



Swissmedic 4.0

Digitalisation in concrete terms

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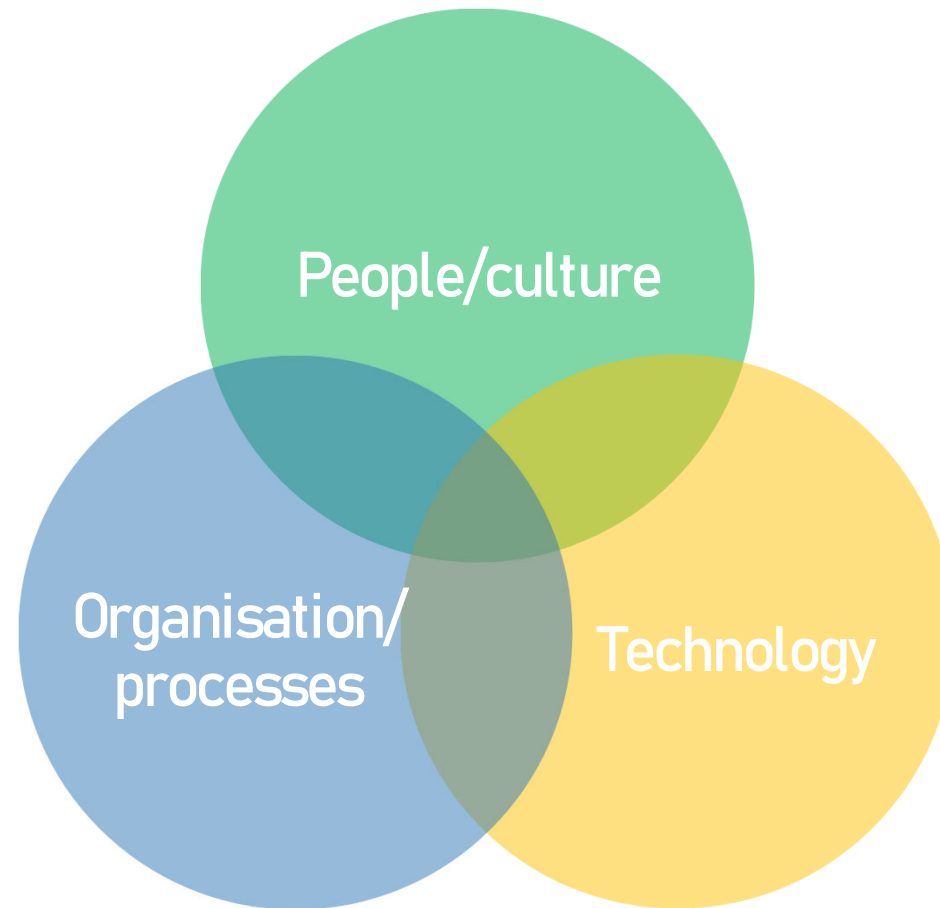


2020 - 2025

An innovation lab to promote interdisciplinary cooperation and develop new digital business models.

Flexible, agile working and rapid prototype development to support regulatory work and improve patient safety.

Impact dimensions



Technology – Data-centric applications

Medicrawl/Nightcrawler

- **Webcrawler for market surveillance**
- Searches sales platforms for suspicious adverts (counterfeits, claims of curative properties).

Tricia

- **Triage of incident reports**
- Supports prioritisation of reports through automated risk assessments.

LiSA

- **Safety signals from literature**
- AI-based analysis of publications for early detection of risks for medicinal products.

DORI – Internal search engine

- Rapid access to internal documents.

Large language models

- Specific use cases, e.g. for questions on pharmacopeia, comparisons of adverse reactions.
- Launch of the LLM Task Force: development of prototypes such as “AskYourDocuments” or “AskYourGuidance”.

Organisation & processes – promotion of agile cooperation

Implementation of agile frameworks

- “Retro as a Service” promoting continuous process improvements and cross-team learning.
- Agile coaching: Support through agile coaching for managers and teams.

Networking and communication

- >60 presentations in Switzerland and abroad
- Publications
- WEF, House of Switzerland
- Bilateral relationships with regulatory authorities such as the FDA, MHRA and HSA

International cooperation

- Cooperation with the EMA, FDA, WHO
- Collabathon GSRS24, Health Canada
- IMDRF AI WG
- LLM Task Force
- Global Coalition for Regulatory Science Research (GCRSR)

People & culture – Development of a data-oriented culture

Innovation and error tolerance

- Willingness to experiment and innovative flair: Employees are encouraged to take creative approaches and try out new ideas.
- Promoting a positive approach to errors: Initiatives such as “fail nights” to consider errors as an opportunity to learn and develop an open culture of innovation.
- Swissmedic 4.0 games/app: Fun approaches to promoting a culture of innovation and feedback within the organisation.

Knowledge transfer and networking

- Swissmedic live updates: Regular events on digital topics and projects to promote sharing knowledge.
- Internal communication: Articles and videos on new tools and technologies via the “Hailo” internal platform to increase acceptance and understanding.
- Community of Practices: Networks for employees to share experience and best practices and utilise synergies.

Outlook/recommendation

- Sustainable further development of existing applications
- Expansion of international cooperation and joint projects, in the area of machine learning and data analysis in particular.
- Focus on people & culture: Increased promotion of data literacy and ongoing training in preparation for future challenges.