Philippine Clinical Research Professionals, Inc.

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03 Jul 2025
PFDA Kapihan Q2 2025
PCRP BOD Attendees: Fridee Ortega, President; Gigi Guerina, Ways & Means Head

Discussion with Dr. Tagaro, Clinical Research Section Head	a) PCRP requested for a courtesy meeting to introduce the new BOD *(Post-Meeting Note: Formal request letter was sent to PFDA on 07 July, acknowledged and endorsed to the Office of the Director General on 08 July)* b) PFDA expects the industry to drive the adoption of ICH GCP E6 R3 c) PFDA assured PCRP of continued collaboration; PCRP can initiate requests and provide proposals to PFDA by submitting a formal letter d) Ongoing manpower issue in PFDA *(Note: Refer to updates from Director Matienzo)* e) Ongoing work on the revision of AO 2020-0010 (Regulations on the Conduct of Clinical Trials for Investigational Products); PFDA's call to the industry - Raise comments and clarifications for the upcoming AO 2020-0010 revision f) Ongoing discussion and collaboration among PHREB, PFDA, SJREB; no further details provided g) Pre-Assessment Process i) Aims to verify completeness and quality of pack (eg, supporting documents and rationale of amended documents must be present; information reflected must be consistent across the pack) ii) If there are issues with GMP documentation, a query may be raised by PFDA and can result to delays in the issuance of a Regulatory Reviewer with Permit (RRP) iii) If the pre-assessment outcome is positive, the pack will be directly assigned to a Regulatory Reviewer to issue an RRP. iv) Together with the suspension of the A.O. 2024-0016 || Implementing Guidelines on the New Schedule of Fees and Charges of the Food and Drug Administration) though not explicitly stated, pre-assessment process is suspended until further notice. Refer to attached Department Circular No. 2025-0240.

	h) Other reminders from PFDA i) Submit a list of sites/PI and include the PHREB Level 3 accredited oversight Research Ethics Committee (REC) ii) It is required to submit as notification the REC acknowledgement receipt for each site during the PFDA submission phase; ensure to reference the document tracking number (DTN) in the notification iii) PFDA may recommend the submission of the REC approval before the release of the Conduct of Approval of Trial i) Dr. Tagaro will be OOO on 16 July – 02 August
Updates from Director Matienzo ***Previous Center for Drug Regulation and Research (CDRR) Director IV***	a) Priority Issuances from CDRR i) Product classification for CPR application ii) Variation for CPR application iii) Revision of AO 67 (Revised Rules and Regulations on Registration of Pharmaceutical Products for Small Molecules and Biologicals) b) Temporary suspension of fees A technical working group (TWG) is currently working on this; no further details provided on the scope of review and possible changes c) AO 2024-013 (General Rules and Regulations on the Registration of Pharmaceutical Products and Active Pharmaceutical Ingredients Intended for Human Use): Tentative public consultation on 17 July 2025 d) Approved manpower budget and position from Department of Budget and Management (DBM) – 10 headcounts pending for hire, and another 20 headcounts for hire by Q4 2025 e) Priorities: i) Manpower ii) Digitalization iii) Payment channels
Q&A	a) Question on pre-licensing inspection for CRO licensing reviewal application of LTO: Will pre-inspection be applicable? Response from Ms. Jen Licensing and Registration Division (LRD) A.O. 2024-0015 (Administrative Order No.2024-0015 || Prescribing the Rules, Requirements and Procedures in the Application for License to Operate of Covered Health Product

	Establishments with the Food and Drug Administration Repealing for the Purpose Administrative Order No. 2020-0017) ○ Regular renewal - with surcharge and pre-licensing inspection ○ Major variation - with pre-licensing inspection ○ Automatic renewal- no pre-licensing inspection b) For Inspection with CAPA submitted and AOR received, what is the next step? Response: Ms. Jen - Once acknowledged by Inspectors and no further comment on CAPA, this confirms closure and PFDA also updates in their system

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