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Good distribution practices (cGDP) and related regulatory affairs at the Brazilian supply chain

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Abstract

ANVISA – Health Surveillance National Agency – recently published the RDC 39 / 2013 in August 14th, which changed the administrative procedure to certify good manufacturing practices to medicine, pharmaceutical raw material, medical devices, health care and home care products. Also, it certificates storage and distribution procedures of these products. This new regulation simplifies the procedures to obtain these certifications by replacing ten other previous legislations. Ensuring these products` quality from production to dispensation in a big country with continental dimensions like Brazil is an important challenge to the current good distribution practices. This presentation will address the RDC 39/2013 certification on good distribution practices (cGDP) compared with guidelines already recognized worldwide as USP 35 / <1079> Good Storage and Shipping Practices and WHO Technical Report Series, No. 908, 2003 / Annex 9 / Guide to good storage practices for pharmaceuticals. Moreover, it will discuss the Brazilian logistic and transport scenario after the current administrative changes and the good practices used throughout the supply chain.

Biography

Frederico Rapussi, pharmacist, has completed his MBA in Project Management from São Paulo University (USP) in 2011 and graduated as a pharmacist from UNESP in 2006. He has expertise at the logistic scenario in activities related to regulatory affair, quality system and logistic projects to storage and distribution according to cGDP. He has expertise upon international planning, training and following up international inspection for GDP certification, government approvals for medicines, pharmaceutical raw material, medical devices, health care and home care products good practices certification, quality management and human resources training for quality guarantee system issues.