EFFECTIVE DATE: 01st JANUARY, 2019

WAIVERS FOR cGMP INSPECTIONS OF PHARMACEUTICAL PRODUCTS, INNOVATOR VACCINES AND BIOLOGICAL PRODUCT MANUFACTURERS

In respect of the above, the Food and Drugs Authority (FDA) Ghana has instituted the following measures;

EXEMPTION CRITERIA

Companies from the following regulatory bodies and regions (countries) can have a waiver of on-site verification audit by the Food and Drugs Authority Ghana if they can provide the underlisted documents to the FDA Ghana for assessment towards registration of products:

<table>
<tr><th>INTERNATIONAL REGULATORY BODIES</th><th>COUNTRY</th><th>REQUIRED DOCUMENTS</th></tr>
<tr><td rowspan="3">ICH (International Council on Harmonization) members</td><td>USA</td><td rowspan="4">1. Copy and a certified English translation of the manufacturing authorization granted by local authorities.

2. Updated Site Master File (SMF) in accordance with WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report, Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14, that is not older than one year from its approval date and any furcated modification, including legible colored printouts of;
• Water treatment
• Air Handling Systems
These should include pipeline and instrumentation drawings (P & I Ds) in A3 or A2 format).

3. List of all the products (medicinal or other, include proprietary names and INN) manufactured on site.

4. A copy and a certified English translated copy of;
i. The last inspection report (full report)
ii. GMP certificates arising from inspections by local authority and/or PIC/S/WHO

• A copy of any warning letter or equivalent regulatory action issued by any authority to which the site provides or has applied to provide a product.</td></tr>
<tr><td>Japan</td></tr>
<tr><td>European Union</td></tr>
<tr><td>Therapeutic Goods Authority (TGA)-Australia</td><td></td></tr>
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		5. Corrective Action and Preventive Actions (CAPAs) and proof of CAPAs implementation emanating from last inspection report observations/deficiencies or any warning letter or equivalent regulatory action. 6. The recent Annual product Quality Review (APQR(s) of the concerned product(s), whose Batch Manufacturing Records (BMR) is submitted as per requirements in "8" below. (WHO good manufacturing practices: main principles for 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 3). 7. A confirmation by the senior QA representative that a full self-inspection or external audit dedicated to the product(s) has been performed and all matters dealt with. 8. Batch Manufacturing/packaging record(s) of the product(s) of interest. • The completed batch manufacturing/packaging record(s) including the analytical part for the most recent released batch of relevant product(s). 9. A list of any recalls in the last three years.
WHO pre-qualification compliant facilities		1. Applicant should have applied to the FDA Ghana to use the Collaborative Registration Procedure CRP-WHO (existing between FDA Ghana and WHO) for registration of the prequalified product from the facility in question. 2. Facility should have been inspected and WHO report available

Note:

- ✓ **All documents must have English versions if they are not originally in English**
- ✓ **Soft copies of documents on labelled CDs in pdf formats should be submitted**