PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PE 009-10 (Intro)
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# GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS



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# INTRODUCTION

## General

In order to further facilitate the removal of barriers to trade in medicinal products, to promote uniformity in licensing decisions and to ensure the maintaining of high standards of quality assurance in the development, manufacture and control of medicinal products, the following Guide to Good Manufacturing Practice for Medicinal Products and its Annexes has been adopted.

The standards set out herein apply to medicines and similar products intended for human use. It is recommended, however, that the same kind of attention be given to the manufacture of veterinary products. Administrative measures of national health authorities should be directed towards the application of these standards in practice, and any new or amended national regulations for good manufacturing practice should at least meet their level. These standards are also intended to serve manufacturers as a basis for the elaboration of specific rules adapted to their individual needs.

It is recognised that there are acceptable methods, other than those described in this Guide, which are capable of achieving the principles of the Guide. This Guide is not intended to place any restraint upon the development of new concepts or new technologies, which have been validated and provide a level of Quality Assurance at least equivalent to those set out in this Guide.

The Guide is divided into two parts and a number of annexes which are common to both parts. Part I covers GMP principles for the manufacture of medicinal products. Part II covers GMP for active substances used as starting materials. The annexes provide detail on specific areas of activity. For some manufacturing processes, different annexes will apply simultaneously (e.g. annex on sterile preparations and on radiopharmaceuticals and/or on biological medicinal products). A glossary of some terms used in the Guide has been incorporated after the annexes. A specific glossary for APIs can be found at the end of Part II.

## History

*Part I of the PIC/S GMP Guide*

Originally, the PIC/S GMP Guide (“PIC Basic Standards” of 1972) derives from the WHO GMP Guide and was further developed in order to comply with stringent manufacturing and health requirements in PIC/S countries, to cover new areas (e.g. biologicals, radiopharmaceuticals, etc.) and to adapt to scientific and industrial technology (e.g. biotech, parametric release etc.). The aim of such improvements was to ensure that high quality medicines were produced in line with the PIC Convention and then the PIC Scheme.

In 1989, the EU adopted its own GMP Guide, which – in terms of GMP requirements – was equivalent to the PIC/S GMP Guide. Since that time, the EU and the PIC/S GMP Guides have been developed in parallel and whenever a change has been made to one, the other has been amended so that both Guides are practically identical.

There are, however, some differences between the two Guides. These differences are the following:

- the definition of Pharmaceutical Product (referred to as “Medicinal Product” in this Guide), which is found in Article 1 of the Pharmaceutical Inspection Convention, has been retained;
- references to the EU Directives, as well as to MRAs, have been deleted;
- the expression “authorised person” (see Glossary) is used in the PIC/S Guide while the expression “Qualified Person” is used in the EU Guide;
- since not all Participating Authorities under the PIC Scheme are parties to the European Pharmacopoeia Convention, the mention of “European Pharmacopoeia” in the Guide has been amended to read “European or other relevant Pharmacopoeia”.

*Part II of the PIC/S GMP Guide*

On 22 May 2001, the PIC/S Committee adopted the “Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients” (ICH Q7A) developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) as a stand-alone guide (PE 007). It is recalled that the first draft of this GMP Guide for APIs was elaborated by PIC/S, before it was transferred to ICH. At its Düsseldorf meeting on 29-30 May 2006, the PIC/S Committee decided to make it Part II of the current Guide.

# ADOPTION AND ENTRY INTO FORCE

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| Adoption by the Committee of PE 009-10 | 2 October 2012 |
| Entry into force of PE 009-10 | 1 January 2013 |

# REVISION HISTORY

| Date | Version Number | Reasons for revision |
|---|---|---|
| 21 December 2000 | PH 1/97 (Rev.) | ➢ Revision of Annex 14<br>➢ Renumbering of all annexes<br>➢ Change in the editor’s address and insertion of copyright statement<br>➢ Inclusion of revision history |
| 10 August 2001 | PH 1/97 (Rev. 2) | ➢ Amendment of para. 42 of Annex 1<br>➢ Revision of Annex 6<br>➢ New Annex 15<br>➢ New Annex 17<br>➢ Amendment to the glossary |

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| 15 January 2002 | PH 1/97 (Rev. 3) | ➢ New Annex 4<br>➢ New Annex 5<br>➢ Reference to Annex 18 of EC GMP Guide |
| 1 September 2003 | PE 009-1 | ➢ Amendment of Annex 1 (mainly section 3) |
| 1 July 2004 | PE 009-2 | ➢ Revision of Annex 13<br>➢ Change in the Editor's co-ordinates |
| 1 January 2006 | PE 009-3 | ➢ Revision of Chapter 1 |
| 1 June 2006 | PE 009-4 | ➢ Revision of Chapter 6 |
| 1 August 2006 | PE 009-5 | ➢ Corrections to revision of Chapter 6<br>➢ Revision of Chapter 8 |
| 5 April 2007 | PE 009-6 | ➢ Reorganisation of the PIC/S GMP Guide in Part I, Part II and Annexes<br>➢ Incorporation of PE 007 (APIs guide) as Part II<br>➢ New Annex 19<br>➢ Revision of the Introduction<br>➢ Change in the Editor's co-ordinates |
| 1 September 2007 | PE 009-7 | ➢ Revision of General Introduction ("History") and Introduction to Part II<br>➢ Deletion of footnotes in Chapter 6 (Part I) and Annex 13 |
| 15 January 2009 | PE 009-8 | ➢ Revision of Chapter 1 (Part I)<br>➢ Revision of Annex 1<br>➢ New Annex 20 |
| 1 September 2009 | PE 009-9 | ➢ Revision of Annex 3 |
| 1 January 2013 | PE 009-10 | ➢ Revision of Chapter 4 (Part I)<br>➢ Revision of Annex 6, 7, 11 & 13 |