

Rules and Guidance for Pharmaceutical Manufacturers and Distributors 'The Orange Guide'

Product Description

Since its first publication in 1971, Rules and Guidance for Pharmaceutical Manufacturers and Distributors (commonly known as "The Orange Guide") has been an essential reference for all involved in the manufacture or distribution of medicines in Europe. The Orange Guide collates in one convenient and authoritative source European and UK guidance documents and information on legislation relating to the manufacture and distribution of medicines for human use.

**Compiled by the Inspection and Standards Division,
Medicines and Healthcare products Regulatory Agency
(MHRA), London, UK.**

Purpose

To bring together the main pharmaceutical regulations, directives and guidance which manufacturers and wholesalers are expected to follow when making and distributing medicinal products in the European Union and European Economic Area.

Key Coverage

- Detailed changes to the EU guide to good manufacturing practice
- Detailed revisions to the EU Directive on medicinal products for human use
- The new Directive on the Principles and Guidelines on Good Manufacturing Practice of Medicinal Products for Human Use

Updates

Content is revised on a regular basis to take into account changes to European and national legislation and guidance documents. All revised content undergoes a series of rigorous checking procedures.

Focus

Covers the UK and EU Member countries

Audience

- Holders of pharmaceutical manufacturer's licences
- Holders of pharmaceutical wholesale dealer's licences
- Qualified Persons (QPs)
- Responsible Persons (RPs)
- Global relevance

Contact us for further information, pricing and trials:

E-mail: sales@medicinescomplete.com

Tel: +44 (0) 20 7572 2464

Web: www.medicinescomplete.com