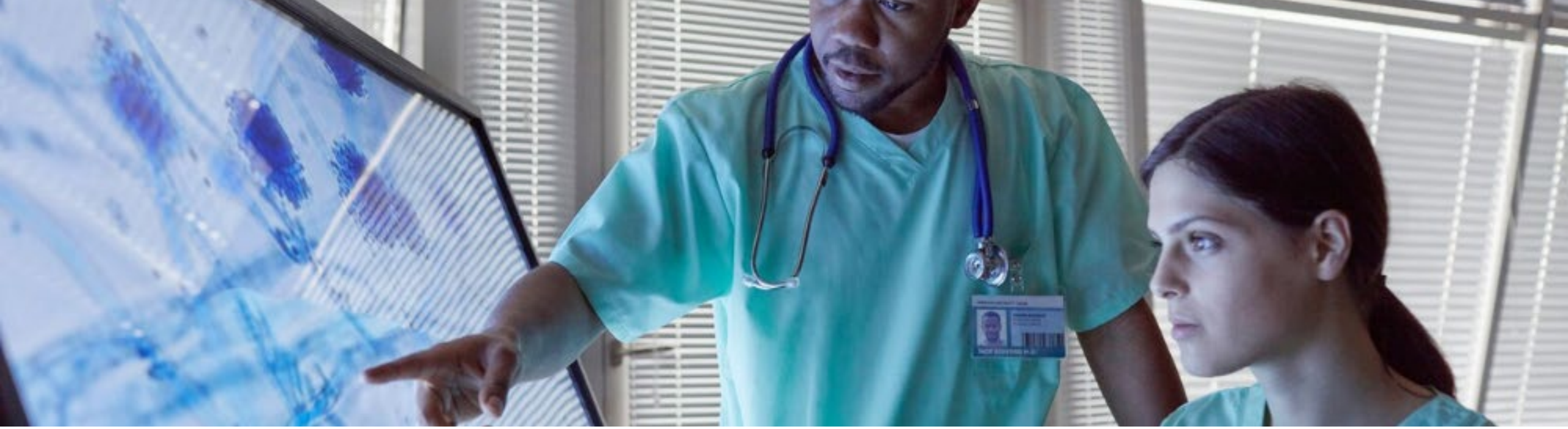

Business Assurance

Impact of MDR in Switzerland

Ibim Tariah Ph.D | OSMA Winter Conference - January 21-23 2025

Speaker

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Dr Tariah's European regulatory affairs experience spans over 25 years and includes knowledge of combination devices incorporating biologics, drugs and drug-biologics together with Quality Management Systems Assessment of Medical Devices. His expertise lies in innovative non-active vascular, orthopaedic & dental, and other long-term implantable devices.

Agenda

- Background: Swiss Medtech Industry Sector Study 2024
- Impact of MDR
- Why consider Switzerland?
- Swissmedic (MedDO, SR 812.213)
- Leveraging existing CE Mark approvals
- Q&A

Swiss Medtech Sector Study

- Swiss medical technology industry is robust, and very important for the Swiss economy.
- Creates above-average number of jobs compared to other industries.
- CGR over 6% in the last two years, twice as fast as Switzerland's nominal GDP in same period.
- Biggest challenges for the industry are the high levels of regulation and cost pressures.

- *Source: Swiss Medical Technology Industry – Sector Study 2024*

Swiss Medtech Sector Study

- Study report date: September 2024
- Approx 1,400 Medtech companies predominantly SME’s,
- Data from over 470 Medtech companies
- Over 4,200 new jobs created in the last two years
- 1 in 100 workers employed in the medical technology field => total workforce in 2023 of approx. 71,700
- Generated 23.4 bn Swiss francs in 2023 (25.66 bn USD)
- In 2023 medtech industry contributed 11.9% to Switzerland’s positive trade balance.

- *Source: Swiss Medical Technology Industry - Sector Study 2024*

Impact of MDR

- MDR described by industry as bureaucratic, costly and hinders innovation
- 80% of manufacturers hired additional staff
- 60% reassigned human resources from R&D
- 50% of manufacturers have reduced their product portfolio by an average of 20%
- Development costs increased by approx. 28%.
- 75% of Swiss companies are calling for an opening of the Swiss market for products with non-European certificates.

Impact of MDR

- MDR implementation challenges becoming obvious throughout the country.
  - ➢Shortages in supplies of both existing and new products.
- Many foreign manufacturers no longer prepared to bear additional administrative costs necessary to fulfill third country requirements.
- "*Switzerland would be well advised to ensure supply for its own population by diversifying the scope for procuring medical devices, as well as initiating acceptance of medical products with FDA approval*,"

Impact of MDR

- For Swiss manufacturers FDA certification for the US market is attractive - fast, regulated and monitored procedures.
- For small Swiss companies with innovative products, delayed availability on the Swiss market due to the “FDA first” logic
- Swiss parliament motion 20.311 requires that medical devices with FDA certification can also be placed on the Switzerland market.
  - Two out of three companies welcome this mandate referred to the Swiss Federal Council by Parliament
- In November 2022 Parliament instructed the Federal Council to allow FDA-certified medical devices in Switzerland already
- Swiss National law must now be revised accordingly.

Summary of Impact of MDR

- Consequences of MDR/IVDR

- 13% increase in product costs
- 10% reduction in product portfolio
- 3% increase in human resources

- Dealing with the FDA

- 62% find acceptance in Switzerland important
- 47% certify products according to FDA
- 21% prefer first approvals according to FDA

Why Consider Switzerland?

- *“Regardless of company size, higher growth is expected in 2025 – smaller companies with greater growth potential”*

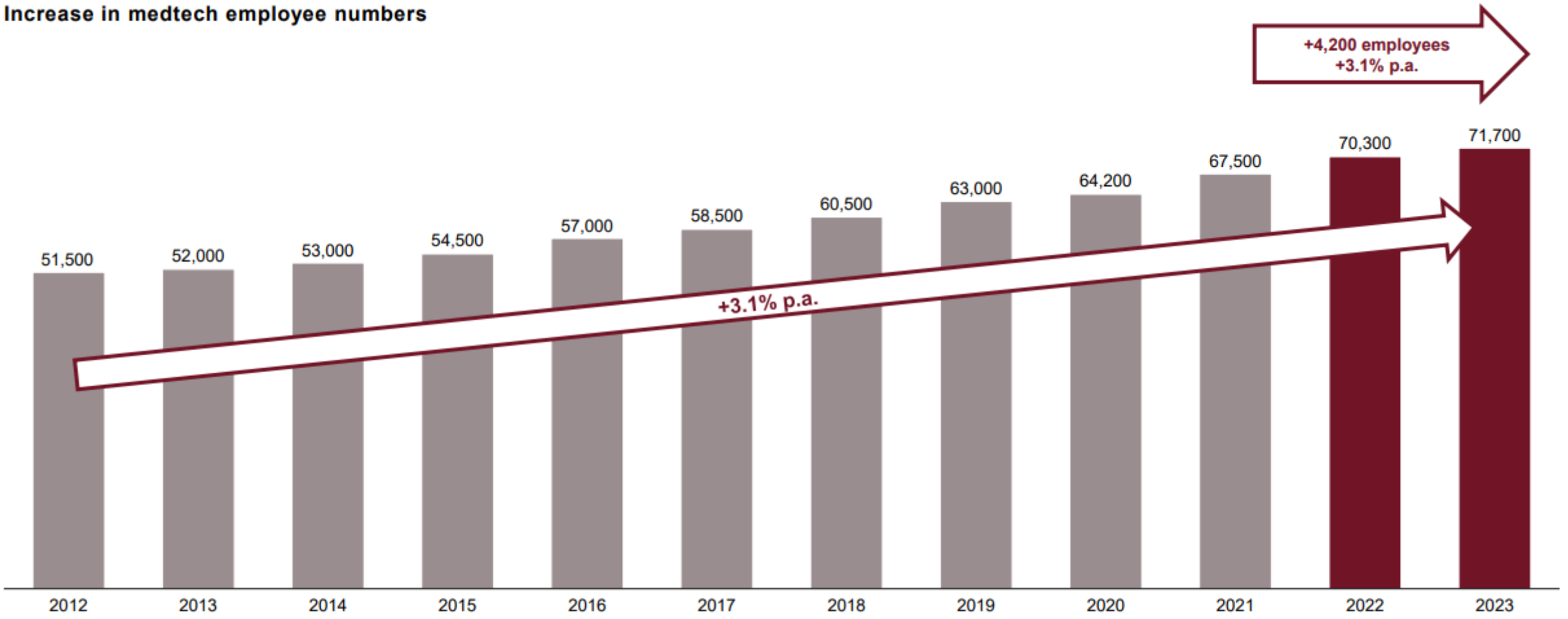
- *Source: Swiss Medical Technology Industry - Sector Study 2024*

Why Consider Switzerland?

Country	Population (Millions)	2022 GDP ($ Trillion)	2022 GDP per Capita ($)
USA	333.29	25.44	76,329
Canada	38.93	2.16	55,522
Brazil	215.31	1.92	8,917
Australia	26.00	1.69	65,099
Japan	125,12	4.26	34,017
UK	66.97	3.09	46,125
Switzerland	8.78	0.82	93,259

Source: https://data.worldbank.org/

Why Consider Switzerland?



Top 10 MedTech employers by number of employees in Switzerland (data 2023)

No.	Company	Core activities in Switzerland	Head office	Employees in Switzerland	Global sales growth (in %)	R&D / sales global (in %)
1	Roche Diagnostics	In vitro diagnostics	CH	2,841	-13.0%	13.1%
2	Jabil	Orthopedics	USA	2,541	n/a	n/a
3	Straumann	Dentistry	CH	1,722	9.8%	n/a
4	J&J Medical	Orthopedics, traumatology, wound treatment	USA	1,650	6.0%	17.0%
5	Ypsomed[2)]	Injection systems (drug delivery) and diabetes treatment	CH	1,627	25.0%	16.0%
6	Hamilton[1)]	Ventilators, in vitro diagnostics, laboratory automation	CH	1,600	n/a	n/a
7	Sonova[2)]	Hearing system technology	CH	1,559	-3.0%	6.5%
8	Biotronik	Cardiology	D	1,350	n/a	n/a
9	Zimmer Biomet	Orthopedics, traumatology	USA	1,250	7.0%	12.0%
10	Medtronic	Cardiology	IRL	1,150	4.0%	12.0%
				∑ 17,290	3.3%	12.9%

Swiss Medical Devices Ordinance (MedDO, SR 812.213)

- MRA Status:

  No agreement between Switzerland and the EU

  Effective May 26th, 2021 Switzerland considered a third country by the EU

- Manufacturers with CE Mark approvals accepted

- Manufacturers with FDA 510(k) or PMA or UKCA currently not accepted :

Swiss Medical Devices Ordinance (MedDO, SR 812.213)

- Manufacturers going to Switzerland for the First Time:

  Must comply with Swiss medical devices regulations

  Must undergo a conformity assessment process to obtain Swiss market approval.

  Conformity assessment process includes:

  - evaluation of design
  - production controls,
  - clinical trials,
  - labelling, and
  - post-market surveillance.

- Exclusive: Swiss rep and listing at Swssmedic
- Manufacturers should contact Swissmedic for guidance, specific requirements and procedures

- Source: Swiss Medical devices legislation

Recommendation for Manufacturers From Outside The EU

- Manufacturers must appoint a Swiss Authorized Representative, who is responsible for regulatory compliance and communication with Swissmedic.
- Swiss Quality Management System (QMS) Certification: Manufacturers must have their quality management system certified according to the Swiss requirements, which are aligned with but not identical to the EU's QMS standards.
- Swiss-Specific Technical Documentation: The technical documentation for the medical device must be adapted to meet the specific Swiss regulatory requirements, even if the device is already approved elsewhere.

Recommendation for Manufacturers From Outside The EU

- Swiss-Specific Labeling: The labeling on the medical device and its packaging must be in all of Switzerland's national languages (German, French, Italian).
- Swiss Device Registration: The medical device must be registered with Swissmedic, the Swiss regulatory authority, before it can be placed on the Swiss market.
- Swiss Vigilance Reporting: Manufacturers must comply with Swiss-specific requirements for reporting incidents, field safety corrective actions, and other vigilance-related activities.
- Swiss Fees and Taxes: Manufacturers must pay the applicable fees and taxes required by the Swiss authorities for medical device registration, surveillance, and other regulatory activities.
- swissdamed – swiss database on medical devices

Recommendation for Manufacturers From Outside The EU

- Database for registration of economic operators, medical devices and IVDs
- Consists of: "Actors-" and "Devices-" modules and a public website.
- August 6th, 2024 – 1st Module – “Actors”: Enables Economic operators to register online
- To be released in 2025 – 2nd Module - "Devices" will go live in several phases:
  - Possible to register certain devices, specifically "Regulation Devices" (MDR and IVDR)…uploaded using XML files in the EUDAMED format.
- From 1 July 2026, devices, systems and procedure packs must be registered; if a serious incident, FSCA, CA or a trend needs to be reported
- 31 Dec 2026, Manufacturers & their ARs deadline for registering their devices.

Leveraging existing approvals: CE*/CE

- Existing USA manufacturer:
- Assuming ISO 13485:2016 is in place:

  (i) Obtain a MDSAP certificate => access five jurisdictions (including USA)

  (ii) Access Switzerland with CE*/CE Mark: (require Swiss top-up)

  MDD CE* = Meets MDD certification extension criteria per Regulation (EU) 2023/607

Leveraging existing approvals: FDA?

- For the future FDA Approval + Swiss top-up……

Summary

- In the absence of an EU Mutual Recognition Agreement (MRA), Switzerland has implemented its own medical device regulations aligned with the EU MDR.
- Manufacturers entering Switzerland with CE Marked devices need to register with Swissmedic and report incidents.
- Manufacturers coming to Switzerland for the first time must undergo a conformity assessment process and comply with Swiss regulations.
- Parliament instructed the Federal Council to allow FDA-certified medical devices in Switzerland already
- Swiss National law must now be revised accordingly.

Thank you!

What questions do you have?

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