Good Distribution Practice – An Industry Perspective

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GDP – Part of the EU Falsified Medicines legislation

Other elements:

- Safety features
  - prescription medicines
  - non-prescription medicines at risk of falsification
- Oversight of actors in the supply chain
  - including wholesalers and brokers
- Greater API oversight
  - QP responsibilities, new rules on import from non-EU countries
- Excipients
  - Specific guidelines on GMP for excipients
- Internet sales

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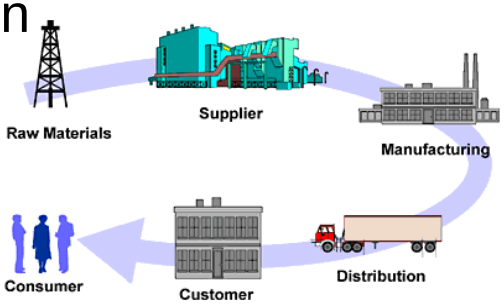
Exp (17): 110500
Batch (10): Batch17
Serial (21): 01234567890123456789



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GDP - Purpose

- Maintain quality and integrity of medicinal products across complex global supply chains
  - Safeguard product quality and integrity (patient impact)
  - Prevent unnecessary product loss or scrap (availability to patients)

- New GDP guidelines both for APIs and finished products
- GDP for APIs – Guideline still pending, the EFPIA position is that this regulation is redundant as it is already well covered in ICH Q7, see comparison on next slide

GDP for APIs – already covered in ICH Q7

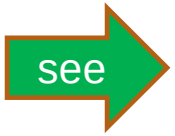
GDP for APIs

Needs are covered by EU GMP Part II

Draft GDP for APIs

Distribution of Active Substances

- Scope
- Quality System
- Personnel
- Documentation
- Orders
- Written procedures
- Records
- Premises and equipment
- Receipt
- Storage
- Deliveries to customers
- Transfer of Information
- Returns
- Complaints and Recalls
- Self-inspections



EU GMP Part II

Agent, Brokers, Traders, Distributors, etc (17)

- Introduction / Scope (17.1; 1)
- Quality Management (17.3 , 2)
- Personal (3)
- Documentation (6)
- *Register* *according to Article 52(a) of Directive 2001/83/EU.*
- Written procedures (2.3, 7.1, 9.11)
- Records(6)
- Equipment (5), Buildings/ Facility (4)
- Receipt (17.2); Storage and Distribution (10)
- Storage (10)
- Contract Manufacturing (16), Traceability (17.2)
- Transfer of Information (17.6)
- Returns (17.8; 14.5)
- Complaints / Recalls (17.7; 15)
- Self-Inspection (2.4)

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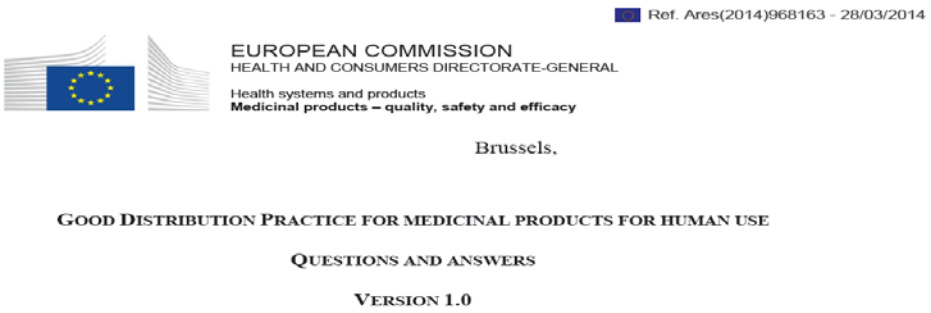
GDP for finished products - History

- European Commission draft published in July 2011 – public consultation closed Dec 2011
- Final version published Sept 2013 and a revision Nov 2013
  - Reason for revision to “correct factual mistakes in chapters 5.5 and 6.3, give more explanations on the rationale for the revision and provide a formal date of coming into operation”
- Valid date 24 Nov 2013
- Q&A document published 28 March 2014



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EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – quality, safety and efficacy

Brussels,

GOOD DISTRIBUTION PRACTICE FOR MEDICINAL PRODUCTS FOR HUMAN USE

QUESTIONS AND ANSWERS

VERSION 1.0

http://ec.europa.eu/health/files/gdp/2014-04_qas_.pdf

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Key EFPIA comments to the draft GDP guideline

- EFPIA seeks to ensure that there is clarity and common understanding across industry and member states.

- Effective and consistent implementation in Industry and Health Authorities is critical in ensuring that the intent of the provisions is achieved.
  - Failing a common interpretation among the European Health Authorities will create uncertainty and unnecessary burdens on the industry to comply with the differences.
- Recommendation to use Q and A's to enhance consistency of interpretation. EFPIA is committed to working with other stakeholders and the EMA as required.

Post the Q&A publication - Key outstanding points

- Storage requirements for EU/non-EU goods
- Acceptable temperature limits for transportation
- Transportation limits and other parties in supply chain
- Temperature monitoring requirements
- Scope – temperature sensitive products
- Scope – investigational medicinal products

- National Q&A documents are being published – harmonisation within EU?
- Supply chains are global – harmonisation with other GDP guidelines?

Chapter 9 – Transportation conditions

- EFPIA believes that the objectives of the guideline can be **attained in a number of different ways**, depending on the shipping scenario and the technology employed. Consequently EFPIA believes that **flexibility** has to be maintained to allow companies to define distribution control strategies as proposed by the guideline.
  - The **use of science and risk based approaches** is a foundation for the effective implementation of this guidance.
  - Transportation requirements and control should be proportionate to the risks and **based on the specific storage or distribution scenario** under consideration.

Chapter 9 – Transportation conditions

- EFPIA's interpretation is that EU GDP embraces ICH Q9 and Q10 principles and thus

- **Science and risk based approaches** can be used to distribute product under limits broader than registered storage conditions.
- **Temperature controls** will be determined by the manufacturer based on a science and risk based assessment.
- Decisions concerning transportation and storage **temperature excursions** can be made with regard to **scientifically supported** impact on product quality and/or potential degradation.
- **Temperature monitoring of all shipments is not mandated** as qualification of routes is permitted as part of defining the control strategy

EU Comission Q&A document from March 2014

Question 22:

CONCERNING CHAPTER 9 – TRANSPORTATION, 9.2.(1), CAN WE DEVIATE FROM STORAGE CONDITIONS IF THE MANUFACTURER AGREES TO THE TRANSPORTATION OF THE PRODUCT WITHIN A CERTAIN TEMPERATURE RANGE (2°-25°C) FOR A LIMITED TIME FRAME OF 6 HOURS?

- Answer: No. Storage temperature limits as described by the manufacturer or on the outer packaging need to be respected for each stage of transport during the whole transport chain.

EFPIA's 2013 inspection survey

- 13 Inspectorates performed GDP inspections
- 8 different EU inspectorates performed 11 GDP inspections

EMA Inspectorate	Sum
France (ANSM)	2
Spain (AEMPS)	2
Germany	2
UK (MHRA)	1
Sweden (MPA)	1
Netherlands (IGZ)	1
Denmark	1
Ireland (IMB)	1
Total	**11**

Inspectorates	Sum
USA	22
EU	11
Brazil	4
Canada	3
Switzerland	3
Peru	2
Russia	2
South Africa	1
Argentina	1
Israel	1
Pakistan	1
Morocco	1
New Zealand	1

EFPIA's 2013 inspection survey

- GDP is being implemented in more and more countries all over the world
- GDP topics are increasingly included in GMP inspection activities
- Nearly all 'GDP only' inspections are performed domestically
- 10 of 22 companies included comments that GDP was explicit in the focus of their inspections

Keep in mind: No clear definition of 'GDP inspection' (e.g. just 'warehouse walk-through', a deep inspection of entire supply chain…)

Summary and conclusions

- EFPIA seeks confirmation that EU GDP embraces ICH Q9 and Q10 principles – important to allow science and risk based decisions
- Supply chains are global - critical with a consistent implementation across EU and harmonisation with global legislation
- EFPIA has put forward an update of the Q&A document, also seeking further dialogue with the Commission and the EMA GMDP Inspectors working group, for a harmonised implementation of the GDP guideline

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