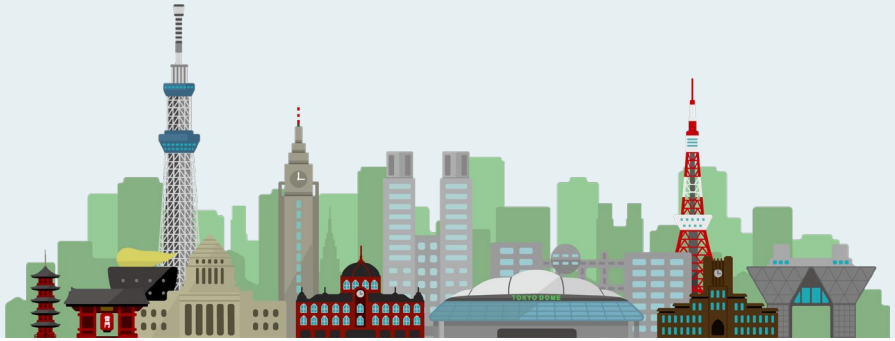
IMDRF International Medical Device Regulators Forum



IMDRF Stakeholder Forum
Regulatory Update, Switzerland (Official Observer)

Mr. André Breisinger, Expert Medical Devices Regulation, Swissmedic

swissmedic

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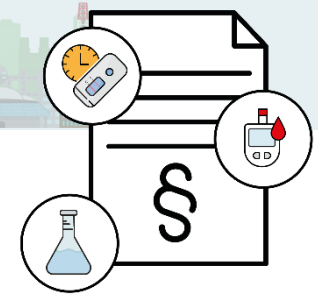

Key changes to regulatory framework

Ordinance on In Vitro Diagnostic Medical Devices (IvDO) of 4 May 2022 (Status as of 1 January 2025)

Restoring Regulatory Equivalence with the EU Regulation (EU) 2024/1860

- **Certificate Validity**: extended validity of legacy certificates until 2027-2029 based on risk class.
- **In-House Devices**: extended deadline for healthcare institutions to prove in-house devices cannot be replaced by CE-marked devices to 31 Dec 2030.

Where we deviate from the EU regulation, to address Swiss Market needs

- **Notification Obligations** for MD&IVD device supply interruptions were not adopted in Switzerland
- **permanent relief: Simplified Labelling** permits the marking of the Swiss Authorised Representative on a document enclosed with the product instead of a direct marking on the product itself in the field of professional use of IVD (excluding self-testing applications).

Art. 87 Placing information about the authorised representative

For devices which are not intended for self-te… and are placed on the market according to the new legislation, the infor… ified in Annex 1 Chapter III Section 20.2 letter d EU-IVDR[70] about t… sed representative according to Article 44 paragraph 1 of this Ordinance may … included in a document accompanying the device until 31 March 2025.

repealed

Details: Amendment of the Ordinance on In Vitro Diagnostic Medical Devices (IVDs) and the Medical Devices Ordinance

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swissdamed

Key changes to regulatory framework

Product registration obligation in swissdamed will enter into force on 1 July 2026.

From 1 July 2026, devices, systems and procedure packs placed on the market in Switzerland must be registered in swissdamed. Manufacturers or their authorised representatives have until 31 December 2026 to register their devices.

From 1 July 2026, **immediate registration*** is required if a **serious incident, a safety corrective action in the field, or a trend** needs to be reported.

For more information, visit our Swissmedic website and fedlex, the federal platform for federal law (available only in German, French, and Italian).

*product registration obligation does not apply to “old devices”

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swissdamed

Search for actors | Actor management | Companies | Login | EN

Search for actors

The search for actors allows you to search and retrieve all records that contain the search terms you enter. At least one search criterion is mandatory.

Company name | CHRN | UID

If you don't know the UID-number of the company, you can find it in Zefix

Actor type: Mandate (Foreign Manufacturer) (MT) | City | Country: All | Actor status: Registered

Clear search | Search

3689 records found:

Action item: Ensuring a smooth transition to mandatory product registration:

Has your CH-REP registered your [manufacturer mandate] details in swissdamed?

No: Please ask your CH-REP to complete the registration.
Yes: Stay tuned for details on **voluntary product registration in 2025**.

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Training objectives for stakeholders in the area of MD conformity and safety in hospitals

1. Awareness and discussion

To increase and **strengthen awareness** and knowledge of the regulatory requirements in health care institutions under Swissmedic's surveillance.

Stakeholders should have the opportunity to direct questions and uncertainties regarding the requirements in the relevant areas directly to Swissmedic (**exchange**).

These interactions enable us to derive targeted preventive measures.

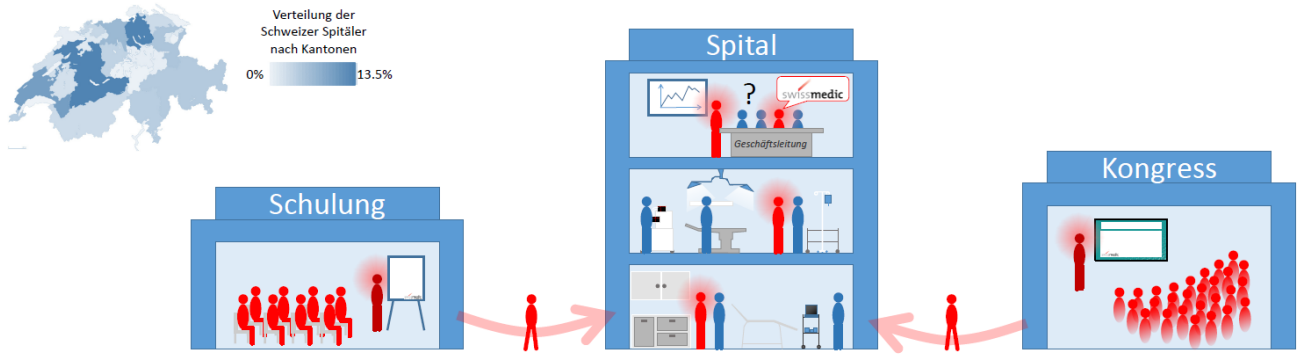
2. Capacity building

To ensure compliance with Swissmedic's requirements, specifically the **Good Practices guidelines**, are communicated to target groups through training sessions and incorporated into the **curriculum** of universities of applied sciences.

3. Promoting collaboration

By fostering trust and **collaboration with experts** in the field, Swissmedic's standing and the measures in MD incidents **prevention** are strengthened.

Our focus on **real-world relevance**, not just compliance, has a real impact on patient safety in our hospitals.



Find out more: [Surveillance of healthcare institutions]

Key changes to regulatory framework

“Swiss Good Practice for Maintenance of Medical Devices (GPM)” outlines mandatory maintenance requirements for hospitals - Developed by Swissmedic in collaboration with professional associations and released on 31 January 2025

Focus on:

- Ensuring proper maintenance of medical devices in hospitals
- Improving patient safety standards.

Inspection and Compliance:

- Swissmedic reviews GPM implementation during inspections.
- A checklist based on GPM is available for hospitals to conduct internal audits

Updated guidelines are only available in German, French, Italian (not English!)

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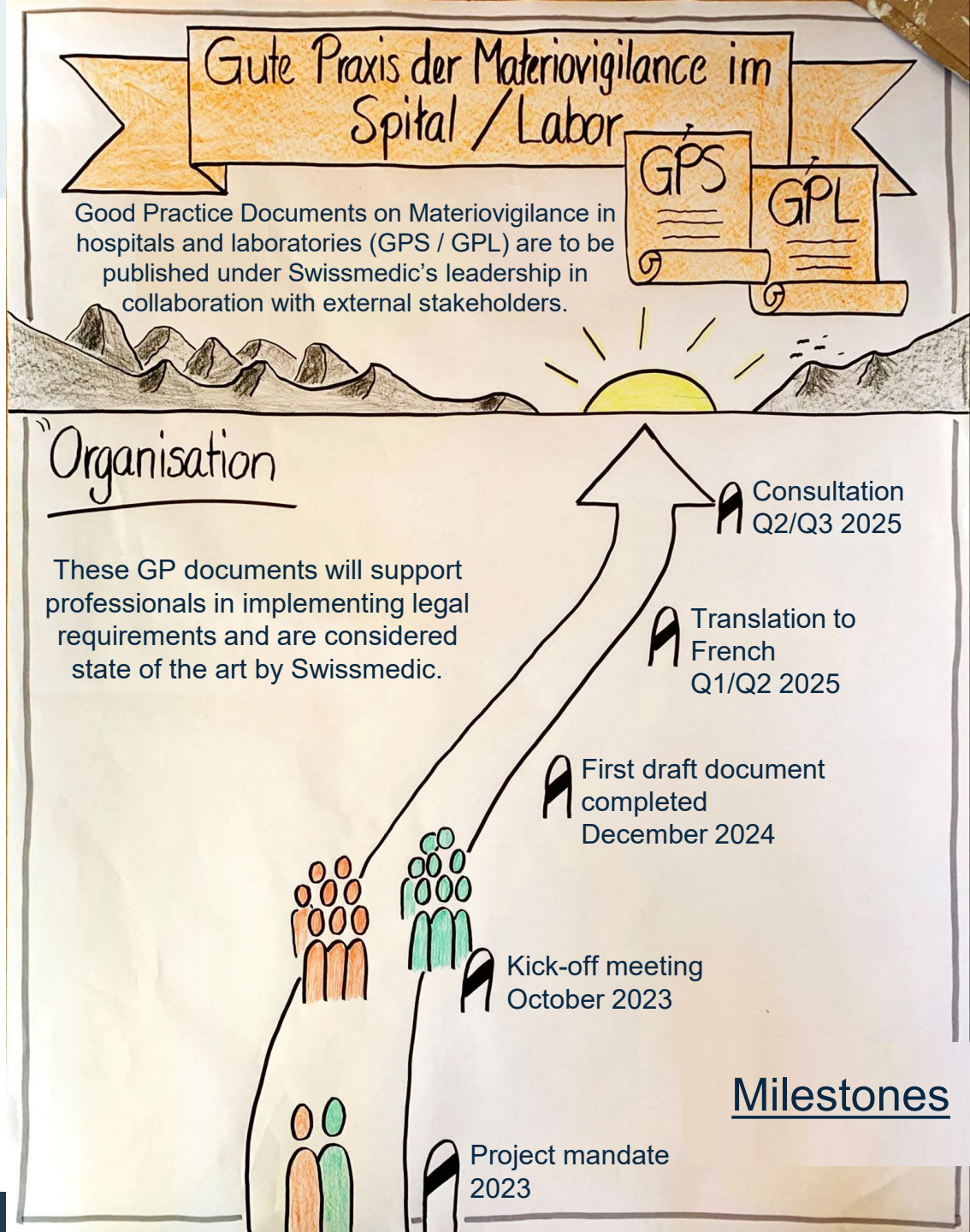
Good Practice of Materiovigilance in Hospitals (GPS) / Laboratories (GPL)

The documents support compliance with Materiovigilance requirements and strengthen patient safety by promoting clear and efficient incident reporting processes.

They help hospitals and laboratories to establish internal reporting systems, appoint vigilance contact persons, and implement manufacturers' corrective actions - ensuring effective collaboration with Swissmedic and improving risk management for medical devices.



Key changes to guidance documents & forms

Healthcare institutions*

- "Swiss Good Practice in the Maintenance of Medical Devices" – "GPM" (revised, 31.01.2025)
- "Checklist on "For the Inspection of the Maintenance of Medical Devices" (revised, 30.01.2025)
- "Swiss Good Practice for the Reprocessing of Medical Devices" – "GPA" (revised, 01.01.2025)
- MU600_00_006e_MB Procurement of medical devices in health institutions (revised, 01.01.2025)

Materiovigilance / Post-Market Surveillance

- MU680_20_009e_WL Incident economic operators (revised, 21.01.2025)

Clinical Trials

- BW610_20_022e_FO Notification of safety measures MD IVD (revised, 30.01.2025)
- BW610_20_021e_FO Modifications, notifications, reports MD IVD (revised, 20.01.2025)
- BW610_20_025e_FO Form Modifications, notifications, reports MD IVD (revised, 20.01.2025)

Notifications

- BW630_30_010e_MB FAQ on in vitro diagnostic medical device notifications (revised, 17.01.2025)

Economic Operators

- MU600_00_016e_MB Obligations Economic Operators CH (revised, 01.01.2025)

Other Guidance

- Reports on breast-implant associated-anaplastic large cell lymphoma (BIA-ALCL) (revised, 07.10.2024)

*Good practice documents are available only in our national languages: German, French, and Italian.

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Market surveillance: Focus campaigns

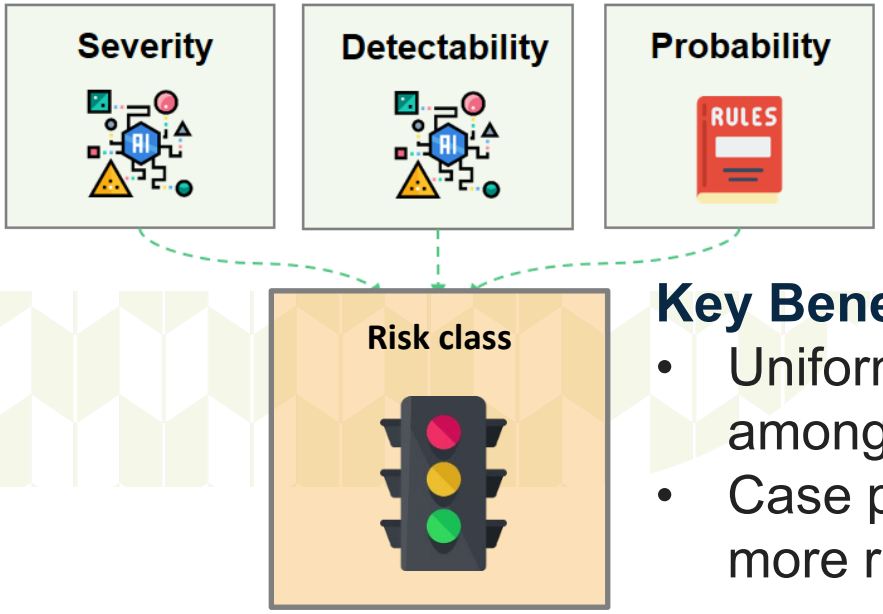
Post-Market Surveillance (PMS) Documentation:
Swissmedic assessed PMS compliance of 30 legacy devices. Despite the requirements being in force since 2021, not all manufacturers are adequately implementing them. Swissmedic urges all manufacturers to review their QMS for compliance.
For more details, see our report: SMC assessment report PMS

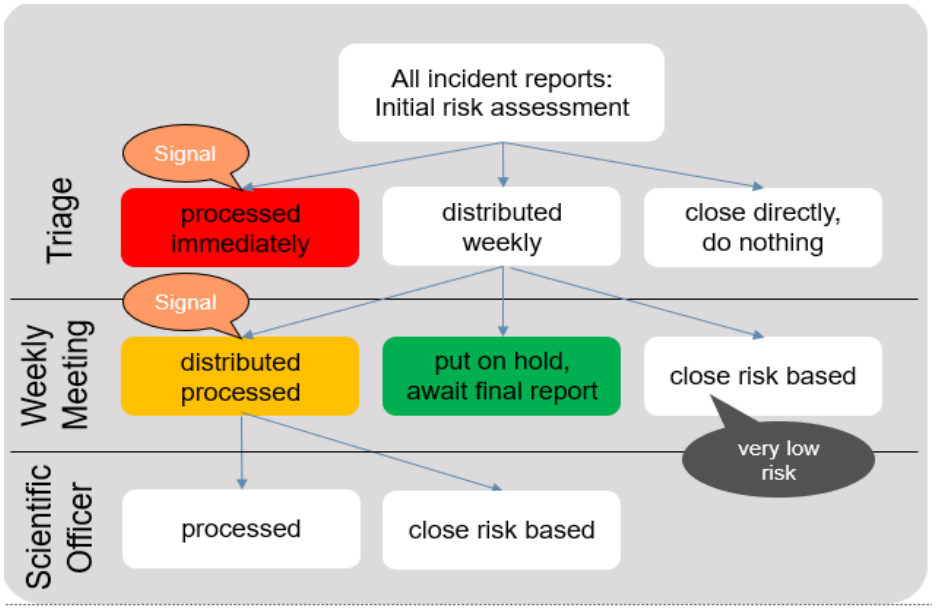
Surveillance of the use of medical devices for anti-wrinkle injections ("fillers")
In collaboration with Swissmedic, the cantonal therapeutic product authorities and the Office for Health of Liechtenstein, inspected the use of fillers in 82 clinics, medical practices, and cosmetic studios.
For more details, see our report: Targeted Action "Dermal Fillers"

Find out more: Focus campaigns

TRICIA – A NLP based tool for risk-based classification of incoming incident reports.

Initial Risk Assessment: The risk score is calculated by multiplying three variables: **Probability, Severity, and Detectability** are used to determine the prioritization of processing new cases based on the score.





Key Benefits of TRICIA:

- Uniform risk assessment of similar cases, ensuring consistency among scientific officers and enhancing Swissmedic's credibility.
- Case prioritization with TRICIA allows Scientific Officers to focus on more relevant cases.

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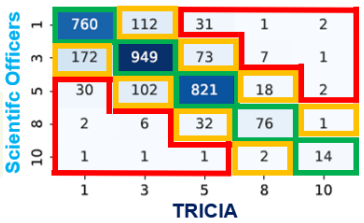
Risk Assessment Challenge: Scientifc Officers vs. TRICIA

Severity



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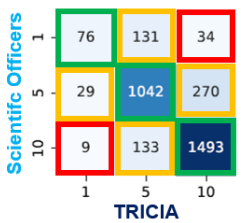
Probability



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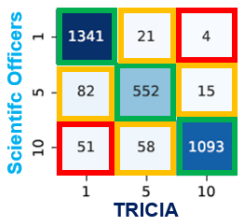
Detectability



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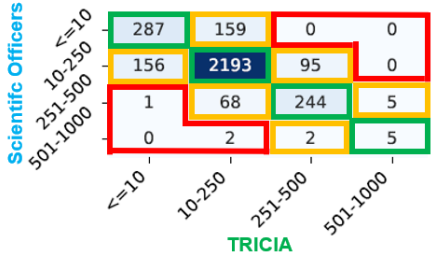
RAT



Risk Assessment Tool (RAT)	N	%
Total	3217	100.00%
Match	2729	84.83%
Mismatch	488	15.17%
Within target range	485	15.07%
Outside target range	3	0.10%

TRICIA has been conducting the RAT since January 2025.

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Swissmedic's active commitment to 6/8 IMDRF WGs

Adverse Event Terminology

Harmonize terminology for reporting adverse events related to medical devices, and further harmonize adverse event reporting datasets to improve signal detection.

Artificial Intelligence/Machine Learning-enabled

Seeking to harmonize internationally, principles to help promote the development of safe and effective AI/ML enabled medical devices.

Clinical Evidence for In Vitro Diagnostic Medical Devices

A working group on Clinical evidence for in vitro diagnostic (IVD) medical devices

Software as a Medical Device

Promote consistency in regulatory assessment for Software as a Medical Device to reach patients more efficiently.

Good Regulatory Review Practices

Develop good review practices for pre-market reviews and evaluations.

Personalized Medical Devices (PMD)

Harmonize the regulatory requirements for medical devices that are intended for a particular individual, considering unique characteristics and risks associated with each type of device.

Quality Management Systems

Ensure alignment of IMDRF QMS and risk management documents with current international standards

Regulated Product Submission

Harmonize the format and content of regulatory submissions.

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Meetings, Workshops and Training (Link) – since the last IMDRF MC 1/2

Date	Organizer	Event, Location
14.03.2025	Swissmedic	Collaboration with patient and consumer organisations
11.02.2025	Training at the Higher Technical School for Medical Technology Sarnen in the field of Hospital Operations Technology	Course - Maintenance, GPI: Role of Swissmedic in hospitals and topics related to maintenance
03.02.2025 & 21.20.2024	Clinical Trial Unit Basel, Dep. of Clinical Research	CAS Clinical Research I, Module 1: Basics, University of Basel
03.02.2025	Swissmedic	Roundtable Medical Devices
29.01.2025	STE Endo Course H+ Education	Course - Endoscope Reprocessing, GPAE: Fundamentals of Medical Device Reprocessing & Quality Management
28.01.2025 & 25.11.2024	Inselspital - University of Berne	IVDR from different perspectives
25.01.2025	Swiss Section of the International Academy of Pathology (IAP)	Challenges in Biomarker Application
24.01.2025	ZHAW School of Management and Law	CAS Health Systems and Policy 2025, Module 1
24.01.2025	Conference of Swiss Pathologists	Presentation - IvDV and IVDR: Legal Requirements for In Vitro Diagnostic Medical Devices
21.01.2025	World Economic Forum (WEF)	Healthcare technology outtakes: the untold stories of AI and data-driven innovation, Davos
15.01.2025	IG WiG Annual Meeting	Presentation - Validation of Packaging Processes: Validation of Packaging Processes
07.12.2024	H+ Education: 12th Refresher for STA "Well Packaged is Half Sterile"	Course - AEMP: Updates from Swissmedic
22.11.2024	SGSV Specialist Conference	Presentation - AEMP: Updates from Swissmedic

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Meetings, Workshops and Training (Link) – since the last IMDRF MC 2/2

Date	Organizer	Event, Location
13.11.2024	Webinar IHS - GPI	Presentation - GPI: Swiss Best Practices for the Maintenance of Medical Devices (BPM)
02.11.2024	H+ Education: 12th Refresher for STA "Well Packaged is Half Sterile"	Course - AEMP: Updates from Swissmedic
29.10.2024	Webinar IHS - GPI	Presentation - GPI: New "Swiss Good Practice for the Maintenance of Medical Devices" (GPI)
21.-25.10.2024	Swissmedic & WHO	Training Course for Regulatory Authorities in Low- and Middle-Income Countries, Bern
17.10.2024	University of Berne	Pharmacy Program: Organization and Operation of Pharmaco- and Materiovigilance
07.10.2024	Swiss Clinical Trials Organisation (SCTO)	Roundtable Discussions: SCTO, swissethics, Swissmedic, Bern
28.09.2024	H+ Education / Swiss Society for Sterile Supply (SGSV)	Refresher for Technical Sterilization Assistants, Aarau
28.09.2024	H+ Education: 12th Refresher for STA "Well Packaged is Half Sterile"	Course - AEMP: Updates from Swissmedic
25.09.2024	BBS Basel Biometric Society	AI in Clinical Research & Drug Development - Regulator in the Loop: Trust in ML-based Systems, Basel
18.–19.09.2024	Global Coalition for Regulatory Science Research, US-FDA	Digital Transformation in Regulatory Science, Little Rock AR, USA
18.09.2024	Vigilance Training Medi	Course - Vigilance: Vigilance
12.-13.09.2024	SGG/SVEP Congress	Presentation - GPAE: Important Hygiene Information Presentation - GPAE, Endoscope Reprocessing
11.09.2024	Inspired Minds Organization	MediCrawl: an ML-based app to enable market oversight within Swissmedic, Basel

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News on international activities

Global Coalition for Regulatory Science Research

Swissmedic looks forward to hosting these two prestigious artificial intelligence events in 2025

3rd LLMs Task Force workshop @ Swissmedic, Bern, 31 March to 2 April 2025
Platform for international regulatory authorities to discuss and collaborate on key issues related to Large Language Models (LLMs).

GSRS25 in Lausanne, Switzerland, 15-17 September 2025
Advancing regulatory science with tomorrow's technologies. It's an in-person meeting featuring plenary sessions and poster presentations.

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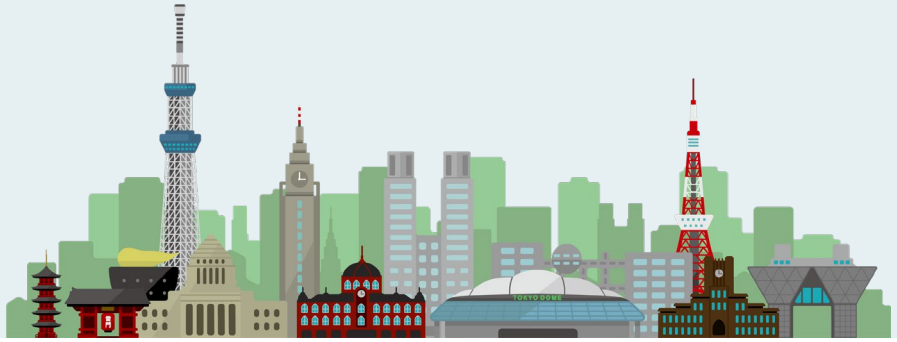

Thank you/Questions

swissmedic

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