swissmedic

Programme

Swissmedic information event

"Regulatory&Beyond"

20 September 2022, Hotel Allegro/Kursaal Bern, 9.00 a.m. to 5.30 p.m.

Time	*Topic*	*Speaker*
From 8.30 a.m.	*Welcome coffee and registration*	
9.00 a.m.	**Introduction & welcome**	Eliane Schmid
9.05–9.15 a.m.	**Executive Director's welcome**	Raimund Bruhin
9.15–10.10 a.m.	**Swissmedic – fit for the future** Podium discussion with the Management Board: • **Raimund Bruhin**, Executive Director, Swissmedic • **Claus Bolte,** Head of Authorisation Sector • **Philippe Girard,** Head of Licensing Sector • **Helga Horisberger,** Head of Legal Affairs Sector • **Daniel Leuenberger,** Head of Infrastructure Sector • **Karoline Mathys,** Head of Market Surveillance Sector • **Jörg Schläpfer,** Head of Management Services & International Affairs Sector • **Barbara Schütz,** Head of Human Resources and Finance Sector	Moderated by Eliane Schmid
10.10–10.30 a.m.	**Innovation@Swissmedic** How innovative can a regulatory agency be? – Opportunities, limits & approaches	Philippe Girard
10.30–10.55 a.m.	**Swissmedic 4.0: Digitalisation in concrete terms**	Michael Renaudin
10.55–11.00 a.m.	*Organisational information*	Eliane Schmid
11.00–11.25 a.m.	*Short coffee break*	

& Beyond: Parallel session: Medicinal products – Life cycle and special topics

Time	*Topic*	*Speaker*
11.30–11.35 a.m.	**Welcome and presentation of the programme**	Claus Bolte
11.35–11.55 a.m.	**Real world evidence**	Lorenzo Hess Leonie Rudofsky
11.55 a.m.–12.10 p.m.	**Centre of expertise for ATMPs** • What does centre of expertise for ATMPs mean? Why is such a centre needed? • Tasks and goals of the centre of expertise for ATMPs • Developments in the field of ATMPs as a challenge • The regulatory response to ATMP innovations – The role of Swissmedic	Julia Djonova
12.10–12.30 p.m.	***Market surveillance of medicinal products: Genotoxic impurities – What Swissmedic expects***	Susanne Wegenast Thomas Hottiger
12.30–1.45 p.m.	*Lunch break with buffet lunch & Swissmedic Info Market*	

Session: Clinical trials and licensing

Time	*Topic*	*Speaker*
1.45–1.50 p.m.	**Welcome and presentation of the programme**	
1.50–2.15 p.m.	**Focus on innovation: Early phase clinical trials and DCTs** • Fast-track evaluation of Phase 1 studies • DCTs	Alex Mion
2.15–3.00 p.m.	**Digitalisation: Opportunity, challenge and limits** • Paperless establishment licences from submission to issuance: Utopia or imminent reality? • Remote assessment instead of on-site inspections: Conceivable? Desirable? Feasible?	Federico Cimini Georges Meseguer Christian Schärer
3.00–3.20 p.m.	**Remote approaches to GCP and GVP regulatory oversight** • Remote GCP/GVP inspections, opportunities and challenges • Desk-based inspections	Simone Ferbitz
3.20–3.40 p.m.	**Changes in narcotics legislation concerning the medical use of cannabis** • What is now possible? • Cultivation of cannabis for medical use	Monika Joos
4.00–5.30 p.m.	*Swissmedic Info Market incl. drinks reception*	

Session: Authorisation and life cycle management

Time	*Topic*	*Speaker*
1.45–1.50 p.m.	**Welcome and presentation of the programme**	Simon Dalla Torre
1.50–2.20 p.m.	**International cooperation** • Review/outlook: Access • Review/outlook: Orbis	Cornelia Bigler Ulrich Rohr
2.20–2.40 p.m.	**Temporary additional indications**	Anna Barbara Stalder
2.40–3.00 p.m.	**Nanosimilars / NBCDs**	Matthias Gautschi
3.00–3.20 p.m.	**Experience with applications per Art. 14 para. 1 let. a$^{bis-quater}$ TPA**	Martina Gerber
3.20–3.40 p.m.	**Experience with patient reports during the COVID pandemic in Switzerland**	Thomas Stammschulte
3.40–4.00 p.m.	**Limits of transparency illustrated by COVID-19** (number of reports, SwissPAR, EPAR in the public eye)	Christoph Küng
4.00–5.30 p.m.	*Swissmedic Info Market incl. drinks reception*	

Session: Veterinary medicinal products

Presentations in German without simultaneous interpreting

Time	*Topic*	*Speaker*
1.45–2.00 p.m.	**Welcome**	Nina Walser
2.00–3.00 p.m.	**Transfer of immunological veterinary medicinal products from IVI to Swissmedic**	Rosa Stebler-Frauchiger Barbara Wieland (IVI) Nina Walser
3.00–3.30 p.m.	**Revised VMP legislation**	Peter Schmid Stefan Herrli
3.30–4.00 p.m.	**International collaboration**	Catharina Lany
4.00–5.30 p.m.	*Swissmedic Info Market incl. drinks reception*	

Session: Complementary and herbal medicines

Presentations in German without simultaneous interpreting

Time	*Topic*	*Speaker*
1.45–2.00 p.m.	**Welcome**	Martin Ziak Bilkis Heneka
2.00–2.20 p.m.	**Presenting our new complementary and herbal medicines website!**	Christine Ruppen Michaela Stach-Rüefli
2.20–2.40 p.m.	**Simplified authorisation procedure for herbal medicines according to Art. 14 para. 1 let. c^{bis} and $a^{bis-quater}$ TPA**	Anne-Isabelle Reich Tobias Schlechtinger
2.40–3.00 p.m.	**Complementary medicines: Requirements for bibliographical evidence in connection with simplified authorisation procedures**	Julie Morciano
3.00–3.10 p.m.	**Medicinal products and procedures authorised in foreign countries for CHM (Art. 13 TPA)**	Julian Affolter
3.10–3.30 p.m.	**Notification procedure for homeopathics/anthroposophics – efficient submissions**	Conwitha Lapke
3.30–4.00 p.m.	**Q&A session**	All
4.00–5.30 p.m.	*Swissmedic Info Market (without CHM stand) incl. drinks reception*	

& Beyond: Parallel session: Medical devices – Life cycle of and special topics

Time	*Topic*	*Speaker*
11.30–11.35 a.m.	**Welcome and presentation of the programme**	Karoline Mathys
11.35 a.m.–12.15 p.m.	**Global Regulatory Requirement for medical devices** *Presentation in English*	Michael King *Senior Director, Product & Strategy, IQVIA*
12.30–1.45 p.m.	*Lunch break with buffet lunch & Swissmedic Market*	
1.45–2.15 p.m.	**Cyber security and medical devices** *Presentation in French*	Solange Ghernaouti *Professor, Director of the Swiss Cybersecurity Advisory & Research Group, University of Lausanne*
2.15–2.45 p.m.	**Clinical data – Challenges since the introduction of the MDR**	Christiane Chène *Senior Scientific Expert, Dr. Regenold GmbH & CE plus GmbH*
2.45–3.15 p.m.	**Transparency and medical devices – Implementation in the EU and Switzerland** *Presentation in English*	Richard Houlihan *CEO, EirMed (@ eudamed.com)*
3.15–3.45 p.m.	**Artificial intelligence in medical devices** *Presentation in German*	André Baumgart *Advisor Medical AI Products / Lead Scientist AI-based Health Systems*
4.00–5.30 p.m.	*Swissmedic Info Market incl. drinks reception*	