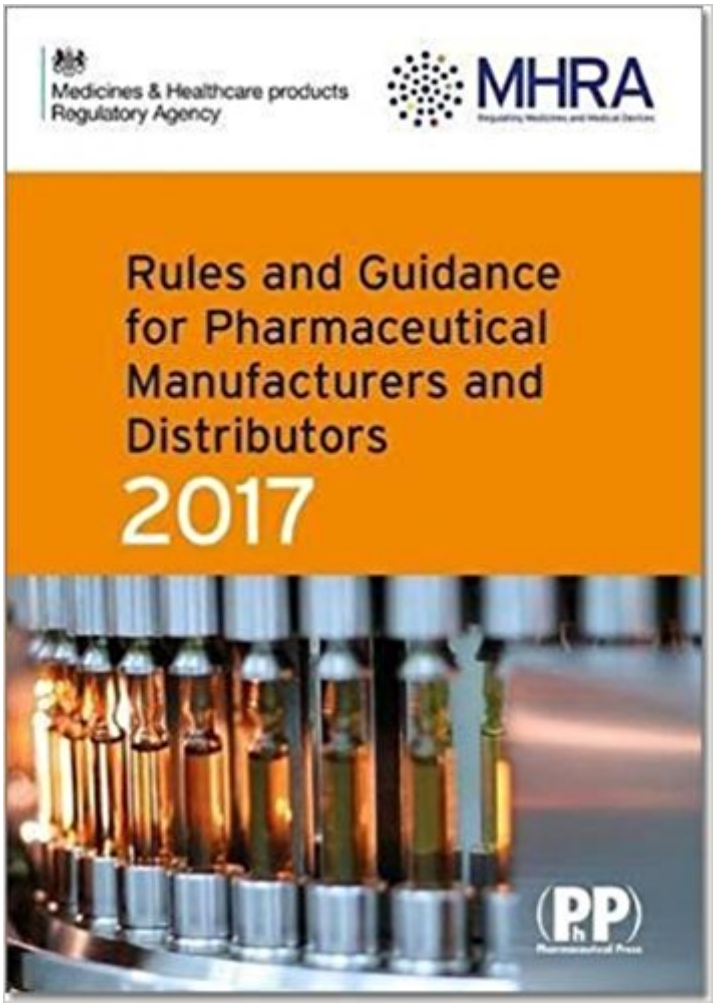
Rules And Guidance For Pharmaceutical Manufacturers And Distributors (Orange Guide) 2017



Synopsis

Familiarly known as the Orange Guide, this title is an essential reference work for all those involved in the manufacture and distribution of medicines in Europe. It is compiled by the UK drug regulatory body, MHRA, and brings together the European and UK guidance documents and information on legislation relating to the manufacture and distribution of medicines for human use. It contains EU guidance on good manufacturing and good distribution practice along with relevant information on EU and UK legislation. Changes in this new edition:Revised Annex 15. The revision of Annex 15 takes into account changes to other sections of the EudraLex, Volume 4, Part I, relationship to Part II, Annex 11, ICH Q8, Q9, Q10 and Q11, QWP guidance on process validation, and changes in manufacturing technology.Revised Annex 16. The GMP Guide Annex 16 has been revised to reflect the globalisation of the pharmaceutical supply chains and the introduction of new quality control strategies. The revision has been carried out in the light of Directive 2011/62/EU amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of falsified medicinal products. This version also implements ICH Q8, Q9 and Q10 documents, and interpretation documents, such as the manufacturing and importation authorisation (MIA) interpretation document, as applicable. Also, some areas, where the interpretation by Member States has not been consistent, have been clarified. This revised Annex came into operation 15 April 2016.The introduction of guidelines on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities.The introduction of guidelines on the formalised risk assessment for ascertaining the appropriate GMP for excipients.The addition of the Guidelines on principles of Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01).These guidelines provide stand-alone guidance on Good Distribution Practice (GDP) for manufacturers, importers and distributors of active substances for medicinal products for human use. These guidelines should be followed as of 21 September 2015.The addition of the principles and guidelines of Good Manufacturing Practice (GMP) for active substances for medicinal products for human use, including active substances intended for export.Revisions to the UK Human Medicines Regulations 2012.MHRA GMP Data Integrity Definitions and Guidance for Industry is now included which sets out MHRA expectations for data integrity in good manufacturing practice (GMP). The Guidance complements existing EU GMP guidance and should be read in conjunction with national medicines legislation and the GMP standards published in Eudralex volume.

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Easy to use and didn't encounter any problem.

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