HSA Health Sciences Authority

IMDRF International Medical Device Regulators Forum

29th IMDRF 2026

Day 2 IMDRF MC - Affiliate Member Update | 10 March 2026

UZBEKISTAN REGULATORY UPDATES

Azambek Sattorov
Leading Specialist, New Medical Device Committee
CENTER FOR PHARMACEUTICAL PRODUCTS SAFETY
MINISTRY OF HEALTH OF THE REPUBLIC OF UZBEKISTAN

Development of the Pharmaceutical Industry in Uzbekistan

Overview of Growth:

- **1990s Landscape:**
  - **Producers: 4 manufacturers**
- **Current Landscape:**
  - **Producers:** Over **230 manufacturers**
  - More **than 5000 registered** local products

Industry Economic Figures

IMPORT
$ 2.4 BILLION

4800+ TYPES OF IMPORTING PRODUCTS

EXPORT
$ 130 MILLION

1200+ TYPES OF EXPORTING PRODUCTS

Tashkent Pharma Park

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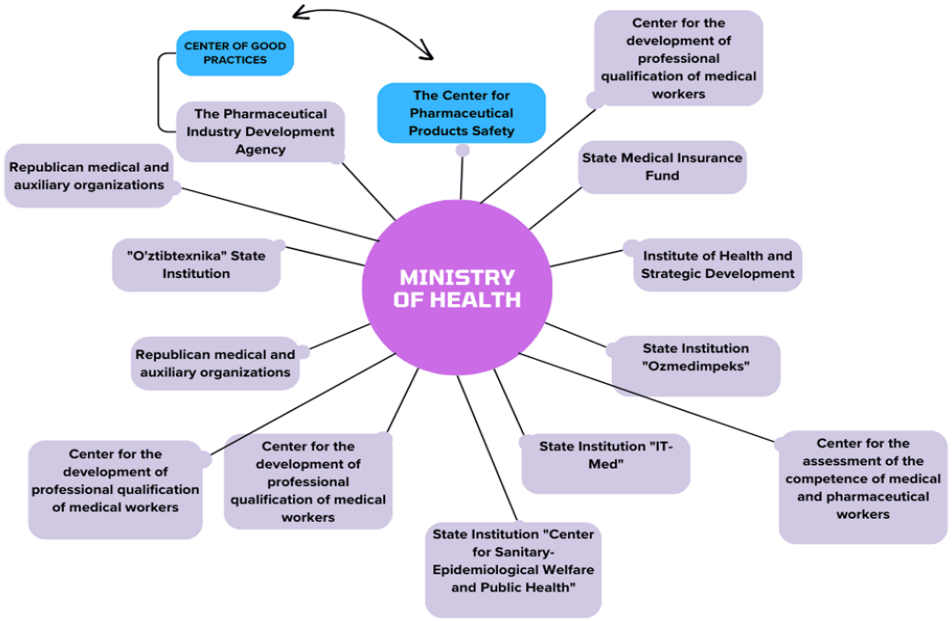
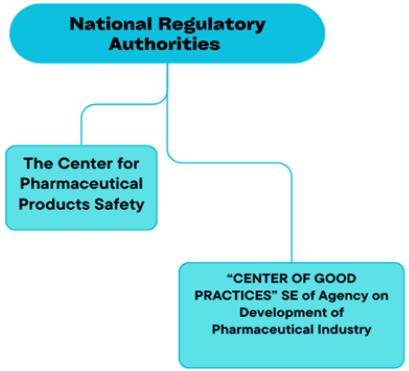
ORGANIZATIONAL STRUCTURE OF THE MINISTRY OF HEALTH OF THE REPUBLIC OF UZBEKISTAN





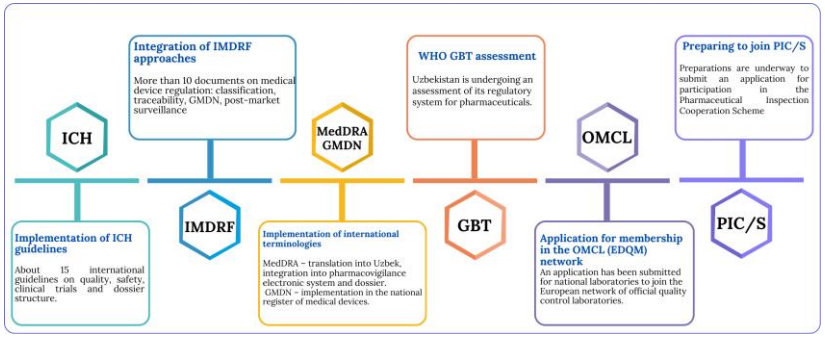
The Center for Pharmaceutical Products Safety

29th IMDRF 2026

CPPS was established **in 1995**, in **2023 was** reorganized in accordance with the Resolution of the President of the Republic of Uzbekistan **No. PP-197** dated June 20, 2023

ORGANIZATIONAL STRUCTURE

ONGOING REGULATORY REFORMS



MAIN FUNCTIONS

1. State registration and maintenance of the register of medicines, medical devices and medical equipment
2. Certification of pharmaceutical products
3. Licensing and control of pharmaceutical activities
4. Metrological control of medical measuring instruments
5. Licensing and control of circulation of narcotic drugs, psychotropic substances and precursors
6. Formation of reference prices for medicines and implementation of a labeling system
7. Conducting examination of pharmaceutical products upon requests from law enforcement agencies
8. Conducting post-marketing surveillance and pharmacovigilance
9. Development of the State Pharmacopoeia

STAFF

General staffing number - **722**

- Head office – **541**
- Regional branches – **181**
  - Andijan – **73**
  - Samarkand – **46**
  - Karshi – **41**
  - Urgench – **21**

Scientific potential: **21** *employees with academic degrees*

- 1 **professor**
- 6 **Doctors of Science (DSc)**
- 14 **PhDs**

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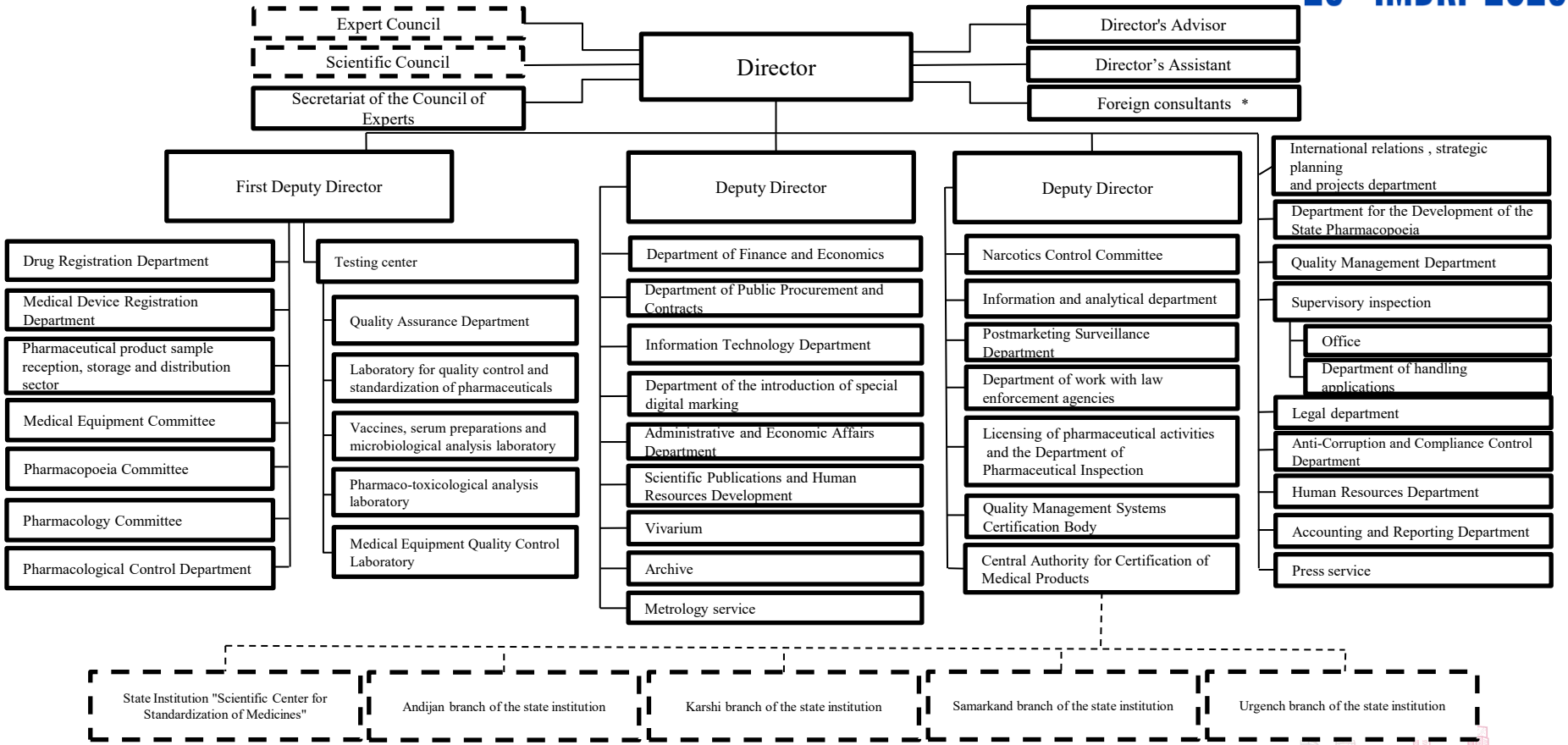
Accreditation of Laboratories

1. **Laboratory of Vaccines, Serum, and Microbiological Analysis**
1. **Laboratory for Quality Control and Standardization of Medicines**
2. **Laboratory for Pharmaco-toxicological Analysis**
3. **Laboratory for Quality Control of Medical Devices**

All laboratories have been accredited under **ISO/IEC 17025:2019** "General Requirements for the Competence of Testing and Calibration Laboratories" since December 7, 2021, and have been included in the **Global Fund** website as certified.

Organizational structure of the state institution "Center for Pharmaceutical Products Safety"



Note: General Staff unit – 576. The total number of employees of the branches was determined by the director of CPPS.

** - Financing of the activities of foreign consultants is carried out at the expense of the Center and other funds not prohibited by law .*

GLOBAL STATUS

ICH — Observer since November 2024
An international platform that sets uniform standards for the quality, safety, and efficacy of medicines

IPRP — Composition of the Management Committee from November 2024
An international platform for the exchange of experience and innovative approaches to drug regulation

GHWP — Full member since December 2024
International Forum on Harmonization of Requirements for Medical Devices and Development of Innovative Approaches

IMDRF — Associate member since March 2025
A leading international initiative to harmonize approaches to medical device regulation

ICMRA — Associate member since April 2025
Alliance of regulators to coordinate response to global health threats

ACHIEVEMENTS

- The State Pharmacopoeia of the Republic of Uzbekistan is fully harmonized with **the European (EDQM)** and **American (USP)** Pharmacopoeia
- Included in **the Pharmacopoeia Index WHO**
- Representatives of Uzbekistan are part of **the Expert Committee WHO** on pharmaceutical product specifications
- **ISO 9001** international certificate received
- Four national quality control laboratories are accredited to **ISO/IEC 17025:2019**
- The laboratories are included in the list of recognized laboratories **of the Global Fund**
- First held **7 international interlaboratory comparative tests**
- 20+ experts from Uzbekistan participate in the IPRP and GHWP working groups on innovative regulation of medicines and medical devices
- **53 specialists** completed international **training** and participated in **global events**

Uzbekistan: National Regulatory Reform

- Strengthening the **national regulatory system** in line with **WHO and international standards** is a **national priority**, set by **Presidential Decree No. PD-137 (19 Aug 2025)**.
- The Decree introduces **recognition-based registration**, **risk-based regulation**, and **ISO 13485 conformity** for medical devices.
- **PD-197 (20 Jul 2023)** established **CPPS** as the central authority for registration, certification, and post-marketing control.
- **National targets set by the Presidential Decree:**
  - WHO GBT ML-3 by 2028
  - WLA status by 2030
  - WHO Prequalification of National Quality Labs
  - ICH membership by 2027

Transparency and Public Information

Publicly Available Materials:

- Register of approved products
- Safety alerts and public warnings
- Inspection results and outcomes
- Information on license withdrawals and product recalls

Frequency / Format:
Published regularly through the CPPS **official website** and **regulatory bulletins**.

Upcoming Transparency Initiatives:
CPPS is currently **updating its official website** to ensure greater public access to regulatory information.
The new platform will provide a **clear overview of the entire registration process for each product**, including:

- Published assessment summaries and review reports
  Nomenclature and classification details
- Post-approval changes and lifecycle data
- Links to safety and quality monitoring outcomes

INTERNATIONAL COOPERATION

More than 8 memoranda of understanding (MoU) have been signed with regulatory authorities of the following countries:

Recently signed MoUs with:
Latvia, Kazakhstan, Kyrgyzstan, Malaysia and Indonesia.

Upcoming MoUs planned with:
Singapore, Nigeria and UAE.

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KEY NORMATIVE DEVELOPMENTS IN THE MEDICAL DEVICE REGULATORY FRAMEWORK

Government Resolution No. 738

24 November 2025

The Cabinet of Ministers approved new regulations governing the state registration procedures for medicinal products and medical devices in the Republic of Uzbekistan

Order of the Minister of Health No. 27

22 December 2025

Approval of the Regulation on Conducting Clinical Investigations of Medical Devices, establishing national requirements and procedures for clinical investigations.

Order of the Minister of Health No. 16

24 December 2025

Adoption of Rules for Nomenclature Classification of Medical Devices and their Risk-Based Classification according to the level of potential risk associated with their use.

National adoption of international quality management standard

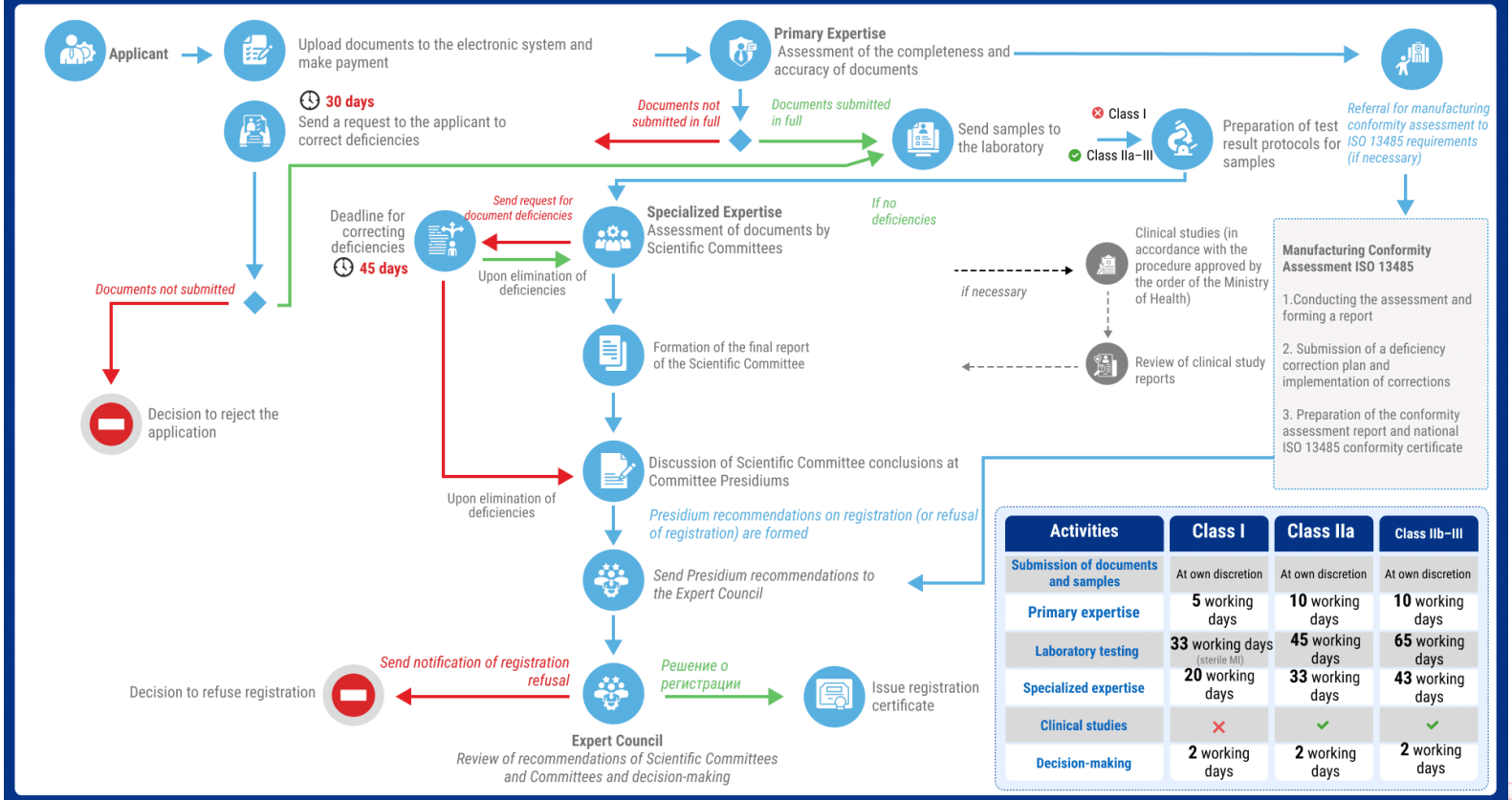
30 September 2025

The national standard O‘zMSt ISO 13485:2025 (ISO 13485:2016, IDT) — Medical devices — Quality management systems — Requirements for regulatory purposes — was adopted.

Alignment of the National Regulatory Framework with IMDRF Principles

- **Harmonization of regulatory terminology**
  National definitions of *medical device* and *in vitro diagnostic medical device (IVD)* were aligned with internationally recognized terminology in accordance with the document:
  "Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic Medical Device'" (GHTF SG1/N071:2012).
- **Implementation of risk-based classification for medical devices**
  National classification rules were established in line with the principles described in:
  "Principles of Medical Devices Classification" (GHTF SG1/N77:2012).
- **Introduction of risk-based classification for IVD medical devices**
  Classification of IVD devices aligned with:
  IMDRF/IVD WG/N64:2019 — "Principles of In Vitro Diagnostic Medical Devices Classification."
- **Integration of Global Medical Device Nomenclature (GMDN)**
  The **Global Medical Device Nomenclature (GMDN)** was implemented within national regulatory systems and device registries to ensure standardized identification and international interoperability.
- **Strengthening of clinical evidence requirements**
  National regulatory requirements for clinical investigations were aligned with international guidance, including:
  IMDRF MDCE WG/N57 — "Clinical Evaluation" and related clinical investigation principles.
- **Implementation of international ISO standards**
  The regulatory framework incorporates internationally recognized standards governing quality systems and clinical investigations:
  ISO 13485 — Medical devices – Quality management systems – Requirements for regulatory purposes
  ISO 14155 — Clinical investigation of medical devices for human subjects – Good clinical practice
  ISO 20916 — In vitro diagnostic medical devices – Clinical performance studies using specimens from human subjects

MEDICAL DEVICE REGISTRATION SYSTEM



Activities	Class I	Class IIa	Class IIb–III
Submission of documents and samples	At own discretion	At own discretion	At own discretion
Primary expertise	5 working days	10 working days	10 working days
Laboratory testing	33 working days (sterile MI)	45 working days	65 working days
Specialized expertise	20 working days	33 working days	43 working days
Clinical studies	✗	✓	✓
Decision-making	2 working days	2 working days	2 working days

State Institution "Center for Pharmaceutical Product Safety"

Registration of Medical devices

Operating results for the up to March of 2026

Medical devices

Domestic manufacturers		Foreign manufacturers
39	Registered	558
10	Renewal	55
2	Changes and additions have been made	71

Certification Activies up to 2025

Medical devices and medical equipment - 17,224,956 packages

CENTRAL AND REGIONAL OFFICES

FOREIGN MANUFACTURERS

Medical devices and medical equipment - 122,579,506 packages

Medical devices and medical equipment - 209 packages

PRIVATE Certification Bodies

Medical devices and medical equipment - 52,574 packages

Certificates of authority from **the medical device certification bodies** have been registered

1,517 episodes — 144 306 167 for "point-of-care medical devices"

560 and — for medical orders and medical equipment

8,251,541 conditional packages of medicines, medical devices and medical equipment **of series 67 were found to be non-compliant with the requirements of regulatory documents**

Certificates of conformity have been issued by the Central Body for Certification of Medical Products and **the certification bodies of the branches of the Ministry of Health.**

8 557 in this series — 294 581 966 for "point-of-care medical devices"

2 053 and — for medical orders and medical equipment

85 series 8 505345 conditional street equipment, medical devices regulatory **requirements**

Thank You!