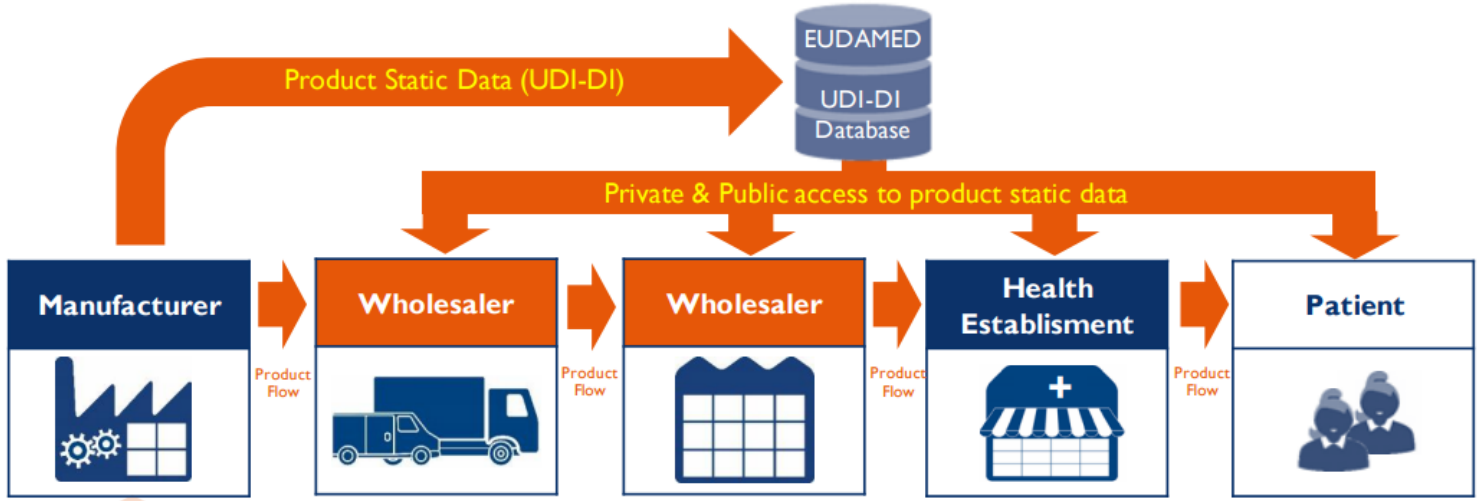
EU MDR (EMA)



This Regulation aims to ensure a high level of protection of health for patients and users, At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products.

This Regulation harmonizes the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market thus allowing them to benefit from the principle of free movement of goods.

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EU MDR (EMA)

CLASSIFICATION OF MEDICAL DEVICES

Class III
- High risk products including active implantable products
- e.g. heart valves, hip replacements, breast implants, meshsurgical, pacemaker, etc.

Class IIb
- High risk, invasive surgery for long-term use, some products implantable
- e.g. intraocular lenses, blood bags, insulin pens, hemodialyzers etc

Class IIa
- Medium risk, invasive products for short-term use.
- e.g. needles, lancets, surgical gloves, tracheal tubes, headphones, etc.

Class I
- Low risk, non-invasive products
- e.g. bandages, elastic stockings, stethoscopes, urine bags, glasses, canes, etc.

Prevailing Regulations (EMA)

- EU MDR transitional period and deletion of the MDR/IVDR 'sell off dates' officially implemented on March 20, 2023

- Regulation (EU) 2023/607 of the European Parliament and of the Council of March 15, 2023, amending Regulations (EU) 2017/745 and (EU) 2017/746, has been published

- The European Union has set deadlines for the certification and sale of various medical devices:
  - The deadline for custom made Class III implantable devices is May 26, 2026.
  - Class III and Class IIb implantable devices must be certified by December 31, 2027, while Class IIb non-implantable devices must be certified by December 31, 2028.
  - The deadline for Class IIa and Class I (Is/Im) devices is also December 31, 2028. - - - Certificates issued before May 26, 2021 will remain valid

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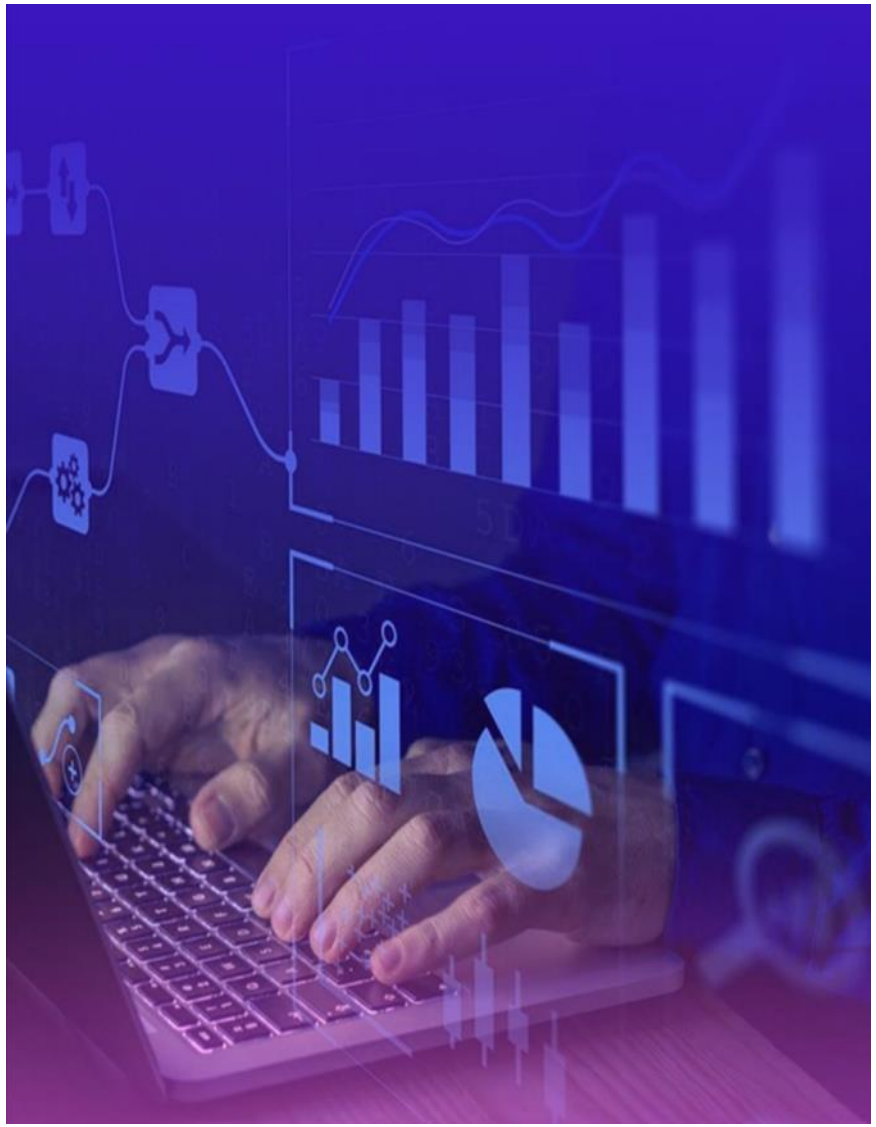
EQMS

Key Features and Functionality

- Out of the box ready smart decision trees and assessments, AI ready and scalable
- Electronic Forms Builder – quickly create any type of protocol, questionnaire, survey and external forms e.g. Audit Questionnaire, Inspection and Survey
- E-signatures, complete audit trail and other 21 CFR Part 11 requirements included
- Built in seamless integration between all quality related processes e.g. Supplier quality management, document management, training management, electronic batch records, CAPA, Change Control
- Additional readily available solutions for regulatory management, clinical, equipment, product registration
- Pure cloud solution
- Includes mobile app



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DSV UNITED KINGDOM

Healthcare

+50
Dedicated Healthcare Employees

1
Dedicated, WDA licenced Healthcare center of excellence

Products/Services

- Air freight
- Courier
- Sea freight
- Road
- Contract Logistics
- Healthcare value added services

3
Healthcare warehouses & cross dock

+40K
Sqm Healthcare warehouse

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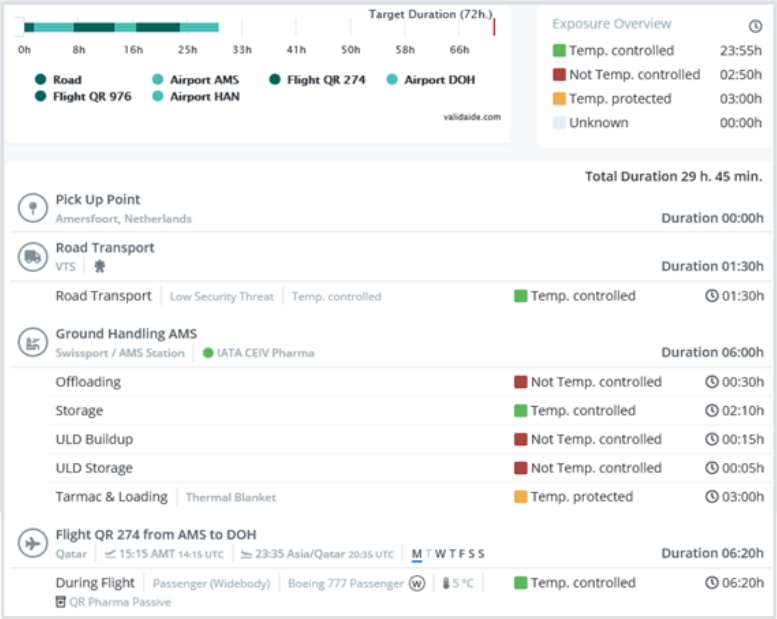
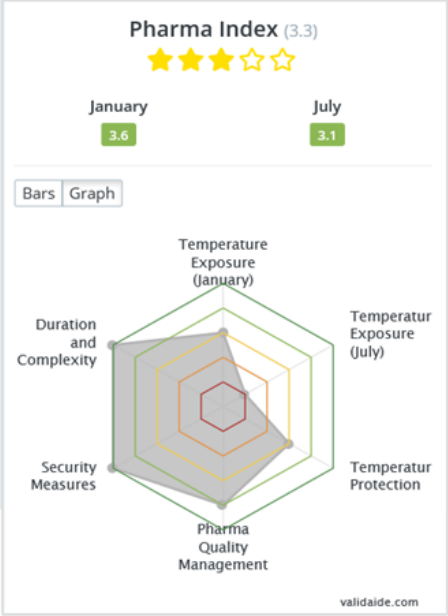
Validaide

Validaide / Digital Lane Risk Assessment

Assessment of Lanes on multiple quality factors





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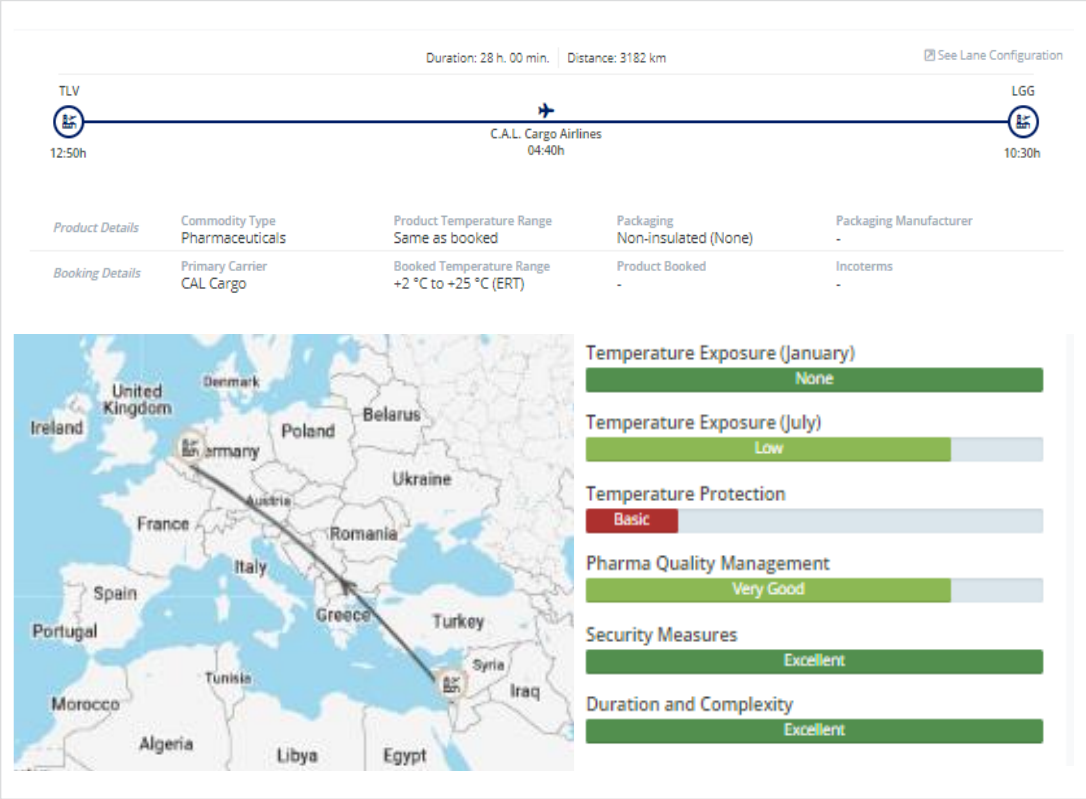
Validaide / Lane Risk Assessment

How do we access lane risk?

Validaide



We use Validaide to assess lane risk in the following categories:

01 Temperature exposure

02 Temperature protection

03 Pharma Quality Management

04 Security measures

05 Duration and complexity of routing

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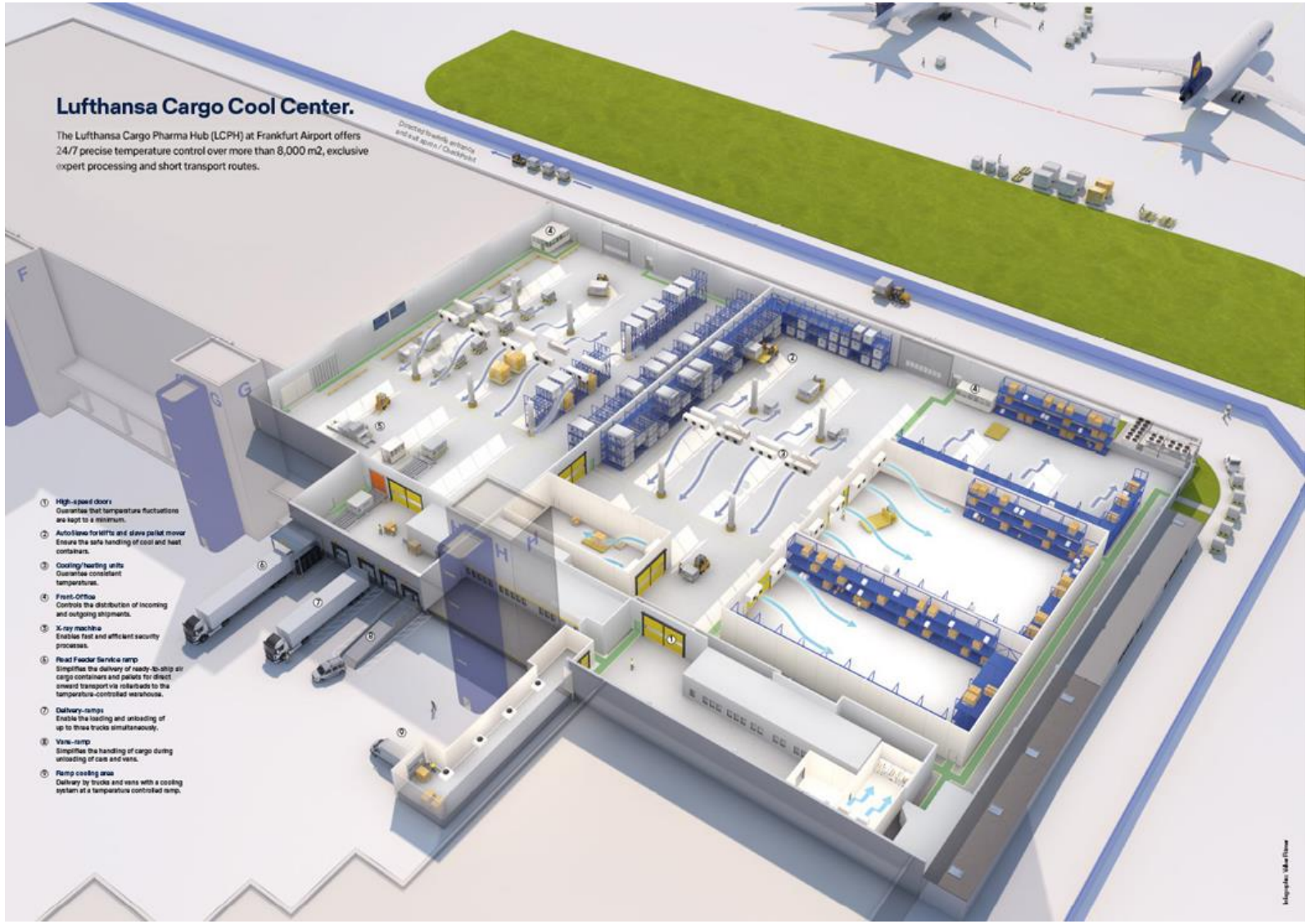
Airlines



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Airlines

General Cargo

Reliable logistics for your standard cargo – for a smooth transport chain.

Active Temp Control

Temperature-controlled transport for your air freight in heated and refrigerated...

Passive Temp Support

Temperature support for sensitive cargo – with state-of-the-art packaging solutions.

COVID-19 Temp Premium

Premium transport solution for COVID-19 vaccines that includes utmost attention and...

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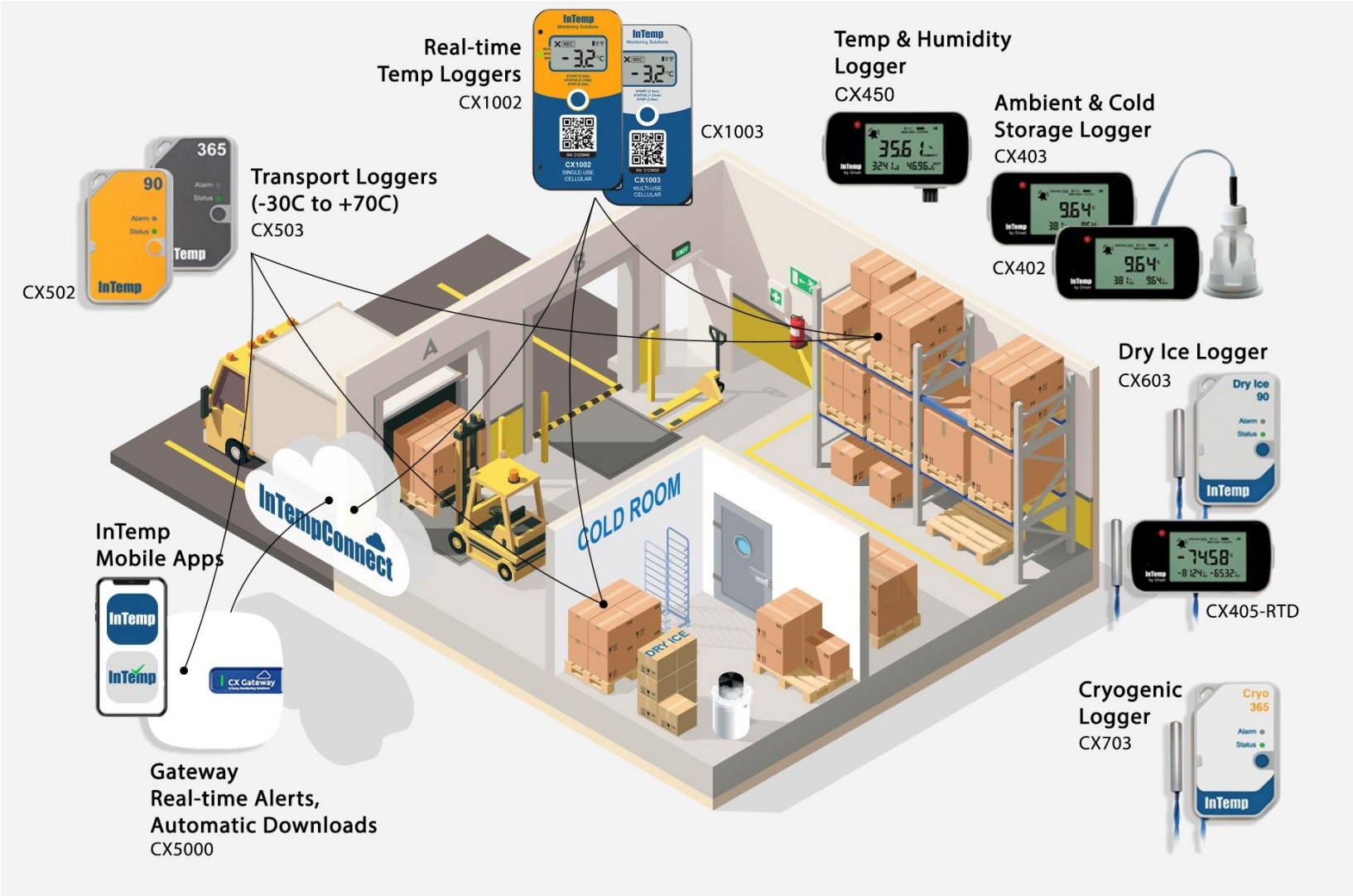
Supply Chain Visibility



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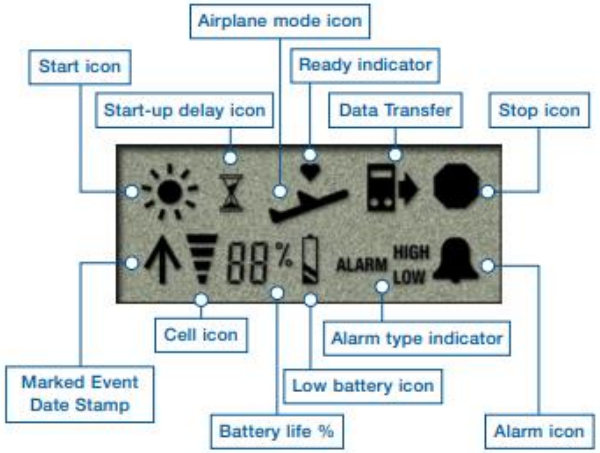
Supply Chain Visibility

TempTale® GEO Features and Benefits

- Provides real-time visibility for temperature and location to support both logistics and quality.
- Gives advance indication to all supply-chain partners where product is located and when it will arrive.
- Reduces risk by enabling active intervention to address correctable temperature deviations before they impact product quality.
- Allows data to be viewed in real time through a self-serve user interface—SensiWatch™ Tracks.
- Manages data in the same private cloud hosted environment as other TempTale® units, which facilitates a view of the entire perishable supply chain to drive sustainable improvements and regulatory compliance.
- Provides PDF reports and allows alternate data download into a secure database via USB.
- Ensures that no data gaps occur when the device travels through areas with no cellular coverage.



Intuitive LCD and LED indicators provide device status and alarm notification

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Temperature Control Packaging

STANDARD CONFIGURATION

va-Q-tainer

The va-Q-tainer is an advanced passive container, perfect for the global transportation of clinical and pharmaceutical goods. The safe, cost-efficient and green solution simplifies handling in challenging environments. With pay-per-use-rental, scalable TempChain Services and a growing global network, the patented system eases the work of pharmaceutical cold chain managers worldwide. Due to an award winning insulation a comprehensive range of temperature is constantly maintained without external energy supply for true 120 hours and more.

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Temperature Control Packaging

Door-to-door solution for an unbroken TempChain

Qualified performance without payload: True 120h and more

7 qualified temperature ranges for shipments from -70 °C to +20 °C available (as low as -50 °C without dry ice)

Comprehensive 4 size container portfolio from 1 Euro pallet to 2 US pallets payload volume

PMC pallet optimized: 4 Euro pallets (with 4 EUROx) or 4 US pallets (with 2 TWINx)

Smooth and cost saving operations: “ready to load & go” service for rental containers

High energy efficiency enables low CO_2 emissions, product carbon footprint calculations are available

Designed for multi-use: Re-qualification of rental containers with va-Q-check® secures day-one-validation

Produced in a global carbon neutral company, Technology “MADE IN GERMANY”

TempChain Service Software: Centralized management of the entire TempChain logistics process

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In Summary

‘Our objective is to act as guardians of Quality & Compliance ensuring the principles of Good Distribution Practice are embedded within our supply chains at all times and ultimately for the purpose of the end customer-The Patient’

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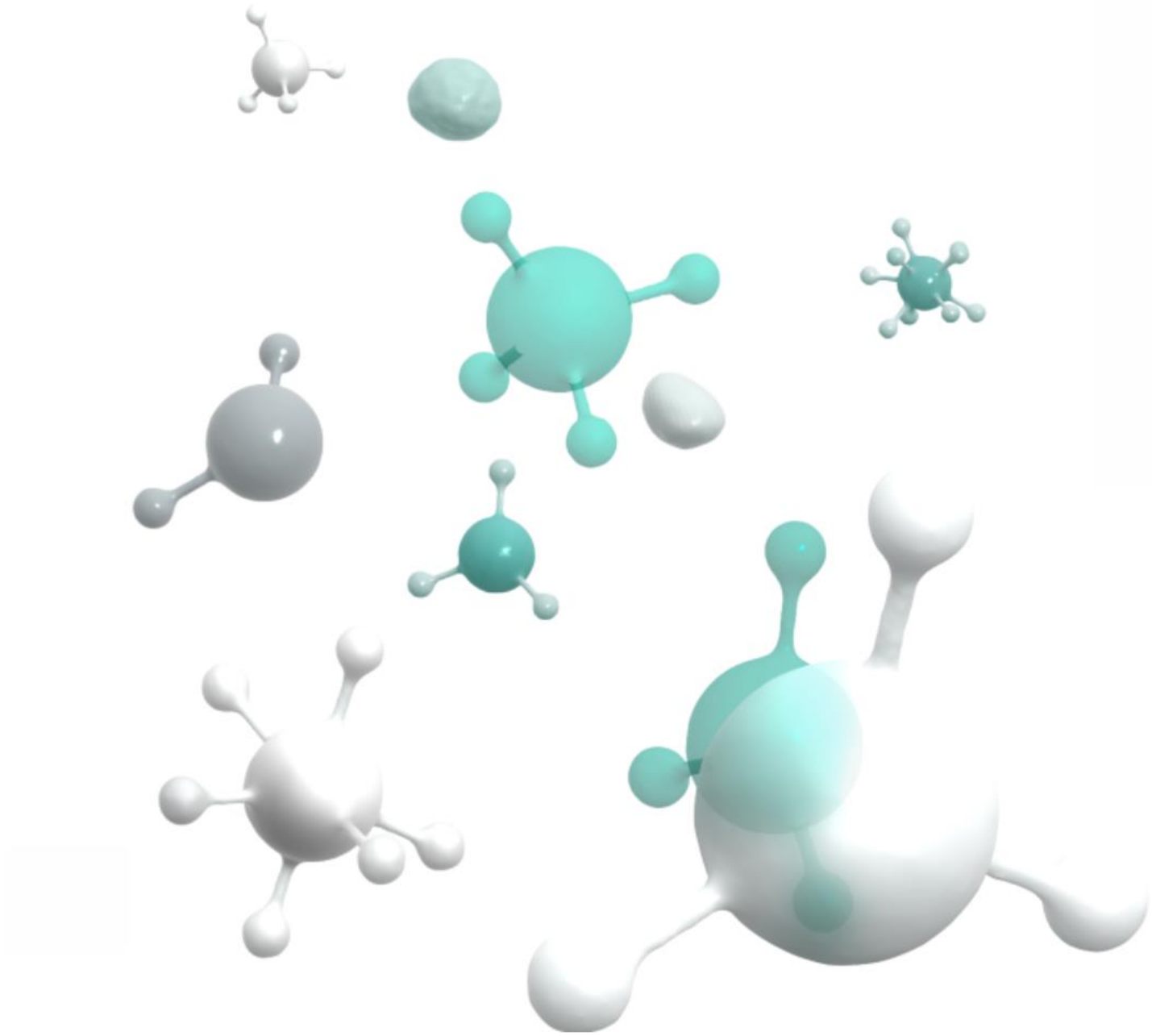
Thank you!



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