

GDP for APIs

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**Guidelines
of 19 March 2015
on principles of Good Distribution Practice of
active substances for medicinal products for
human use**

(2015/C 95/01)

Introduction & Scope of the Guideline



INTRODUCTION:

- Legal basis Article 47 (4) of Directive 2001/83/EC
- Same principles as Chapter 17 (Agents, Brokers, Traders, Distributors, Repackers, and Relabellers), Part II GMP Guide
- Stand-alone guidance for importers and distributors
- Any manufacturing activities are subject to GMP (1252/2014 and Part II)
- Distributors of APIs for medicinal products for human use by **21 September 2015**

Chapter 1 - SCOPE:

- Active substances for medicinal products for human use
- Distribution shall comprise all activities (procuring, importing, holding, supplying or exporting), apart from brokering
- Guideline does not apply to intermediates of active substances

Content of the Guideline



- **Chapter 2 – Quality System**
- **Chapter 3 – Personnel**
- **Chapter 4 – Documentation**
- **Chapter 5 – Premises and Equipment**
- **Chapter 6 – Operations**
- **Chapter 7 – Returns, Complaints and Recalls**
- **Chapter 8 – Self-Inspections**
- **Annex – Glossary of terms**