Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Egypt's Regulatory Updates

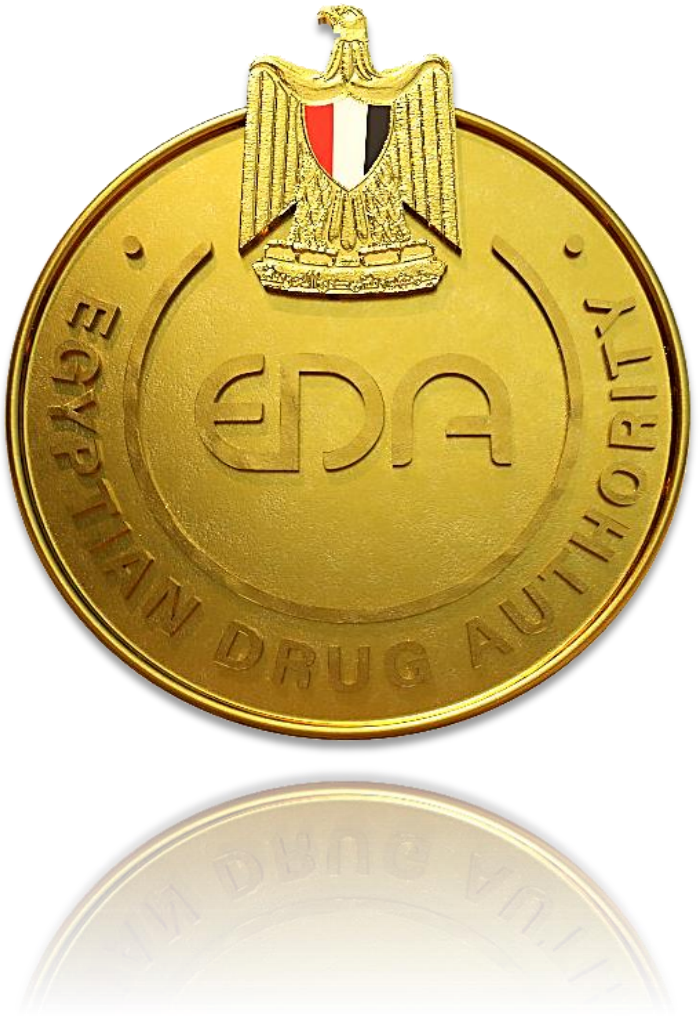
Dr. Rania Soliman,

General Manager of General Administration of

Medical Devices Marketing Authorization,

Central Administration of Medical Devices (CAMD)

The Egyptian Drug Authority (EDA)



28th GHWP Annual Meeting and 287th GHWP TC Meeting, 9th - 12th Dec 2024
Kuala Lumpur,Malaysia

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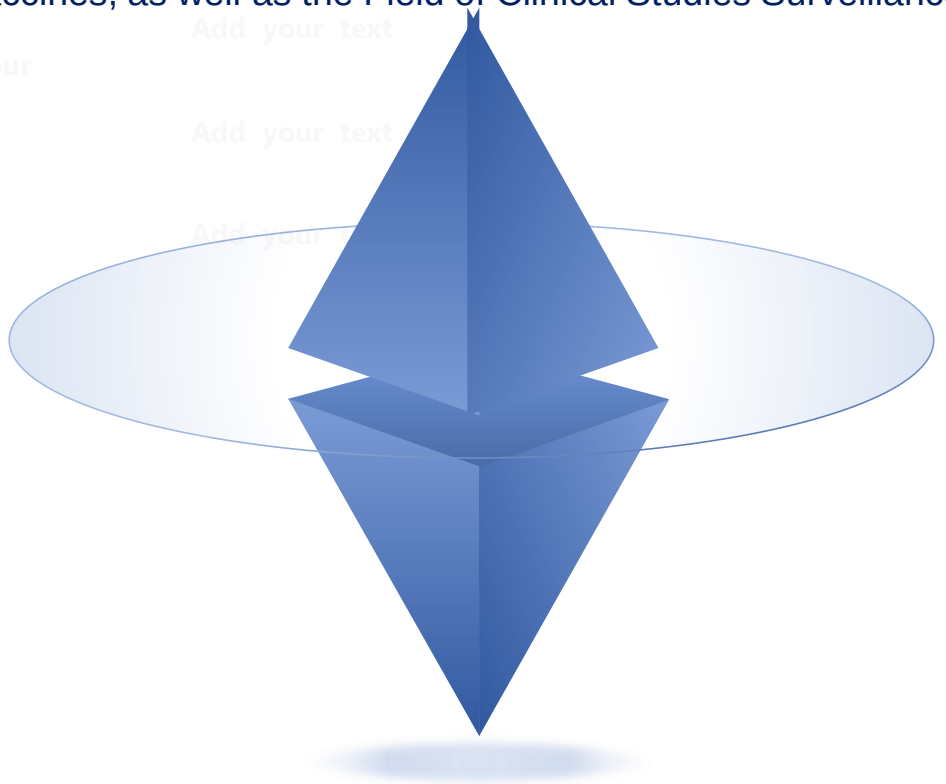
EDA Participation in International or Regional Organizations

Approved by African Union Development Agency (AUDA-NEPAD) as Regional Centre of Organizational Excellence (**RCORE**) in the African Continent for Registration, Inspection, Analysis and Release of Vaccines, as well as the Field of Clinical Studies Surveillance

An observer of the International Cooperation on Cosmetics Regulation (**ICCR**)

Member Global Harmonization Working Party (**GHWP**)

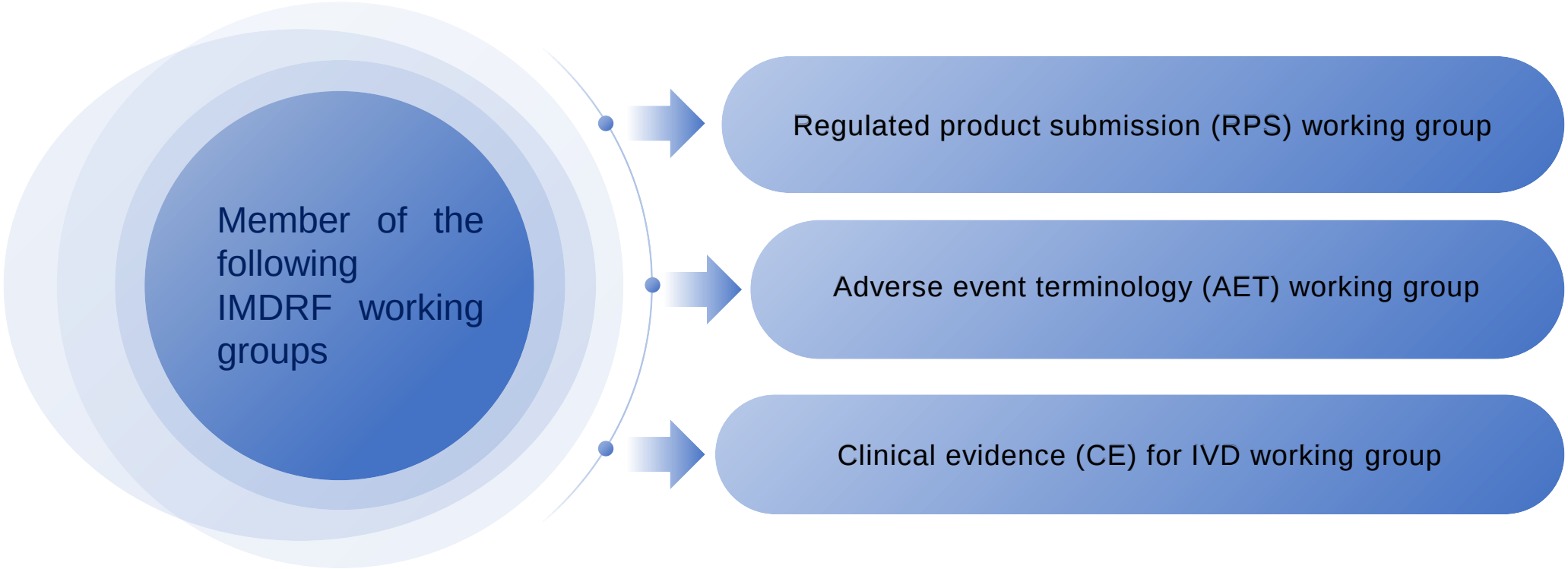
Member of the African Medical Devices Forum (AMDF)

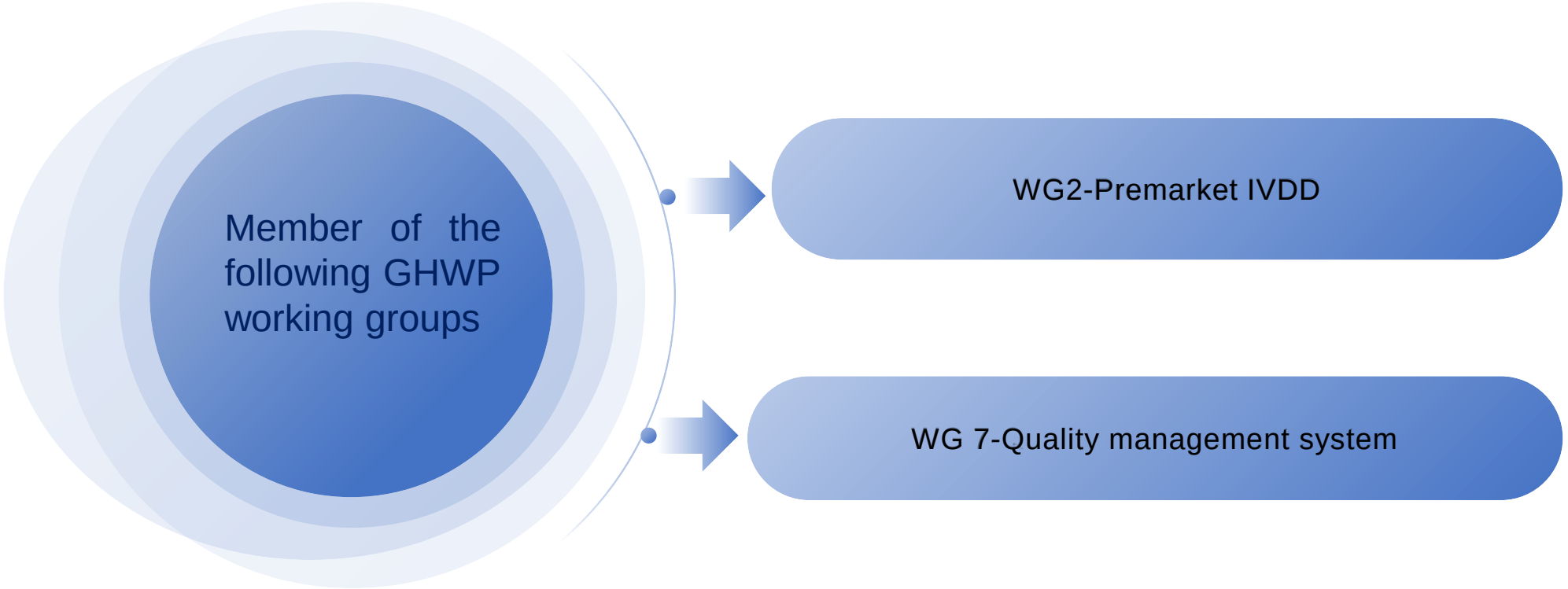


A member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (**ICH**)

A member of the International Pharmaceutical Regulators Programme (**IPRP**)

An associate member of the International Coalition of Medicines Regulatory Authorities (**ICMRA**)


Member of the following IMDRF working groups
Regulated product submission (RPS) working group
Adverse event terminology (AET) working group
Clinical evidence (CE) for IVD working group


Member of the following GHWP working groups
WG2-Premarket IVDD
WG 7-Quality management system

WHO Accreditation

The Egyptian Drug Authority has reached the **Third Maturity Level on March 2022** to regulate locally produced and imported vaccines, and thus is eligible for inclusion in the WHO list of reference regulatory authorities the world.

November 2024 EDA had a visit from the WHO for revising pharmaceutical regulatory updates.

Issuance of medical equipment listing application that helped importers to decrease reluctance of regulatory requirements especially when talking about accessories and consumables

MeDevice Platform Enhancement

Issuance of variation application for previously registered medical devices

Personal use medical devices

Publishing a list for custom clearance to get clearance directly without the need for import approvals

Total number of trainees through 32 training programs

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Thank You