

Implementing the 3Rs in WHO guidelines – understanding the impact on quality control and batch release testing of biologicals in Europe

2 March 2022, by Zoom

10.00 – 10.05	Welcome and introduction <i>Dr Ian Ragan, Chair of the NC3Rs working group to review animal use requirements in WHO biologics guidelines</i>
10.05 – 10.15	Aims and objectives for the meeting <i>Professor Klaus Cichutek, Paul-Ehrlich-Institut, Germany and outgoing Chair of ECBS</i>
Scene setting	
10.15 – 10.30	Project overview: Reviewing animal use requirements in WHO guidelines and opportunities for 3Rs approaches <i>Dr Elliot Lilley, NC3Rs</i>
10.30 – 11.15	Keynote address – EU Pharmacopeia and WHO guidelines...how aligned are they? <i>Dr Laurent Mallet, Head of Department of Biological Standardisation, EDQM</i>
11.15 – 11.30	BREAK
How aligned are we across Europe?	
11.30 – 12.40	National perspectives on non-animal approaches for quality control and batch release testing of biologicals and the influence of WHO guidelines <ul style="list-style-type: none"> - Federal Service for Surveillance in Healthcare, Russia (TBC) - Dr Pavlinka Stoyanova, Bulgarian Drug Agency, Bulgaria (TBC) - Dr Volker Öppling, Head of Section Microbiological Vaccines, Paul-Erlich-Institut, Germany - Dr Geneviève Waeterloos, Sciensano, Belgium
12.40 – 13.00	An industry consensus: How does (dis-)harmonisation in acceptance of 3Rs/non-animal approaches for quality control and batch release testing of biologicals impact manufacturers? <i>Dr Philippe Juvin & Dr Emmanuelle Coppens, Sanofi and representing IFPMA</i>
13.00 – 13.45	BREAK
Panel session	
13.45 – 14.00	Introduction to the session and voting instructions
14.00 – 15.15	Panel discussion Moderator: <ul style="list-style-type: none"> - Dr Svein Rune Andersen, Norwegian Medicines Agency, Norway

	<p>Panellists:</p> <ul style="list-style-type: none"> - Dr Emmanuelle Charton, EDQM - Dr Shahjahan Shaid, GSK - Dr Mark van Ooij, Janssen - Dr Anne Dybwad, Norwegian Medicines Agency, Norway - Dr Geneviève Waeterloos, Sciensano, Belgium - Dr Paul Stickings, NIBSC, UK - Federal Service for Surveillance in Healthcare, Russia (<i>TBC</i>) <p>The panel discussion will include opportunities for delegates to ask questions of the panel and to respond directly to questions themselves using an interactive voting system.</p>
15.15 – 15.25	Wrap up
~	Meeting close

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