No.F.3-2/2005-Reg-I/Vol-II)
Government of Pakistan
**Drug Regulatory Authority of Pakistan**
TF Complex, 7th Mauve Area, G-9/4, Islamabad
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Islamabad, the 27th September, 2022

**CIRCULAR**

SUBJECT: - **VIRTUAL INSPECTION OF MANUFACTURERS ABROAD FOR REGISTRATION OF FINISHED DRUGS AND BIOLOGICALS**

I am directed to refer to the subject cited above.

2. The Policy Board of the Drug Regulatory Authority of Pakistan (DRAP) in the 40th meeting held on 09th March 2022 has granted approval for conducting remote virtual GMP Inspections for manufacturing facilities abroad.

3. Accordingly, DRAP will conduct remote virtual inspections for verification of GMP compliances by overseas manufacturing facilities. This Remote Virtual Inspection (RVI) program will utilize a risk-based approach based on the complexity of each product. The applicants will ensure adequate communication tools, both for desktop review of information and video inspection at the site including videoscopes, inspection cameras, borescopes, fiberscopes, etc., depending on the operations at the manufacturing site. However, in order to avoid any potential serious threat to public health where the manufacturing sites cannot be assessed remotely, a hybrid inspection approach or an onsite inspection will be considered.

4. Furthermore, DRAP has reviewed methodologies for remote virtual inspection being adopted by various Reference Regulatory Authorities (RRAs) and recommends adaptation of "US FDA - Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency, published on April 2021 as guidance for industry on the conduction of remote virtual inspections for finished pharmaceutical drugs and biologicals (available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/remote-interactive-evaluations-drug-manufacturing-and-bioresearch-monitoring-facilities-during-covid).

5. It is hereby circulated for compliance and information of all stakeholders.

**Muhammad Sarfraz Nawaz**
Assistant Director (I&V-I&II)

**Distribution: -**
i. Chairman, Pakistan Pharmaceutical Manufacturers Association, Islamabad.
ii. Executive Director, Pharma Bureau, Karachi.
iii. Executive Director/Chairman, Pakistan Chemist & Druggists Association (PCDA), Karachi.

**Copy for information to: -**
1. Director, Pharmaceutical Evaluation & Registration, DRAP, Islamabad.
2. Director, Biological Evaluation & Research, DRAP, Islamabad.
3. PS to Chief Executive Officer, DRAP Islamabad.
4. Director, MIS Division, with the request to upload on DRAP website.
5. Office File.