Implementing the 3Rs in WHO guidelines

Understanding the impact on quality control and batch release testing of biologicals

Tuesday 19 – Wednesday 20 September 2023, London, UK Free to attend, in person and virtual meeting

Register now:

nc3rs.org.uk/events/workshop-implementing-3rs-who-biologicals-guidelines

This workshop comes at the culmination of a three-year project led by the UK National Centre for the Replacement, Refinement and Reduction of Animals in Research to promote harmonised integration of the 3Rs in the World Health Organization (WHO) guidelines for quality control and batch release testing of vaccines and biological therapeutics. Co-funded by the Bill and Melinda Gates Foundation, the project has identified opportunities for the scientifically evidenced integration of 3Rs approaches and will recommend these to the Expert Committee on Biological Standardization (ECBS) in October 2023.

The project has been approved by ECBS (<u>TRS1024</u>, <u>Section 2.2.2</u>, <u>page 8</u>) and further details have been published in <u>Biologicals</u>.

Five themes will be discussed at the meeting:

- Adventitious agents testing.
- Neurovirulence testing.
- Pyrogen and endotoxin testing.
- Potency and immunogenicity testing.
- Specific toxicity testing.

Each session will introduce the recommended revisions to current, relevant WHO guidance, summarising the 3Rs approaches being proposed. Discussions will be led by experts, manufacturing and regulatory representatives, and each session will include a panel discussion on the recommendations and their potential barriers to uptake.

Confirmed speakers include:

- Prof Coenraad Hendrikson
- Dr lan Ragan
- Dr Laurent Mallet, EDQM
- Dr Shahjahan Shaid, GSK

- Dr Emmanuelle Coppens, Sanofi
- Dr Eriko Terao
- Dr Masaaki lwaki
- Dr Pradip Das, Biologcal E



National Centre for the Replacement Refinement & Reduction of Animals in Research