



## **FOOD AND DRUGS AUTHORITY, GHANA**

# **GUIDELINE FOR GMP INSPECTION OF MANUFACTURING FACILITIES**

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## 1.0 INTRODUCTION

- 1.1 In pursuance to **Sections 124, 130 and 131 of the Public Health Act, 2012, Act 851 of the Republic of Ghana**, these Guidelines are hereby made to provide prospective applicants with information on the general requirements for the inspection of pharmaceutical product, herbal product and food supplement storage facilities.
- 1.2 These Guidelines apply to business entities duly registered by the Registrar-General Department with intention to establish Manufacturing facilities for the manufacture of pharmaceutical products, herbal products and food supplements.
- 1.3 The manufacturing process facilities shall be carried out under the supervision of a Pharmacist or a person approved by the Authority as having specialist knowledge in the article to be manufactured (Refer to FDA “Guidelines for Selection of Authorized Person in the Pharmaceutical and Chemical Industry”).

## 2.0 GLOSSARY

GMP : Good Manufacturing Practice  
GSP : Good Storage Practice  
TRS : Technical Report Series  
WHO : World Health Organization

## 3.0 REQUIREMENTS

GMP inspections of pharmaceutical facilities and food supplements shall be conducted in line with relevant WHO guidelines and their stated references. The latest versions of each guideline as revised by the WHO shall be applicable in each case;

- 3.1 WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty- eight Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. [http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/expert\\_committee/trs\\_986/en/](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/)
- 3.2 WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. <http://www.who.int/medicines/publications/44threport/en/>
- 3.3 WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-six Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2

[http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/expert\\_committee/trs\\_970/en/](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/)

- 3.4 WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4 [http://whqlibdoc.who.int/trs/WHO TRS 929\\_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1)
- 3.5 WHO guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 5 [http://whqlibdoc.who.int/trs/WHO TRS 961\\_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)
- 3.6 Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4 [http://whqlibdoc.who.int/trs/WHO TRS 937\\_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1)
- 3.7 WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1 <http://www.who.int/medicines/publications/44threport/en/>
- 3.8 WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2 <http://www.who.int/medicines/publications/44threport/en/>
- 3.9 WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6 [http://whqlibdoc.who.int/trs/WHO TRS 961\\_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)
- 3.10 WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7 [http://whqlibdoc.who.int/trs/WHO TRS 961\\_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)
- 3.11 Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health

Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9 [http://whqlibdoc.who.int/trs/WHO\\_TRS\\_961\\_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)

- 3.12 General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-First Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3 [http://whqlibdoc.who.int/trs/WHO\\_TRS\\_943\\_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1)
- 3.13 WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2 [http://whqlibdoc.who.int/trs/WHO\\_TRS\\_961\\_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)
- 3.14 WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2 [http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/expert\\_committee/trs\\_981/en/](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/)
- 3.15 WHO guidelines on variation to a prequalified product. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 3 [http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/expert\\_committee/trs\\_981/en/](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/)
- 3.16 WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14 [http://whqlibdoc.who.int/trs/WHO\\_TRS\\_961\\_eng.pdf?ua=1](http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1)
- 3.17 WHO Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 3 [http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/expert\\_committee/WHO\\_TRS\\_992\\_web.pdf](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf)
- 3.18 WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4 [http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/expert\\_committee/WHO\\_TRS\\_992\\_web.pdf](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf)

- 3.19 WHO Technical supplements to Model Guidance for storage and transport of time- and temperature – sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5  
[http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/expert\\_committee/WHO\\_TRS\\_992\\_web.pdf](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf)
- 3.20 WHO Recommendations for quality requirements when plant – derived artemisin is used as a starting material in the prosecution of antimalarial active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 6  
[http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/expert\\_committee/WHO\\_TRS\\_992\\_web.pdf](http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf)
- 3.21 WHO good manufacturing practices for biological products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 3  
[http://www.who.int/medicines/publications/pharmprep/WHO\\_TRS\\_996\\_annex03.pdf](http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex03.pdf)
- 3.22 Guidance on good data and record management practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 5  
[http://www.who.int/medicines/publications/pharmprep/WHO\\_TRS\\_996\\_annex05.pdf](http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf)
- 3.23 WHO general guidance on variations to multisource pharmaceutical products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10  
[http://www.who.int/medicines/publications/pharmprep/WHO\\_TRS\\_996\\_annex10.pdf](http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf)
- 3.24 WHO good manufacturing practices for biological products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 3  
[http://www.who.int/medicines/publications/pharmprep/WHO\\_TRS\\_996\\_annex03.pdf](http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex03.pdf)

**(SEE APPENDIX FOR THE TIMELINES FOR INSPECTION ACTIVITIES)**

## **APPENDIX: Timeline for GMP Inspection activities**





**TIMELINES FOR GMP INSPECTION**

