Our new standard for Good Warehousing Practices (GWP)

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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

MEMBERS

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EXCIPIACT is a registered trademark
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

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

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2021
The Excipient supply chain

- Direct delivery
- Single Vehicle
- Likely only if the two parties are in close proximity and in the same economic zone

EXCiPACT GMP applies to the Excipient manufacturer and covers the logistics of the supply chain
The Excipient supply chain

• Manufacturer provides excipients to Distributor
• Repacks excipient
• May relabel excipient

• EXCiPACT GMP applies to the Excipient manufacturer and EXCiPACT GDP applies to the distributor
The Excipient supply chain

- Excipient Manufacturer provides excipients to Logistics company
- Intermediate warehouses in the supply chain
- No repacking or relabelling
- Identity preserved

**REQUEST**

- EXCiPACT GMP applies to the Excipient manufacturer and EXCiPACT GWP applies to the warehouses

**Diagram**

- Excipient Manufacturer
  - EXCiPACT GMP
- Pharmaceutical Manufacturer
  - EXCiPACT GWP
- Excipient Warehouse
  - EXCiPACT GWP
The Excipient supply chain – reality?

Excipient Manufacturer
EXCIPACT GMP

GMP

GDP

Pharmaceutical Manufacturer

GWP

GWP
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
The EXCiPACT Certification Program

- Certificate Validation
- Registers Auditors
- Registers Certification Bodies
- Process Oversight
- Transparency
The EXCiPACT Certification Program

VERIFIES CB, AUDITOR, CERTIFICATE @ WEBSITE

AUTHENTICATES AUDIT REPORT

PHARMA MANUFACTURER
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

- SGS
- COY
- DQP
- Bureau Veritas
- Blue Inspection Body
- AENOR
- AJA Europe
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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