



Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2015: The Orange Guide

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Familiarly known as the "Orange Guide," this title is an essential reference work for all those involved in the manufacture or distribution of medicines in or for Europe. It is compiled by the UK drug regulatory body, the 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. This 2015 edition of Rules and Guidance for Pharmaceutical Manufacturers and Distributors (the Orange Guide) has been updated to incorporate changes made to Chapter 6 Quality Control of the detailed European Community guidelines on Good Manufacturing Practice (GMP) which came into operation on 1 October 2014 and the revised EU Guidelines on Good Distribution Practice.

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