

Manufacturer of VMPs, control laboratory and manufacturer of APIs are obliged to follow requirements defined in the Act No. 378/2007 Coll., on pharmaceuticals, and guidelines of European Commission and European Medicine Agency (EMA)

ÚSKVBL publishes further guidance documents to facilitate compliance of stakeholders with these requirements and publishes EU GMP Guide (Volume IV of The Rules Governing Medicinal Products in the European Union – EU Guidelines to Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use - English version available on web page of European Commission) in the Czech language.