

## VOLUME 4 Good manufacturing practices

### Medicinal products for human and veterinary use :

EudraLex <http://dg3.eudra.org/F2/eudralex/vol-4/home.htm>

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	Commission Directive <a href="#">2003/94/EC</a> , 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 <a href="#">91/356/EC</a> of 13 June 1991 to cover good manufacturing practice of investigational medicinal products.	
	Commission Directive <a href="#">91/412/EEC</a> of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products.	
	<b>BASIC REQUIREMENTS</b>	
<b>Chapter 1</b>	Quality Management	EN
	● <b>"Product Quality Review - Addition to Chapter 1 to the EU Guide to Good Manufacturing Practice"</b>	EN
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	● <b>"On going Stability - Addition to Chapter 6 to the EU Guide to Good Manufacturing Practice"</b>	EN
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[EMEA's inspection website "Compilation of Community Procedures"](#)