

# Rules And Guidance For Pharmaceutical Distributors Green Guide 2015

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2 USP, Chapter <797>: Pharmaceutical Compounding - Sterile Preparations, (It is important to note that while FDA states that compounding does not include products prepared according to package labeling, FDA-approved labeling (ie, the product package insert) rarely describes environmental quality (eg, ISO Class air designation, exposure durations to non-ISO classified air, personnel

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For the purposes of this guidance document, the definition of a pharmaceutical has been adapted from the definition of a drug under Chapter 43-15 NDCC Therefore, "pharmaceutical" refers to any articles recognized as drugs in the official United States pharmacopeia, official national

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Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2013: "The Orange Guide" , Mhra, May 1, 2013, Medical, 448 pages

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