Philippine Clinical Research Professionals, Inc.

16 October 2025
2025 (Q3) CDRR Kapihan at Talakayan with the Industry

PCRP BOD Attendees: Fridee-May Ortega, President; Geradine Guerina, Head of Ways and Means Committee

PFDA Attendees: Dr. Charmaine Rabago, OIC, Director IV, CDRR; Dr. Iris Conela Tarago, CRS Head; Other CDRR Heads and PFDA Team

**Note: Photos of slides presented will be appended in this communication for more details. Captured below key highlights relevant to our industry.*

I. Opening Remarks	Presented by: Dr. Charmaine Ann M. Rabago (OIC, Director IV, CDRR) • Welcomed all participants from various stakeholders. • First Kapihan of Dr. Maan, with CDRR for 4 mos. • Key priorities: To co-create, collaborate with stakeholders ensuring honesty, transparency and maintaining open discussion. Having solution-focused mindset and reform-oriented.
II. Status of Deliverables from the Previous Kapihan	Presented by: Ms. Gladys Jane Martinez (FDRO III) • Suspension of fees- 23Oct F2F Public Consultation, details to be provided by PPO to stakeholders once settled
III. FDA & CDRR Updates	Presented by: Dr. Charmaine Ann M. Rabago (OIC, Director IV, CDRR) & Ms. Melody Zamudio (FDRO V, Chief, CDRR) • Digitalization and backlog reduction - eLTO, eCPR systems - Payment channel integration: auto-posting • Policy Reforms - Approval & renewal system: risk-based approach; reliance mechanism on stringent regulatory authorities (SRAs) - workforce strengthening: additional human resources - Maturity level 3: evidence-based and scientific-driven approach; enables mutual recognition or work-sharing on drug reviews which can accelerate access to medicines - Revision of A.O. 2020-0010 planned in Q3 2026 - FDA Circular on Regulatory Review
IV. FDAC Updates	Presented by: Ms. Blezelda A. Espinosa (Information Officer III) • Soft launch of the new FDAC effective 29 Oct 2025, full operations on Nov 2025 reference: FDA Advisory No. 2025-1366 • The following frontline transactions shall be accommodated during the FDAC Soft launch: -Receiving inquiries, follow-ups and complaints via the Public Assistance and Compaint Desk (PACD)

	-Receiving parcels, product samples and documents via PhilPost and courier services. • FDAC transition from analog-type telephones to soft phones • Plan to have Officer of the Day per Center (await for PFDA Advisory) • Scheduling of Over-the Counter Payment at FDA Cashier -FDA Advisory No. 2025-1363 -FDA Advisory No. 2024-0320
V. Discussion of Key Takeaways/Ways Forward	Presented by: Dr. Charmaine Ann M. Rabago (OIC, Director IV, CDRR) • Currently, the FDA is advancing its digitalization efforts and addressing existing backlogs. • The FDA aspires to be recognized as a mature regulatory authority by international standards (i.e. ML-3 under the WHO GBT, PIC/S GMP) • Strategy through evidence-based approach, mutual recognition of the regulatory reviews in medicine approvals and regulatory compliance. • In 2025, the FDA has undertaken preparatory activities and submitted its progress report under the WHO Global Benchmarking Tool (GBT). Re-benchmarking efforts are ongoing, with a virtual IDP follow-up targeted for Q1 2026 and possible formal benchmarking in Q2-Q3 2026.
VI. Others/Offline Discussion with Dr. Tagaro	Q & A: a. Q: Use of genAI tools and PFDA stand. A: PFDA is aligned with innovation per ICH GCP E6 R3 b. Q: PFDA's stand in accepting Phase 1 (treatment) including FIH trials. A: Acceptable, ensure capacity of Phase 1 CT site, required medical team managing medical emergencies c. Q: SJREB-related changes to the Country ICF for prior approval of PFDA. A: Current recommendation, PFDA accepts parallel submission, will release once SJREB approval is received. To be captured in revision of A.O. open to industry inputs Other Matters: a. No application holiday apart from regular government declared holidays b. Open to receive industry position papers c. Encouraged and requested PCRP to provide consolidated inputs even prior receipt of Draft A.O. for revision d. Feedback on Format requirement for submissions: no explicit formal requirement as long as TOC per A.O. 2020-0010 is complied with e. Requests received from PFDA for old studies on EOT, IP Disposition reports: Part of PFDA strict surveillance particularly on IP status of return or destruction after study closure. In case company is unable to obtain evidence or back-track (for old studies), ensure to

	declare to PFDA and provide available rationale and efforts of retrieval, IP report/accountability in lieu of the requested dispostion, if applicable.
VII. Closing Remarks	Presented by: Ms. Melody Zamudio (FDRO V, Chief, CDRR) Expressed thanks to the stakeholders for the constant open communication and sought patience as well on the internal transitions and further improvements ongoing within FDA.
VIII. Adjournment	The meeting was adjourned at 12:12 PM.
Group Photos	 

---------- End ----------