Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

The Egyptian Drug Authority's Path to Global Innovation via regulatory updates

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June 2025, EDA, Egypt hosted the **Global Harmonization Working Party (GHWP) TC leaders meeting** for the **1st time on African lands,the land of civilization,the land of Pharos.**

Transforming market access through strategic regulatory agility through dynamic regulatory updates.

A New Era of Regulatory Innovation

The Egyptian Drug Authority (EDA) has implemented comprehensive regulatory reforms designed to enhance operational efficiency, leverage international expertise, and accelerate patient access to safe and effective medical devices and In Vitro Diagnostics (IVDs).

Regulatory Reliance

Leveraging approvals from stringent international authorities

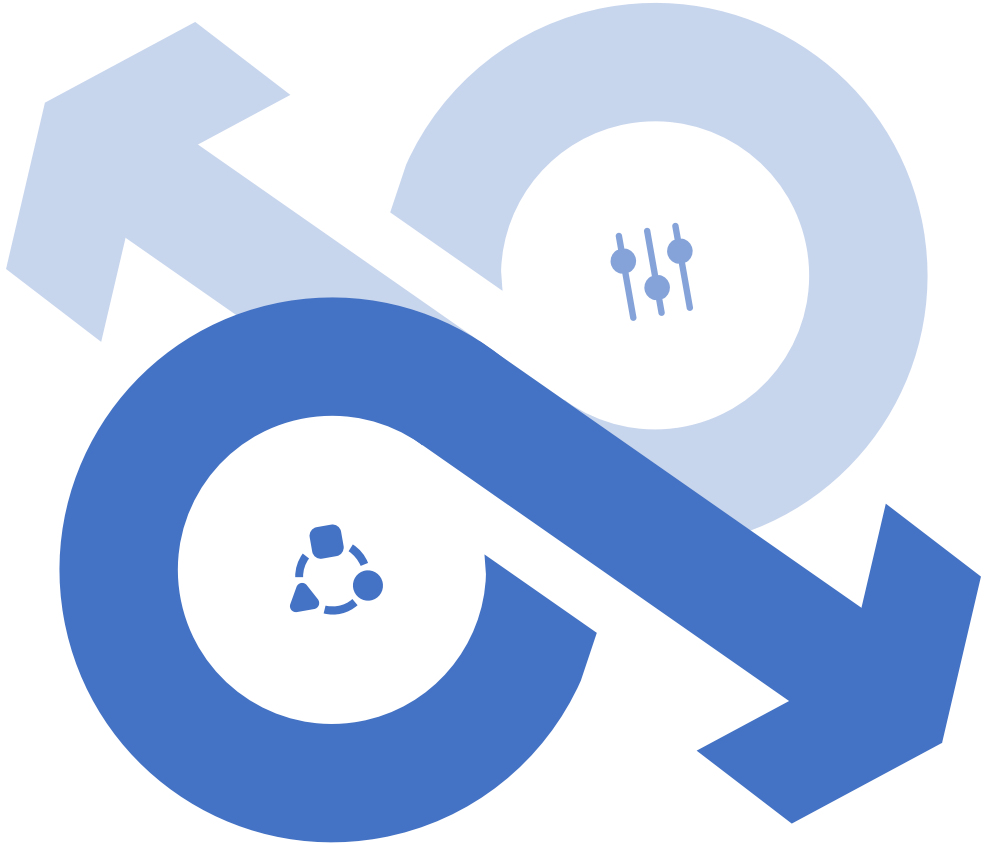
Digital Transformation

Modern platforms for streamlined submissions

Fast Track Pathways

Accelerated review for critical healthcare products

The Egyptian Drug Authority (EDA) continues its drive toward regulatory modernization, primarily through digitalization and harmonization.



EDA regulatory updates consistently align with the principles of the **International Medical Device Regulators Forum (IMDRF)** and **WHO** Global Reliance Practices, fostering a risk-based and lifecycle approach to regulation.

Fast Track Pathways for Critical Innovations

The EDA's Fast Track initiative prioritizes products addressing urgent clinical needs, unmet patient requirements, and emerging public health challenges.

Priority Designation

Products addressing critical therapeutic gaps receive expedited review designations and resource prioritization.

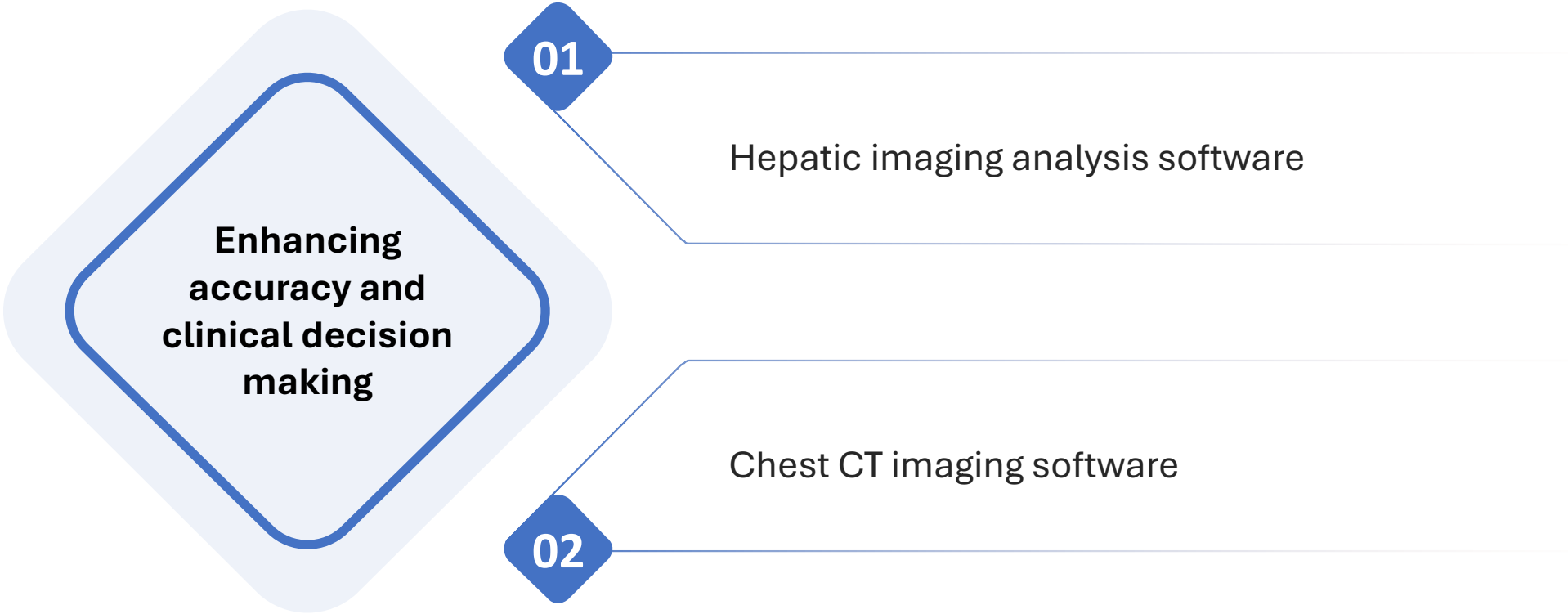
Stakeholder Alignment

Early engagement with manufacturers clarifies regulatory expectations and accelerates product development timelines.

Conditional Approval Options

Innovative products may qualify for conditional market authorization with post-market surveillance requirements.

First time registration of Software as a medical device(SaMD)in Egypt



Addition of a sub-agent/distributor to the registration certificate holder

Add sub-agent/distributer

Manufacturers can add new sub-agent/distributer

Notify medical device registration

Manufacturers are notified about medical device registration

Modify distributor data

Manufacturers can modify their distributor data

Grant Import Permit

Sub-agent&distributors can be granted import permit without new registration

In case of a discrepancy between the country of origin stated on the labels and invoices and that stated in the CFG certificates

Regarding medical devices that have obtained the US CFG certificate issued by the USFDA and are submitted to obtain import Permits,the rules issued by the agency responsible for US Customs and Border Protection (Customs and Border Protection - CBP) will be followed.

An official letter from the legal manufacturer explaining the reason for this difference is required, in accordance with CBP's applicable rules.

Approval of the country of origin stated in the invoice as the country of Last Substantial Transformation.

Regarding the free sale certificate from a reference country for medical devices classified as Procedure Packs under EU Medical Device Regulation (MDR) 2017/745

If a Certificate of Free Sale is not issued by a reference country for medical supplies classified as Procedure Packs according to the European Regulation for Medical Devices (EU MDR 2017/745), the company must submit the following documents.

1. Certificate of free sale for each single medical device within procedure pack
2. CE for each single medical device within procedure pack.
3. Declaration of conformity as procedure pack according to MDR article 22
4. ISO 13485:2016 Certificate for the actual manufacturer

Annual import approval for medical equipment and its spare parts

Establishing a single, comprehensive annual review allows the EDA to verify the registration and quality compliance of the product line before multiple import transactions occur.

- Shifting the burden from repetitive customs-level approvals to one annual administrative approval.
- Better control over the expected volume and type of medical devices entering the market, linking all imports to a definitive, valid license.

New Classification

If a device become classified as medical according to the updated European classification MDR or IVDR, All quality certificates are required as per each class

New Classification

Importation is permitted by submitting the available certificates, provided, stating the required period for quality certificates issuance for each classification

Free Sale certificate

Must mention actual manufacturer,in addition to other Quality certificate.

CE,ISO 13485:2016 and Declaration of Conformity

Mentioning actual manufacturer,with a manufacturer commitment letter for the country of origin.

Free Sale certificate

Directed to a country other than Egypt is not allowed.

Free Sale certificate

Directed to any country is not allowed.

Quality certificate expiry

Require renewal before requesting Import permit.

Quality certificate expiry

Require declartion from manufacturer that product is manufactured before certificates expirey.

Proforma invoice date

Can not exceed one year from issuance date.

Proforma invoice date

No restriction on issuance date.

Spare parts

The applicant is allowed to import spare parts for a medical device that have a valid scientific committee approval .

Spare parts

The applicant is allowed to import spare parts for a medical device that has Expired scientific committee approval without going though the renewal and re-evaluation process.

The electronic MeDevice submission system is now the mandated platform for all new registration files, variations (changes), and import approvals.

Applicants must comply to 100% digital submissions and actively monitor the portal, as all official communications and decisions flow through this channel. The EDA continues to hold training programs emphasizing its full adoption.

The 'Me Device' Electronic Submission Portal is transforming the entire regulatory ecosystem—eliminating paper bottlenecks, providing real-time tracking, and enabling preliminary immediate validation

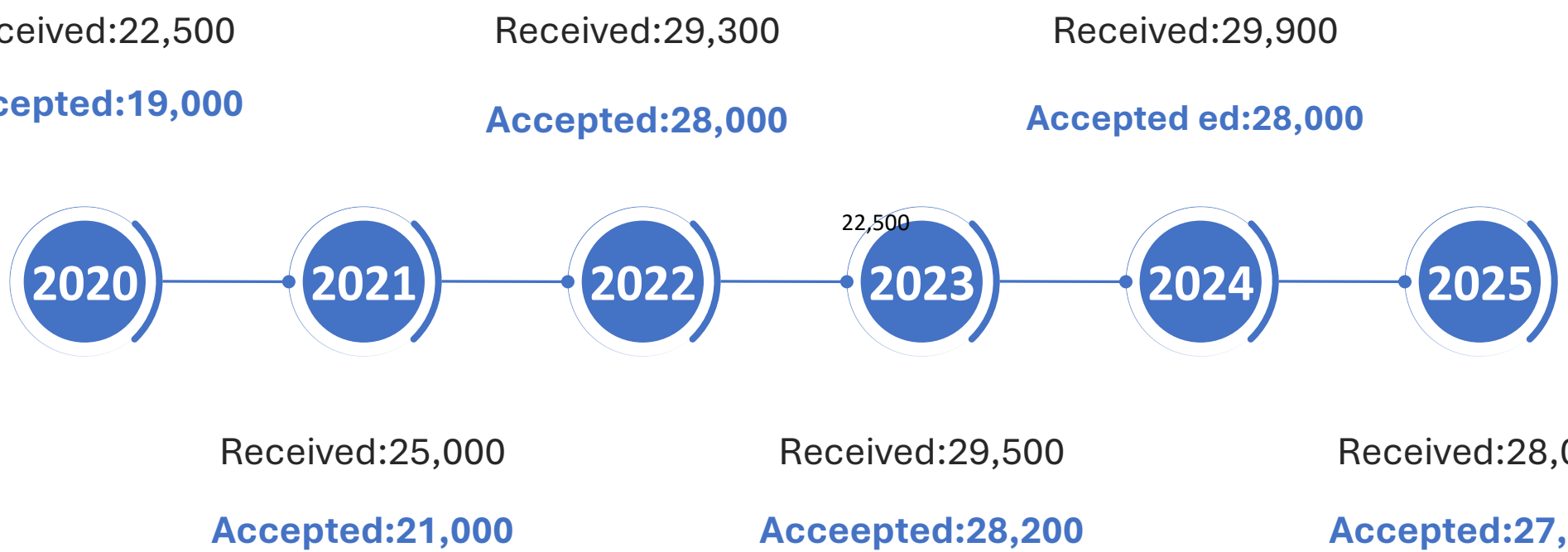
Standardized Documentation

Unified requirements, automated checks, and real-time application tracking eliminate uncertainty and administrative delays.

Transparency & Speed

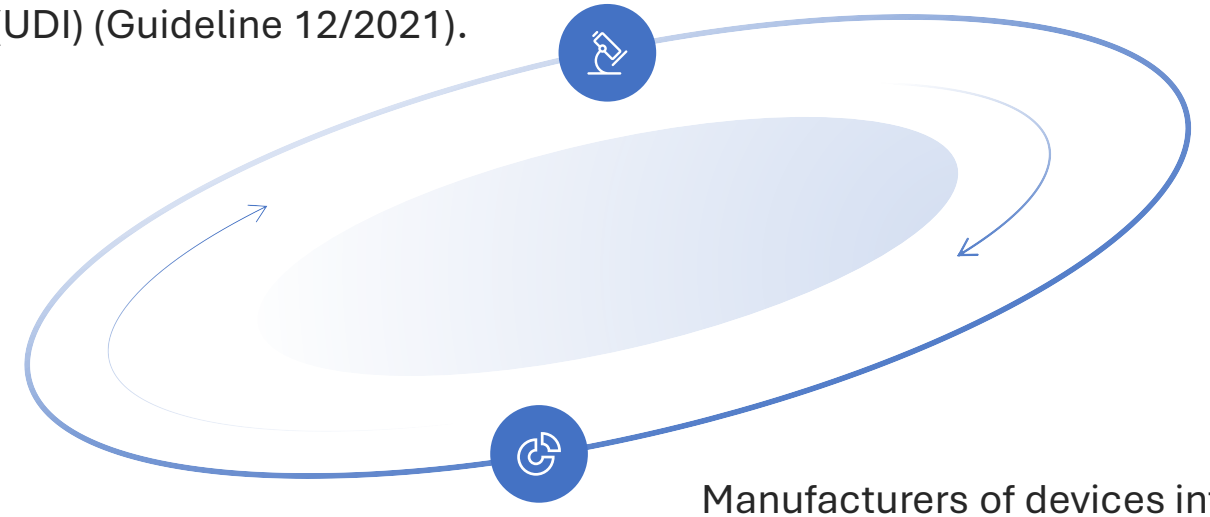
Manufacturers can now predict timelines accurately and reduce time-to-market for critical innovations.

Impact of digital transformation on Import approvals



UDI Implementation

The EDA previously issued the Regulatory Guideline on Requirements for Unique Device Identification (UDI) (Guideline 12/2021).



Manufacturers of devices intended for the Egyptian market must prepare for do UDI generation and data submission, ensuring alignment with the international standards.

Medical device vigilance

The Guidance for Implementing the Updated Safety Requirements specifies accelerated reporting timelines for severe incidents (e.g., death or serious deterioration of health). The reporting period can be as short as 2 days for immediate threats and 10 days for serious incidents.

The Marketing Authorization Holder (MAH) must submit a periodic Summary of Marketing History (SMH), prepared annually or biennially, based on device classification, to the Medical Devices Safety Unit.

The Egyptian Drug Authority's regulatory agility framework positions Egypt as a gateway for medical device innovation worldwide.

International manufacturers now have a clear, efficient, and transparent pathway to access Egypt's strategic healthcare market while maintaining highest safety and efficacy standards through proven Stringent Regulatory Authority approvals.

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Thank You