FOOD AND DRUGS AUTHORITY

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GUIDELINES FOR PUBLICATION OF REDACTED GFDA GMP INSPECTION REPORTS

Draft[1]

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Comments should be submit to manufacturingfacilities@fda.gov.gh	
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[1]Leave the wording 'Draft' if the guideline is adopted for release for public consultation. Delete the wording 'Draft' – but do NOT the delete the subtitle line it sits in.
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16 ## Document Revision History

Date of Revision	Version Number	Changes made and/or reasons for revision
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Guideline on <…>

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Executive summary

This document is a guideline that prescribes how GMP inspection reports shall be published on the FDA website after the conduct of inspection of manufacturing facilities for the purpose of licensing.

The guideline highlights the criteria for publishing of redacted versions of inspection reports, the format of the report as well as the role of the inspected facility in corroborating or otherwise the content of the report to be published.

The objective of publishing redacted GMP inspection reports is to build confidence and accountability of the licensing structure via enhanced transparency through public availability of information on inspections performed and reports from those inspections.

1. Introduction (background)

As part of the FDA's efforts at continual improvement to build confidence and accountability of the licensing structure it has become necessary for the Authority to enhance transparency through public availability of information on inspections performed and reports from those inspections.

This guideline thus provides guidance to FDA and the industry in respect of fulfilling this requirement to increase transparency in the operations of the inspectorate as well as customer satisfaction.

This guideline is hereby written to describe how redacted GMP inspection reports of manufacturing facilities shall be published on the FDA's website.

1.1. Legal Basis

1.1.1 The Food and Drugs Authority Ghana is the National Regulatory Authority under the ministry of Health of Ghana responsible for the safety and efficacy of medicines on the Ghanaian market towards the protection of the health of the Ghanaian populace.

1.1.2 In exercise of the powers conferred on FDA by Public Health Act, 2012, Act 851, Part Seven, Section 148, these guidelines apply to the publication of redacted GMP inspections reports for regulatory inspections performed for regulated products.

1.1.3 This guideline provides guidance to publication of redacted GMP inspection reports in accordance to Sections 97, 130 and 131 of the Public Health Act, 2012, Act 851 of the Republic of Ghana.

1.2. Scope

1.2.1 This guideline applies to publication of redacted GMP inspection reports of manufacturing facilities for FDA regulated products that has met the minimum requirements to be described a GMP compliant facility.

1.2.2 The redacted GMP inspection report shall provide a summary overview of the GMP inspection conducted in a particular facility that has met the minimum GMP requirements and would include a summary of the observations and findings made during the inspection.

1.2.3 These redacted GMP inspection reports shall be known and described as 'Ghana Food and Drugs Authority Public Inspection Report' (Abbreviated as; GFDAPIR).

2. Definitions and Abbreviations

2.1. Abbreviations

FDA : Food and Drugs Authority
GFDAPIR : Ghana Food and Drugs Authority Public Inspection Report
GMP **:** Good Manufacturing Practices
MS : Microsoft
SOP : Standard Operating Procedure
WHO : World Health Organization

2.2. Definitions

Authority
Means Food and Drugs Authority

Standard operating procedures
An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material (e.g. equipment operation, maintenance and cleaning; cleaning of premises and environmental control; sampling and inspection).

3. Requirements

3.1. Condition for publication of a facility's Inspection report

3.1.1 The GFDAPIR is prepared only when all critical or major non-compliances" have been satisfactorily corrected by the manufacturers or organizations. A GFDAPIR will be **prepared if the process of inspection and closing an inspection leads to an outcome that the site is compliant with** the GMP guidelines used in the conduct of the inspection.

3.1.2 The format of the GFDAPIR shall be as per appendix I of this guideline.

3.2. Content Requirement of the GFDAPIR Report

3.2.1 Products covered in the inspection shall be referred to in the report by their dosage forms and/ or therapeutic class and NOT by their Generic or proprietary name.

3.2.2 SOPs and any Standard documents shall be referred to by their titles and /or content but not by their unique reference numbers.

3.2.3 Equipment and machinery shall be referred to by their type (e.g., blender) but not model or asset number.

3.2.4 Statements on findings/ non-compliances shall be followed by a summary statement of what has been accepted, from the company's implemented or proposed corrective and preventive actions.

3.3 In-Put of The Inspected Facility

3.3.1 Draft GFDAPIR in "MS Word" format shall be sent to the inspected company requesting comments and corrections in "track change" mode, specifying that confidential and proprietary information should be removed.

3.3.2 Comments from the inspected company shall be considered and appropriately incorporated into the draft GFDAPIR.

3.3.3 The draft GFDAPIR shall be finalized only when the FDA and the inspected company have agreed on its content.

3.4 Validity of the Inspection Report on the Website

3.4.1 A published GFDAPIR shall remain valid over the validity period of the license or until the next inspection EXCEPT when other regulatory measures require otherwise.

References

Annex

APPENDIX 1

FDA GHANA, PUBLIC INSPECTION REPORT

(FDAGPIR)

Finished Product Manufacturer Name

Part 1	**General information**
Manufacturers Details	
Company information	
Name of manufacturer	
Corporate address of manufacturer	
Inspected site	
Address of inspected manufacturing site if different from that given above	
Unit / block / workshop number	
Manufacturing license number, (delete if not applicable)	
Inspection details	
Dates of inspection	
Type of inspection	
Introduction	
Brief summary of the manufacturing activities	

General information about the company and site	
History	
Brief report of inspection activities undertaken	
Scope and limitations	
Areas inspected	
Restrictions	
Out of scope	
Dosage form lines inspected	

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Abbreviations		
AHU	air handling unit	
ALCOA	attributable, legible, contemporaneous, original and accurate	
API	active pharmaceutical ingredient	
APQR	annual product quality review	
BDL	below detection limit	
BMR	batch manufacturing record	
BPR	batch packaging record	
CAPA	corrective actions and preventive actions	
CC	change control	
CFU	colony-forming unit	
CoA	certificate of analysis	
CpK	process capability index	
DQ	design qualification	
EM	environmental monitoring	
FAT	factory acceptance test	
FBD	fluid bed dryer	
FMEA	failure modes and effects analysis	
FPP	finished pharmaceutical product	
FTA	fault tree analysis	
FTIR	Fourier transform infrared spectrometer	

GC	gas chromatograph	
GMP	good manufacturing practice	
HACCP	hazard analysis and critical control points	
HPLC	high-performance liquid chromatograph	
HVAC	heating, ventilation and air conditioning	
IR	infrared spectrophotometer	
IQ	installation qualification	
KF	Karl Fisher	
LAF	laminar air flow	
LIMS	laboratory information management system	
LoD	limit of detection	
LOD	loss on drying	
MB	microbiology	
MBL	microbiology laboratory	
MF	master formulae	
MR	management review	
NMR	nuclear magnetic resonance spectroscopy	
NRA	national regulatory agency	
OQ	operational qualification	
PHA	*process hazard analysis*	
PM	preventive maintenance	
PpK	process performance index	
PQ	performance qualification	
PQR	product quality review	
PQS	pharmaceutical quality system	
QA	quality assurance	
QC	quality control	
QCL	quality control laboratory	
QRM	quality risk management	
RA	risk assessment	
RCA	root cause analysis	
SOP	standard operating procedure	
TAMC	total aerobic microbial count	
TFC	total fungi count	
TLC	thin layer chromatography	
URS	user requirements specifications	
UV	ultraviolet-visible spectrophotometer	

Part 2	Brief summary of the findings and comments (where applicable)

Brief summary of the findings and comments

1. Pharmaceutical quality system

2. Good manufacturing practices for pharmaceutical products

3. Sanitation and hygiene

4. Qualification and validation

5. Complaints

6. Product recalls

7. Contract production, analysis and other activities

8. Self-inspection, quality audits and suppliers' audits and approval

9. Personnel

10. Training

11. Personal hygiene

12. Premises

13. Equipment

14. Materials

15. Documentation

16. Good practices in production

17. Good practices in quality control

PART 3

Conclusion

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, a ,located at was considered to be operating at an acceptable level of compliance with WHO Good Manufacturing Practices for pharmaceutical products.

All the non-compliances observed during the inspection that were listed in the full report as well as those reflected in the FDAPIR, were addressed by the manufacturer, to a satisfactory level, prior to the publication of the FDAPIR.

This FDAPIR will remain valid for <x years>, provided that the outcome of any inspection conducted during this period is positive.

PART 4

List of GMP guidelines referenced in the inspection report

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/

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. 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/

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
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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

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

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/

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/

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

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

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

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

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

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/

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/

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

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

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

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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

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

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

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