Programme

Swissmedic information event

"Regulatory&Beyond"

20 September 2022, Hotel Allegro/Kursaal Bern, 9:00 to 17:30

Conference Room "Arena"

Time	***Topic***	***Speaker***
From 8:30	*Welcome coffee and registration*	
9:00	**Introduction & welcome**	Eliane Schmid
9:05–9:15	**Executive Director's welcome**	Raimund Bruhin
9:15–10:10	**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	**Innovation@Swissmedic** How innovative can a regulatory agency be? – Opportunities, limits & approaches	Philippe Girard
10:30–10:55	**Swissmedic 4.0: Digitalisation in concrete terms**	Michael Renaudin
10:55–11:00	*Organisational information*	Eliane Schmid
11:00–11:25	*Short coffee break*	

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

Conference Room "Arena"

Time	*Topic*	*Speaker*
11:30–11:35	**Welcome and presentation of the programme**	Claus Bolte
11:35–11:55	**Real world evidence**	Lorenzo Hess Leonie Rudofsky
11:55–12:10	**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	***Market surveillance of medicinal products: Genotoxic impurities – What Swissmedic expects***	Susanne Wegenast Thomas Hottiger
12:30–13:45	*Lunch break with buffet lunch & Swissmedic Info Market*	

Session: Clinical trials and licensing

Conference Room "Aare"

Time	*Topic*	*Speaker*
13:45–13:50	**Welcome and presentation of the programme**	
13:50–14:15	**Focus on innovation: Early phase clinical trials and DCTs** • Fast-track evaluation of Phase 1 studies • DCTs	Alex Mion
14:15–15:00	**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
15:00–15:20	**Remote approaches to GCP and GVP regulatory oversight** • Remote GCP/GVP inspections, opportunities and challenges • Desk-based inspections	Simone Ferbitz
15:20–15:40	**Changes in narcotics legislation concerning the medical use of cannabis** • What is now possible? • Cultivation of cannabis for medical use	Monika Joos
16:00–17:30	*Swissmedic Info Market incl. drinks reception*	

Session: Authorisation and life cycle management

Conference Room "Arena"

Time	*Topic*	*Speaker*
13:45–13:50	**Welcome and presentation of the programme**	Simon Dalla Torre
1:50–14:20	**International cooperation** • Review/outlook: Access • Review/outlook: Orbis	Cornelia Bigler Ulrich Rohr
14:20–14:40	**Temporary additional indications**	Anna Barbara Stalder
14:40–15:00	**Non-biological complex drugs (NBCDs)**	Matthias Gautschi
15:00–15:20	**Experience with applications per Art. 14 para. 1 let. a$^{bis-quater}$ TPA**	Martina Gerber
15:20–15:40	**Experience with patient reports during the COVID pandemic in Switzerland**	Thomas Stammschulte
15:40–16:00	**Limits of transparency illustrated by COVID-19**	Christoph Küng
16:00–17:30	*Swissmedic Info Market incl. drinks reception*	

Session: Veterinary medicinal products *Presentations in German without simultaneous interpreting*

Conference Room "Panorama 4"

Time	*Topic*	*Speaker*
13:45–14:00	**Welcome**	Nina Walser
14:00–15:00	**Transfer of immunological veterinary medicinal products from IVI to Swissmedic**	Barbara Wieland (IVI) Rosa Stebler-Frauchiger Peter Schmid
15:00–15:30	**Revised VMP legislation**	Peter Schmid Stefan Herrli
15:30–16:00	**International collaboration**	Catharina Lany
16:00–17:30	*Swissmedic Info Market incl. drinks reception*	

Session: Complementary and herbal medicines *Presentations in German without simultaneous interpreting*

Conference Room "Panorama 1"

Time	*Topic*	*Speaker*
13:45–14:00	**Welcome**	Martin Ziak Bilkis Heneka
14:00–14:20	**Presenting our new complementary and herbal medicines website!**	Christine Ruppen Michaela Stach-Rüefli
14:20–14:40	**Simplified authorisation procedure for herbal medicines according to Art. 14 para. 1 let. c^{bis} and $a^{bis\text{-}quater}$ TPA**	Anne-Isabelle Reich Tobias Schlechtinger
14:40–15:00	**Complementary medicines: Requirements for bibliographical evidence in connection with simplified authorisation procedures**	Julie Morciano
15:00–15:10	**Medicinal products and procedures authorised in foreign countries for CHM (Art. 13 TPA)**	Julian Affolter
15:10–15:30	**Notification procedure for homeopathics/anthroposophics – efficient submissions**	Conwitha Lapke
15:30–16:00	**Q&A session**	All
16:00–17:30	*Swissmedic Info Market (without CHM stand) incl. drinks reception*	

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

Conference Room "Szenario 1 & 2"

Time	*Topic*	*Speaker*
11:30–11:35	**Welcome and presentation of the programme**	Karoline Mathys
11:35 –12:15	**Global Regulatory Requirement for medical devices** *Presentation in English*	Michael King *Senior Director, Product & Strategy, IQVIA*
12:30–13:45	*Lunch break with buffet lunch & Swissmedic Market*	
13:45–14:15	**Cyber security and medical devices** *Presentation in French*	Solange Ghernaouti *Professor, Director of the Swiss Cybersecurity Advisory & Research Group, University of Lausanne*
14:15–14:45	**Clinical data – Challenges since the introduction of the MDR** *Presentation in English*	Christiane Chène *Senior Scientific Expert, Dr. Regenold GmbH & CE plus GmbH*
14:45–15:15	**Transparency and medical devices – Implementation in the EU and Switzerland** *Presentation in English*	Richard Houlihan *CEO, EirMed (@ eudamed:com)*
15:15–15:45	**Artificial intelligence in medical devices** *Presentation in German*	André Baumgart *Advisor Medical AI Products / Lead Scientist AI-based Health Systems*
16:00–17:30	*Swissmedic Info Market incl. drinks reception*	