



Kigali on 15/02/2024

Ref. N°: FDISM/FDIC/0699/FDA/2024

Good Manufacturing Practices (GMP) Stakeholders (All)

RE: Circular on public consultation and call for comments on regulatory documents

Reference is made to the Law N° 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority (Rwanda FDA) and determining its mission, organization and functioning especially in its article 8 paragraph 2, the Authority regulate compliance with quality standards relating to the manufacture, storage, sale, distribution, use, import and export, labels, packages and raw materials used in the manufacture of products regulated under this Law.

Rwanda FDA would like to inform GMP stakeholders and the general public that the draft of updated Guidelines on Good Manufacturing Practice Inspections for Pharmaceutical Manufacturing Facilities, Doc. No. FDISM/FDIC/GDL/012, is being circulated for public consultation and comments starting from 16th February 2024.

These guidelines have been uploaded to Rwanda FDA website <https://rwandafda.gov.rw/> under stakeholders rubric and will be available for 30 calendar days. The Authority Would to invite all GMP stakeholders to provide inputs/comments using comment form No ODG/QMS/FMT/023 and send the completed form to the email: info@rwandafda.gov.rw not later than 11/03/2024. Thereafter, there will be a stakeholder meeting to validate the inputs/comments.

Sincerely,

Prof Emile BIENVENU
Director General

