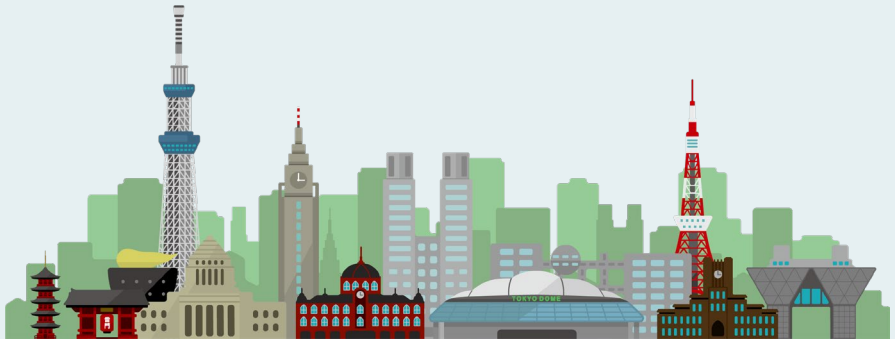
IMDRF International Medical Device Regulators Forum



Sanitary Regulation Superintendency Updates - 2025

Mario Ernesto Vega Valenzuela

Head of the Medical Devices Registration Unit

Overview

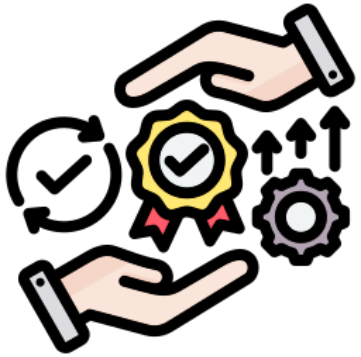
1. Participation in IMDRF Working Groups
2. Post-market Surveillance Regulation
3. Clinical Trials Law
4. Accreditation of the Quality Control Unit
5. Strategic plan for the diffusion of information in the CA region
6. Training opportunities for SRS staff
7. IMDRF MC Sessions

Participation in IMDRF Working Groups

As an affiliate member of the International Medical Device Regulators Forum (IMDRF), the Sanitary Regulation Superintendency (SRS) currently participates in the following working groups:

Personalized Medical Devices (PMD)

Adverse Event Terminology



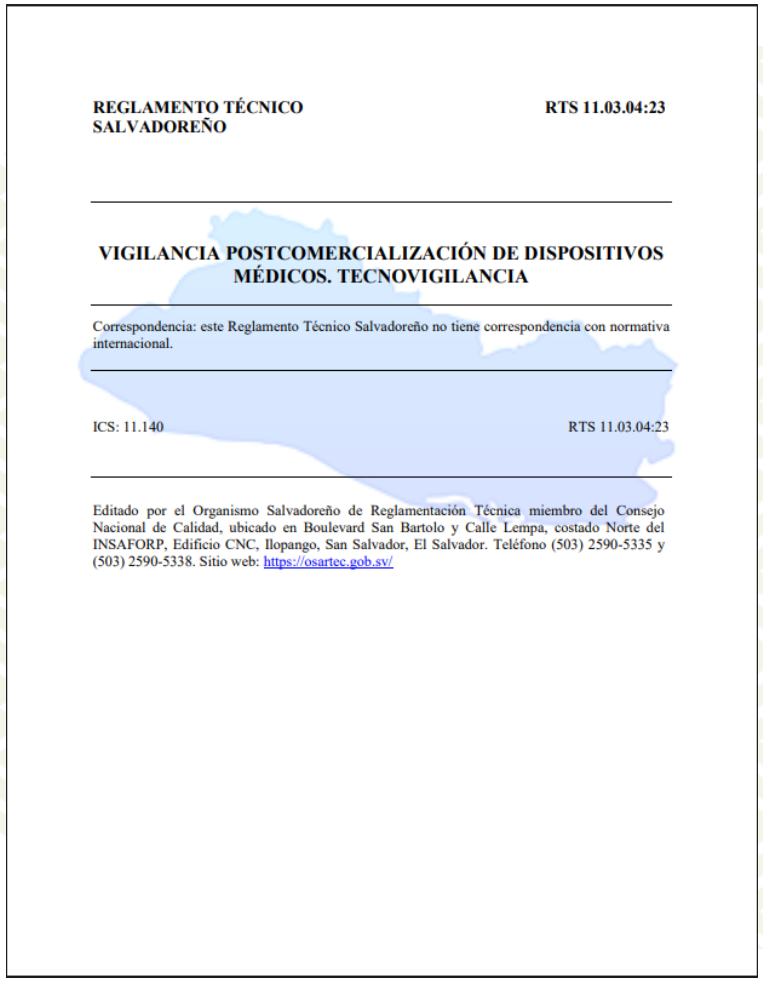
Quality Management Systems

Clinical Evidence for IVD Medical Devices

Post-market Surveillance Regulation

In October 2024, the technical regulation for the implementation and execution of post-marketing surveillance activities (known in El Salvador as technovigilance) came into force. This technical regulation has definitions and requirements of at least 3 IMDRF technical documents:

IMDRF/GHTF Document	Name of the document
IMDRF MDCE WG/N65FINAL:2021	Post-Market Clinical Follow-Up Studies
GHTF/SG2/N57R8:2006	Medical Devices Post Market Surveillance: Content of Field Safety Notices
GHTF/SG2/N54R8:2006	Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices



REGLAMENTO TÉCNICO SALVADOREÑO

RTS 11.03.04:23

VIGILANCIA POSTCOMERCIALIZACIÓN DE DISPOSITIVOS MÉDICOS. TECNOVIGILANCIA

Correspondencia: este Reglamento Técnico Salvadoreño no tiene correspondencia con normativa internacional.

ICS: 11.140

RTS 11.03.04:23

Editado por el Organismo Salvadoreño de Reglamentación Técnica miembro del Consejo Nacional de Calidad, ubicado en Boulevard San Bartolo y Calle Lempa, costado Norte del INSAFORP, Edificio CNC, Ilopango, San Salvador, El Salvador. Teléfono (503) 2590-5335 y (503) 2590-5338. Sitio web: https://osartec.gob.sv/

RTS 11.03.04:23 Post-market Surveillance of Medical Devices. Technovigilance

IMDRF International Medical Device Regulators Forum

Clinical Trials Law

The draft of the “Clinical Trials Law” was presented last month to the Health, Agriculture and Environment Commission, obtaining its approval and moving on to the next and final phase of approval by the Legislative Assembly.

The Health, Agriculture and Environment Commission approved the draft of the new Clinical Trials Law.

CHAPTER VI

CONDUCT OF CLINICAL TRIALS

General Considerations for the conduct of clinical trials

Art. 28.- The clinical trials with products subject to this law regulated by the Superintendency, in addition to the principles enunciated in article 4, must comply with the following:

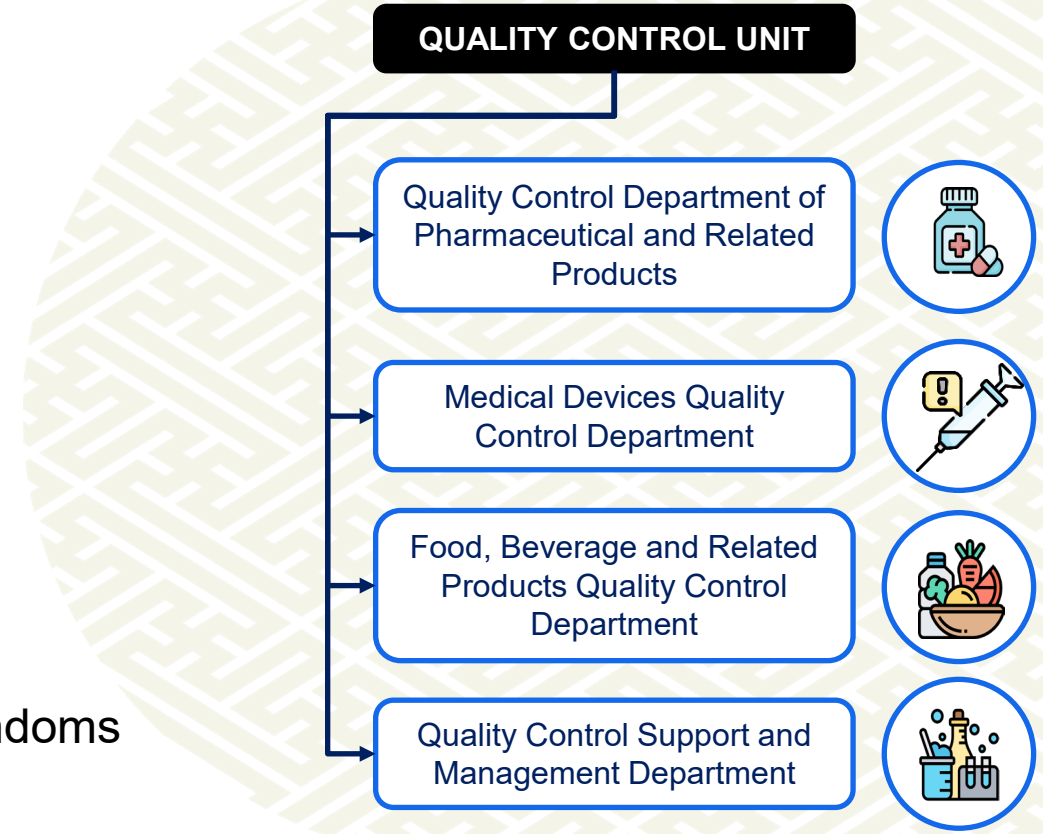
a) To be conducted under the main national, regional and international clinical trial guidelines such as the Declaration of Helsinki and its updates; the Ethical Guidelines of the Council for International Organizations of Medical Sciences (CIOMS); the Good Clinical Practice (GCP) of the World Health Organization (WHO); Good Data Management, Record Keeping and Documentation Practices; as well as those issued by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH); the International Organization for Standardization (ISO); and the International Medical Device Regulators Forum (IMDRF)…

Accreditation of the Quality Control Unit

This year, the staggered accreditation project of the SRS Quality Control Unit (QCU) with the Salvadoran Accreditation Organization (SAO), based on the ISO/IEC 17025:2017 standard, has begun.

Currently, the installed capacity of the Medical Devices Quality Control Laboratory allows for the analysis of 21 types of medical devices, which includes:

- Gloves
- Surgical tape
- Male Condoms
- Syringes
- Cotton
- Face masks



Strategic plan for the diffusion of information in the CA region

Our superintendent, Msc. Noe Geovanni García Iraheta, has initiated the strategic plan for the diffusion of regulatory information in the Central American region, whose objectives include:

- Promote regulatory harmonization at the regional level.
- Promote the affiliation to the IMDRF.
- Make SRS technical capacity available to NRAs.
- Internship opportunities for international students.

Training opportunities for SRS staff

In 2024, the SRS staff had the opportunity to participate in some trainings provided by IMDRF members:

- PMDA-ATC Medical Devices Webinar 2024 and APEC CoE Workshop: PMDA-ATC Medical Devices Workshop 2024
- 2024 SCH APEC Medical Device CoE Training (Online Training)
- 2024 APEC Medical Devices Regulatory Science Center of Excellence Workshop

IMDRF MC Sessions

The Sanitary Regulation Superintendency had the opportunity to attend the 2024 IMDRF MC Sessions:

25th IMDRF Management Committee Session held in March 2024 in Washington DC.
26th IMDRF Management Committee Session held in September 2024 in Seattle, Washington.

SRS services catalog

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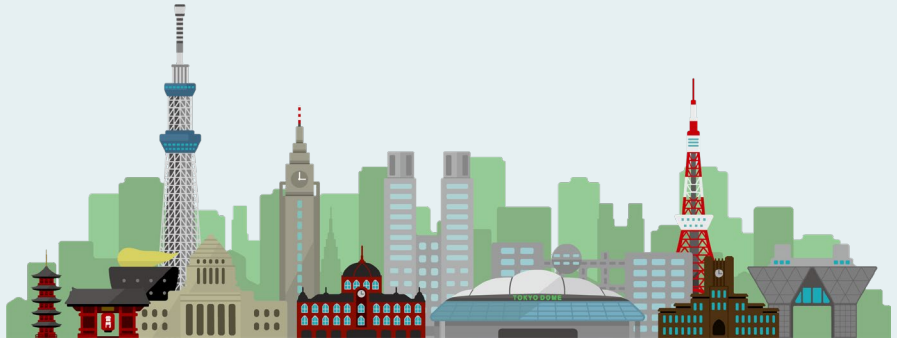
IMDRF International Medical Device Regulators Forum



Thank you/Questions

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