



Good Distribution Practice & the value of Data

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1. Today
2. Trends
3. Actions
4. Summary



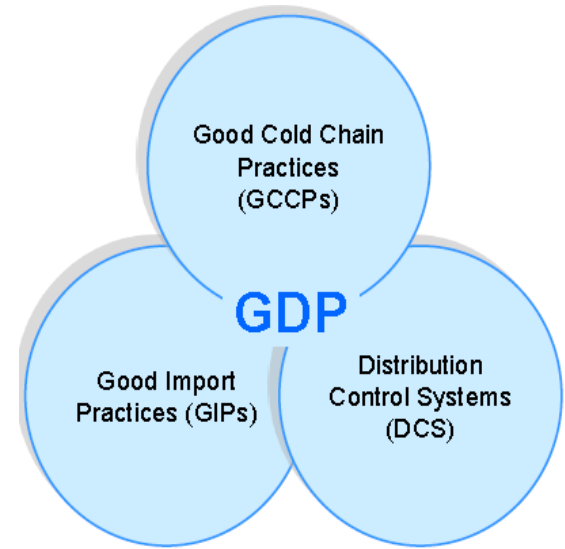
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Good Distribution Practice (GDP)

- Applies to all drugs including active pharmaceutical ingredients, excipients, intermediates and finished goods.
- With such protocol in mind, a level of quality exists throughout the distribution network so that authorized medicinal products are distributed without any alteration.
- We can acknowledge the intricacies of this practice and demonstrate compliance of , required to be a reliable and trustworthy resource for the transportation of pharmaceutical products.





The five pillars of GDP

STABILITY

Storage Temperature

Shipping
Temperature

Testing to support
temperature for
distribution

DISTRIBUTION CONTROL MANAGEMENT

Qualification Training

Premises &
Equipment

Material Handling

Storage & Inventory
Control

Transport

Product Distribution

Protection

Exception

PERFORMANCE MANAGEMENT

Reporting Metrics

Self Inspection

Review Meetings

Supply Chain Partner
Management

QUALIFICATION VALIDATION

Passive Ship systems

Ambient Temp
Profile

Active Ship systems

Facility Qualification

WMS validation

Distribution Validation
Plan

CONTINUOUS IMPROVEMENT

Industry

Regulatory

Validation

Quality Audit

Quality Agreement
SOP

Continuous Business
Review



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The Challenge Ahead?

- To what extent is temperature control really required for all products throughout the supply chain?
- What are the options to implement best practices?
- What strategies should be put in place?



Health
Canada

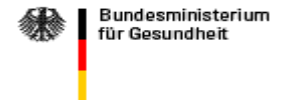
Santé
Canada



Australian Government

Department of Health

Therapeutic Goods Administration





The convergence of logistics compliance

- What are the key developments?
- What kind of cost implications are there in meeting the needs of the pharmaceutical sector?
- What are the things I need to put in place to serve the requirements of the pharmaceutical industry ?
- GDP - an opportunity or a threat?



Moving cold chain to the next level

- Last mile delivery; still an issue in many emerging economies
- In air temperature monitoring; transmitted in real time
- GDP 'like' inspections by the regulators in the last-mile
- Maximizing the benefits of investment temperature monitoring by integrating solutions





The pharma regulation 'be the solution'

The customer demands

- Higher level of quality for shipment execution to ensure product integrity and on-time performance
- Improved temperature controlled handling
- Improved transparency, visibility and control
- Streamline the logistics process

Elements to success

- GDP knowledge and competence
- Dedicated, industry trained staff
- Process excellence
- Technical infrastructure
- Additional Life Science specific service offering





The pharma regulation 'be the solution'

- GDP quality based solutions
- Temperature-controlled transportation management
- Historical and real time data
- Meaningful data that can be used as an auditable system(s)
- Protect the Patient
- Protect the Product
- Adhere to strict quality procedures





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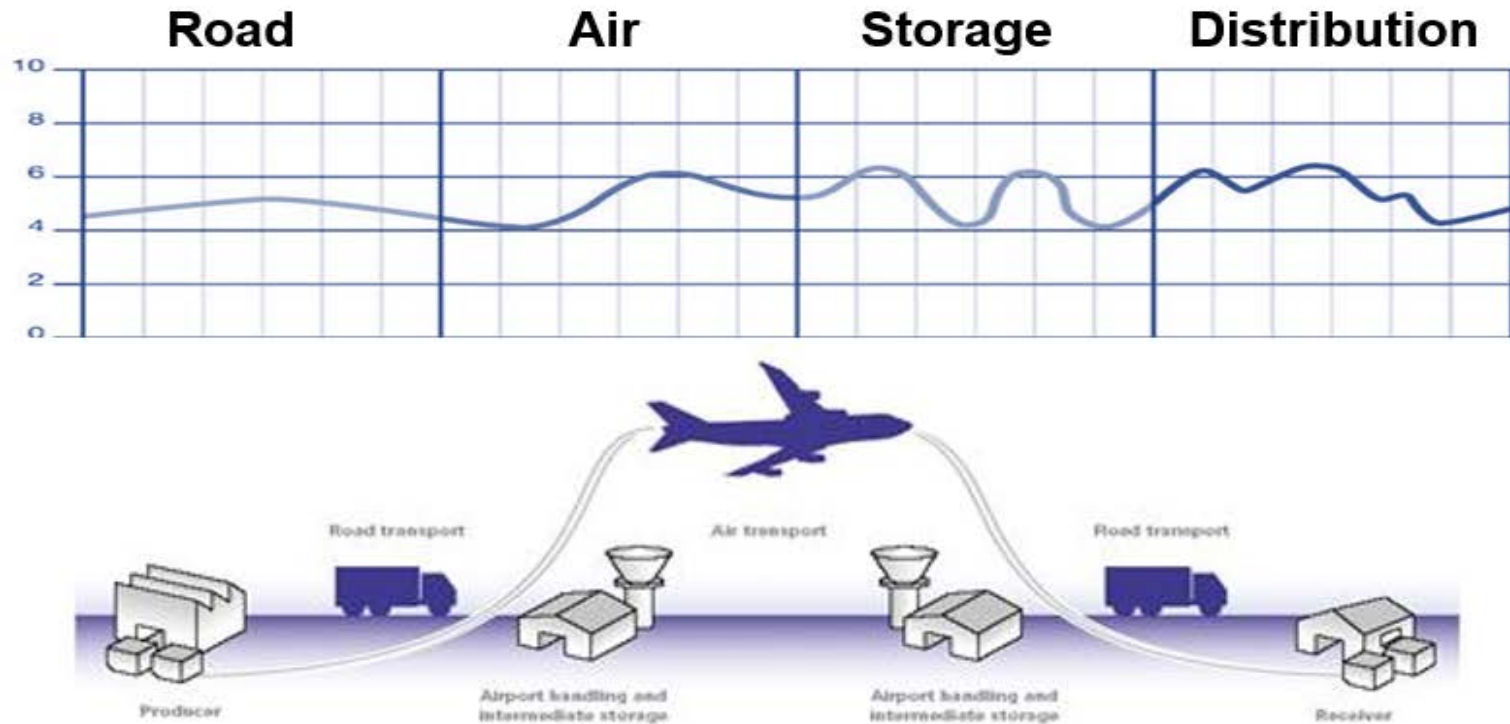


Network is crucial

Expertise in pharmaceutical and transport regulations, As the costs and risks to the supply chain increase so does the need to assure the integrity of the product.



Visibility in the supply chain





Data integration

If this is integrated into existing enterprise systems or workflows, the software technology solution can then provide insights into a complete transport network.

- Product identification
- Product tracing
- Product verification
- Detection and response
- Notification





Data will drive the cold chain

"It doesn't matter if your reports have all of the information. If people can't read and understand it, it's meaningless and you've wasted your time."

"Without the right framework for visualization, good data and actionable insights will slip away."

"Tailor visualization for the business persona you're serving and create actionable outcomes."





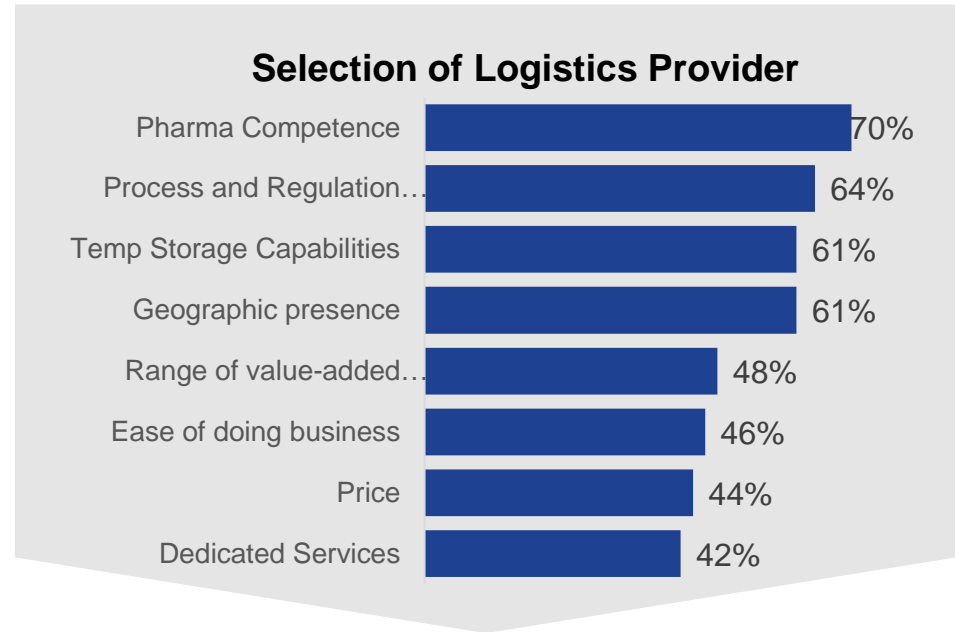
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Customer Selection Criteria

Addresses crucial aspects required by the industry, and are considered an important factor for differentiation.



Competency and Regulatory Knowledge service level in all regions are most important criteria.



The optimized customer benefit

A focused investment by Envirotainer strengthens our market advantage.

- Availability
- Flexibility
- Innovation
- Quality
- Trust
- Competence

Envirotainer°



Joint innovation

Develop joint innovation leadership – with our customer

Quality

Deliver quality consistently

Trust & Competence

Earn our customer's trust through dedicated and competent people



Think inside the box

Yoram Eshel, Director of global logistics, Teva-Israel

Active temperature controlled containers form the core of our solutions. To protect pharma products and the patients who depend on them; we design, manufacture and test all of our containers to strict quality standards. Because when patient outcomes and our customers' reputations are on the line, we don't take risks





Ultimately, we are dedicated to serve the patient

- Worldwide functionality
- A dedicated global team serving customer requirements within compliant parameters
- A clearly defined and agreed-upon process supporting regulatory demand
- A pro-active approach, with a strategic focus on client relationship
- Over 30 years of industry specific expertise
- Leveraged by a value driven process
- Strong link to operational excellence



Thank you!

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