



## **EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines.**

Volume 4 of "The rules governing medicinal products in the European Union" contains guidance for the interpretation of the principles and guidelines of good manufacturing practices for medicinal products for human and veterinary use laid down in Commission Directives 91/356/EEC, as amended by Directive 2003/94/EC, and 91/412/EEC respectively.

### **Introduction**

- Introduction (7/02/2011)
- Commission Directive 2003/94/EC, of 8 October 2003, laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use  
Replacement of Commission Directive 91/356/EC of 13 June 1991 to cover good manufacturing practice of investigational medicinal products.
- Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products.

### **Part I - Basic Requirements for Medicinal Products**

- Chapter 1 Pharmaceutical Quality System (into operation since 31 January 2013)
- Chapter 2 Personnel (into operation since 16 February 2014).
- Chapter 3 Premise and Equipment (into operation since 1 March 2015)
  - See transitional arrangement for toxicological evaluation on page 1 of Chapter 3
  - Previous
- Chapter 4 Documentation (January 2011)

# Eudralex Volume 4 Gmp Guide

**Yi-Tong Ma**



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