Labmix24 GmbH
Kesseldorfer Rott 24
46499 Hamminkeln
Germany

Tel: +49 (0) 2852 96064 00
Fax: +49 (0) 2852 96064 24
Web: www.labmix24.com
E-Mail: info@labmix24.com

cGMP: A Quality Systems Approach for APIs (Classroom)

Art. ID	USP-CH-GMP-01
Unit	Each
Deliverydetails	No Dangerous Good

Description

"Active Pharmaceutical Ingredients (APIs) have to be manufactured in accordance with cGMPs, according to the Food, Drug, and Cosmetic Act. However, the relevant specific regulations for APIs are not included in 21 CFR, but were published in a Guidance for Industry, “Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients,"" in August 2001. In this two-day classroom course, the basic concepts of Good Manufacturing Practices (GMPs) and their applications to the manufacture of APIs as set forth by the ICH Q7 Guideline will be discussed. An introduction to ICH Q7 Guideline (FDA Q7A Guidance) and Quality Management Systems (QMS) for API manufacture will be provided along with their principles and applications for API manufacture. Furthermore, general requirements for qualification of API manufacturing personnel, buildings, facilities, manufacturing equipment, materials management, warehousing, and distribution procedures will be discussed. The attendees need to have a working knowledge of cGMPs for drug products (21 CFR, Parts 210-211) along with a basic understanding of chemical and biological processes in the manufacture of APIs."