



Our new standard for Good Warehousing Practices (GWP)

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President of EXCiPACT asbl

2021



Certification Standards for Pharmaceutical Excipient Suppliers

Good Manufacturing Practices (GMP)
Good Distribution Practices (GDP)
Good Warehousing Practices (GWP)

Requirements for Auditor Competency and Third-Party Organisations Providing Certification of the Management System

2021



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www.excipact.org

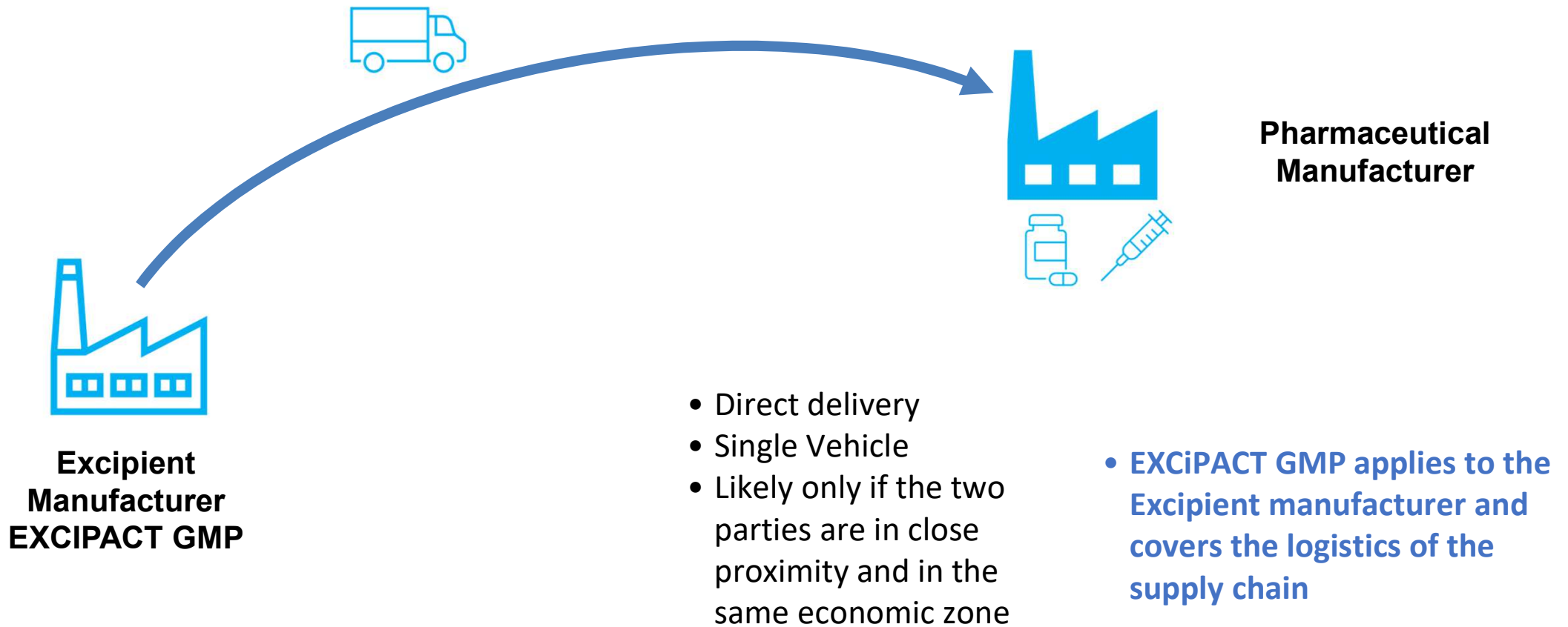
EXCI PACT is a registered trademark

GMP and GDP

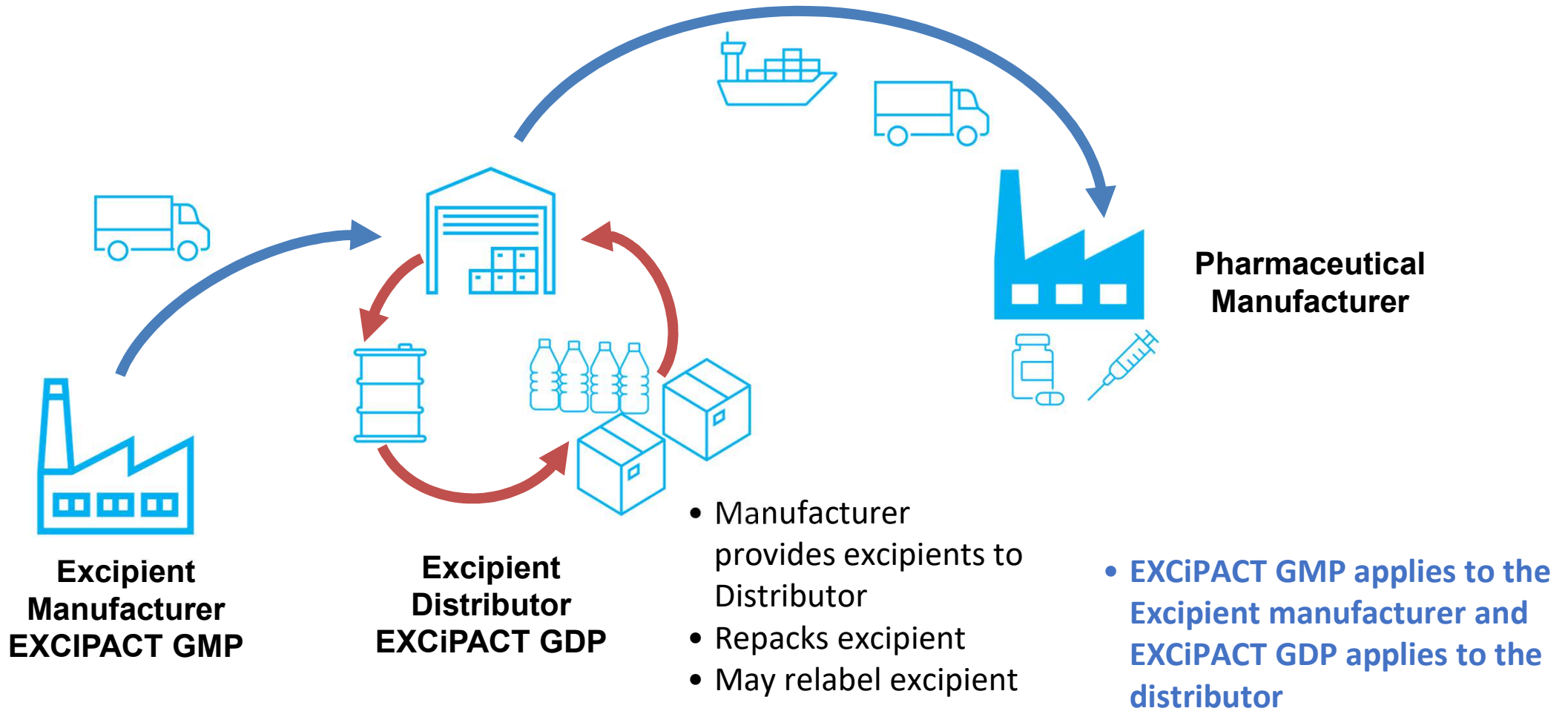
- The original 2012 standards covered Good Manufacturing practices and Good Distribution Practices (GMP and GDP)
- GDP is for excipients suppliers who:
 - Store packed excipients
 - Repack and relable these excipients



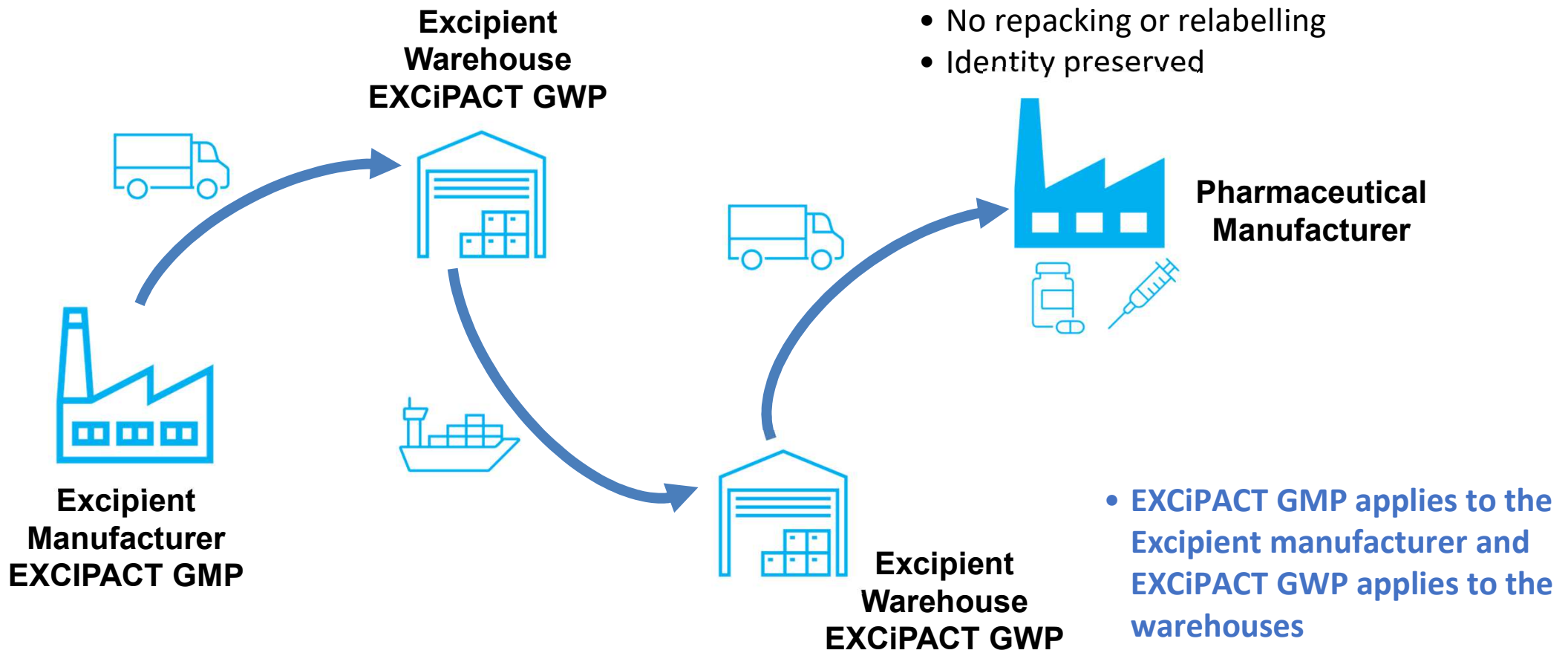
The Excipient supply chain



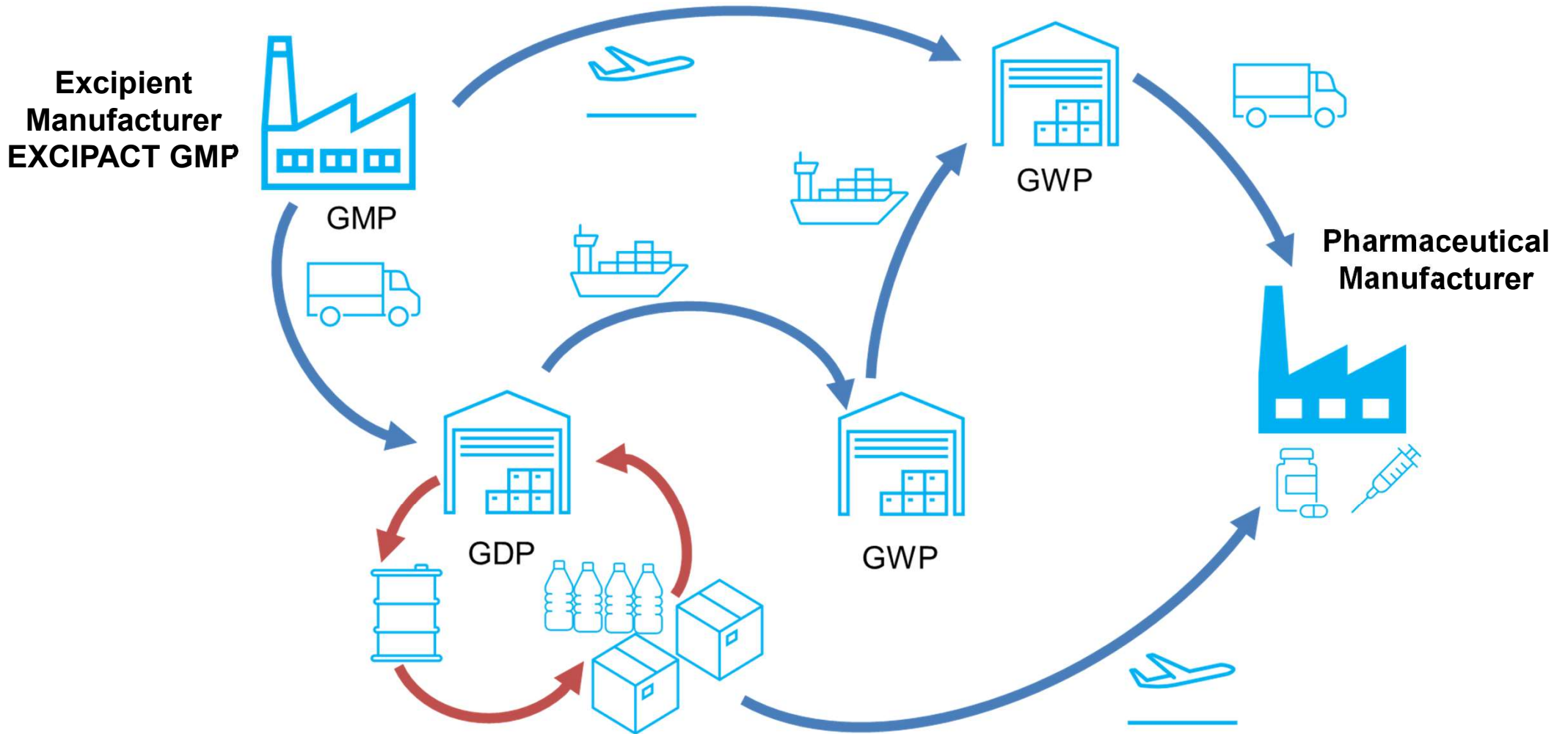
The Excipient supply chain



The Excipient supply chain



The Excipient supply chain – reality?



GMP, GDP and GWP

- The 2021 edition of the standards includes GWP as a new Annex
- There are also some adjustments to the ISO 17021-1 annex (Certification Body quality requirements) to accommodate GWP and as a result of improvements to the Certification scheme following an internal review
- Implementation of GWP follows the same process as for GMP and GDP



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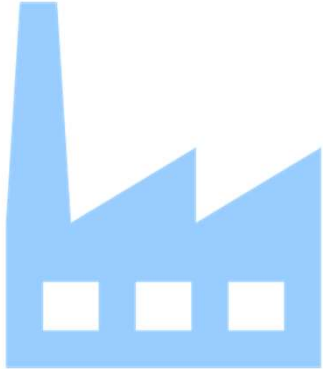
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The EXCiPACT Certification Program



- Certificate Validation
- Registers Auditors
- Registers Certification Bodies
- Process Oversight
- Transparency

The EXCiPACT Certification Program

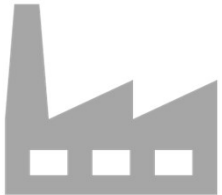


**PHARMA
MANUFACTURER**

VERIFIES CB, AUDITOR, CERTIFICATE @ WEBSITE

AUTHENTICATES AUDIT REPORT

Three icons representing audit and compliance elements: a document with a gear, a checklist with checkmarks, and a document labeled 'CAPA'.



100+ EXCiPACT Certification Holders Worldwide

- Austria
- Germany
- Finland
- France
- UK
- Belgium
- Netherlands
- Romania
- Spain
- Switzerland
- **USA Canada Mexico**
- Saudi Arabia
- Israel
- India
- Indonesia
- Italy
- China
- Japan
- Singapore



For full details of certificate holders – see www.excipact.org

Current EXCiPACT Registered Certification Bodies



EXCiPACT Advantages

- Minimizes risk
- Reduces audit burden
- Unbeatable cost-efficiency: usually free access for Pharma Manufacturers
- Allows pharma company to focus on specific supplier issues
- Speeds up the audit process
- Entire GMP/GDP levels of the supplier available for evaluation
- Satisfies (or surpasses) international regulatory guidelines
- Independent oversight guarantees transparency and reliability
- Excipient supplier provides certificate and audit report
- Maximizes benefits



Q&A

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