World Health Organization

Production

Good manufacturing practice (GMP) is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization. GMP is aimed primarily at diminishing the risks inherent in any pharmaceutical production, which may broadly be categorized in two groups: cross contamination/mix-ups and false labelling. Above all, manufacturers must not place patients at risk due to inadequate safety, quality or efficacy; for this reason, risk assessment has come to play an important role in WHO quality assurance guidelines.

WHO good manufacturing practices

:: Quality assurance of pharmaceuticals: a compendium of guidelines and related materials [pdf 4.82Mb]
Volume 2, 2nd updated edition

:: Good Manufacturing Practices for Pharmaceutical Products: Main Principle [pdf 632kb]
Annex 4, WHO Technical Report Series 908, 2003

:: Good manufacturing practices: requirement for the sampling of starting materials (amendment)
Annex 2, WHO Technical Report Series 929, 2005

:: Frequently Asked Questions: Good Manufacturing Practice (GMP) in Pharmaceutical Practice

:: Active pharmaceutical ingredients (bulk drug substances)
Annex 2, WHO Technical Report Series 957, 2010

:: Pharmaceutical excipients [pdf 7Mb]
Annex 5, WHO Technical Report Series 885, 1999

:: Sterile pharmaceutical products [pdf 1Mb]
Annex 4, WHO Technical Report Series 957, 2010

:: Biological products [pdf 1.5Mb]
Annex 3, WHO Technical Report Series 834, 1993

:: Pharmaceutical products containing hazardous substances [pdf 1Mb]
Annex 3 WHO Technical Report Series 957, 2010

:: Investigational pharmaceutical products for clinical trials in humans [pdf 4Mb]
Annex 7, WHO Technical Report Series 863, 1996

:: Herbal medicinal products [pdf 4Mb]
Annex 3, WHO Technical Report Series 937, 2006

:: Radiopharmaceutical products [pdf 632kb]
Annex 3, WHO Technical Report Series 908, 2003

:: Water for pharmaceutical use
Annex 3, WHO Technical Report Series 929, 2005

:: Heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms
Annex 2, WHO Technical Report Series 937, 2006

:: Validation
Annex 4, WHO Technical Report Series 937, 2006

Risk analysis

:: Application of Hazard Analysis and Critical Control Point (HACCP) Methodology in Pharmaceuticals [pdf 632kb]

Annex 7, WHO Technical Report Series 908, 2003

Training materials

:: WHO Basic Training Modules on GMP
(Includes an introduction, resource and study pack for trainers)

:: WHO supplementary training modules on GMP
(Includes drafts of GMP for Validation, Water, and Air Handling Systems)