



Use of Quality Risk Management for ensuring Good Distribution Practice

By Adrian Busuttil

LAP Lambert Academic Publishing Okt 2014, 2014. Taschenbuch. Book Condition: Neu. 220x150x16 mm. Neuware - The European Commission introduced Quality Risk Management (QRM) for medicinal product wholesale dealers (MPWD) to ensure Good Distribution Practice (GDP), through the publication of the new EU-GDP guidelines in March 2013. This book serves as a template in the setting up of a QRM system by a MPWD. First, a Quality Management System (QMS) consisting of a number of Standard Operating Procedures (SOPs) regulating each distribution activity is set up. Then medicinal product distribution steps and risks are identified. Finally a QRM exercise is applied to the identified risks. Risks are classified as being acceptable or not acceptable. Corrective and Preventive action is proposed to mitigate unacceptable risks in the distribution of medicinal products. A model Quality Risk Management SOP and a Disaster Recovery SOP are proposed and also presented in this publication. 272 pp. Englisch.

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