

Agenda

Swissmedic Roundtable Innovation (RTI) on

3R Regulatory Implementation: Status of New Approach Methodologies (NAMs) in Drug Safety

December 4th, 2023, 10:00 - 12:00

Swissmedic, Hallerstrasse 7, Bern; Meeting Room H044

MS Teams Link

10:00-10:10	Welcome and Introductions Dr. Elisabeth Klenke, Head Sector Authorization a.i., Head Nonclinical Assessment & GLP Inspectorate, Swissmedic
10:10-10:25	Academic perspectives Prof. Johannes Mosbacher, FHNW Professor for Precision Pharmaceuticals
10:25-10:40	Industry perspectives PD Dr. Birgit Ledermann, Novartis 3Rs Leader
10:40-10:55	European regulatory perspectives Dr. Sonja Beken, Chair 3Rs Working Party EMA, FAMHP Belgium
10:55-11:50	Open discussion Moderator: Dr. Tatjana Petkovic, Assessor, Nonclinical Assessment & GLP Inspectorate, Swissmedic
11:50-12:00	Closing remarks and next steps Dr. Elisabeth Klenke

End of the Roundtable Innovation