



# GDP CERTIFICATION

Céline CRAHAY – 3CeL consultancy

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# GDP / GDSP



## EU Good Distribution Practice

Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01)



## WHO Good Distribution & Storage Practices

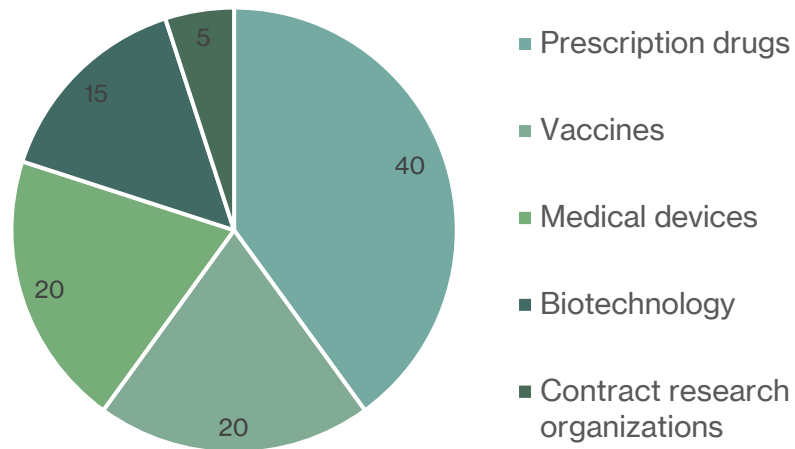
Good storage and distribution practices for medical products ,  
Technical report Series, No 1025, 2020 \_ Annex7

# Agenda

1. Context: GDP / GDSP
2. Life sciences quick overview
3. What are the different types of certifications? (Wholesaler, GDP compliance, IATA CEIV Pharma)
4. What are the benefits of such certifications?
5. What is the GDP certification process with ESCEM / TÜVRheinland?
6. Testimonials from CFL Logistics and INCO Logistics

# Life Sciences quick overview

- **Market Value:** The global life sciences market was valued at approximately **€7.5 trillion in 2023**.
- **Growth Rate:** The life sciences market is expected to grow at a Compound Annual Growth Rate (CAGR) of **8-11.8%** over the next five years.



- **Temperature-controlled:** 30-40%
- **Non-temperature-controlled:** 60-70% (This encompasses a wider range of products with less stringent storage requirements.)

- The life sciences market is constantly evolving, with significant investment in areas like gene editing, personalized medicine, and advanced therapies.

# Types of certification

Wholesaler license	IATA CEIV Pharma	GDP compliance
Delivered by the Health Minister	Air Cargo specific IATA Temperature Control Regulations and CEIV Guidelines	Scope: EU GDP / WHO GDSP



LE GOUVERNEMENT  
DU GRAND-DUCHÉ DE LUXEMBOURG  
Ministère de la Santé



# Boost Your Pharma Logistics Business with GDP Certification



**GDP Certification** Ensures compliance with regulations for safe storage & transport of pharmaceuticals

## **Benefits for Logistics Providers:**

- **Increased Credibility:** Stand out in the competitive market, attract pharma clients.
- **Improved Operations:** Standardized practices, risk management, cost reduction.
- **Stronger Client Relationships:** Build trust, secure repeat business.

# GDP certification process



EU GDP / WHO GDSP

Entity (es) / Address(es)

1. QMS
2. Personnel
3. Premises & equipment
4. Documentation
5. Operations
6. Complaints, returns, suspected falsified medicinal products and medicinal product recalls
7. Outsourced activities
8. Self-inspections
9. Transport
10. Specific Provisions for Brokers

Temperature ranges



On site audit  
1 / 2 day(s)  
Audit report

Closure of NCs  
Validation by auditor



On site audit  
1 day  
Audit report

On site audit  
1 / 2 day(s)  
Audit report

# Testimonials

*CFL logistics scope: EU GDP & WHO GDSP*

*for GDP Warehousing & stock management +15/25°C*

*& Road Transport +15/25°C*



- CFL multimodal: Mrs Lise Schmitt
- CFL logistics: Mrs Aurore Lorber

*INCO logistics scope: EU GDP*

*for National and International freight forwarding of pharmaceutical  
road transport*



- INCO logistics: Mr Claus Ewerhardt





- 3CeL: Mrs Céline Crahay, [celine@crahay.eu](mailto:celine@crahay.eu)
- ESCEM: Mr Stefan Zerwes, [zerwes@escem.com](mailto:zerwes@escem.com)
- CFL multimodal: Mrs Lise Schmitt, [lise.schmitt@cfl-mm.lu](mailto:lise.schmitt@cfl-mm.lu)
- CFL logistics: Mrs Aurore Lorber, [aurore.lorber@cfl-logistics.lu](mailto:aurore.lorber@cfl-logistics.lu)
- INCO logistics: Mr Claus Ewerhardt, [cewerhardt@inco-ils.eu](mailto:cewerhardt@inco-ils.eu)
- *\*new\** GDP Training for logistics providers now in LUX!

Session on 17/18 September 2024



HOUSE OF  
TRAINING



CLUSTER  
FOR  
LOGISTICS  
LUXEMBOURG  
ADDING VALUE IS THE KEY.

# Thank you!

