3Rs WG – Q2 Meeting

May 11th, 2021
1. Welcome to New Members

• Appreciate the engagement of new DCVMN members in the 3Rs Working Group
• Now, WG has representatives from 9 countries!
• Welcome to:

  • Jie Song, Head Quality Control, IMBCAMS, China
  • Lingyun Zhou, Department of Quality Research, Shanghai Zerun Biotechnology Co., Ltd., China
  • Patricia Carneiro, QC Manager, Butantan Institute, Brazil
2. Sharing case studies on successful 3Rs implementation

• DCVMN encourage members to share successful case studies in implementing 3Rs. How?
  • During the 3Rs WG meetings
  • Present the process implemented (selection of the opportunity, team of people engaged, time needed, dialogue with regulators, impact (number of animals, costs saved, others)
  • Difficulties encountered and lessons learnt
2. Sharing case studies on successful 3Rs implementation

• Examples for Safety Tests
  • Abnormal Toxicity Test,
  • deletion of Specific Toxicity Test for Tetanus,
  • deletion of the pertussis irreversibility test and replacement of HIST with CHO-cell assays
  • Next Generation Sequencing (adventitious viruses/agents)

• Examples for Potency Tests
  • Serological assays
  • Single dilution
  • SRID, RIA, etc.
  • Antigen quantification
  • In vitro relative potency test
2. Sharing case studies on successful 3Rs implementation

• Volunteers to share case studies in the next call?

• Shall we plan to engage the DCVMN Regulatory Working Group?

• How?
3. Single dilution assay for DT vaccines

• Could it be a next project for DCVMN members?
• Experience to share?
• ISS/Italy available to support
4. DCVMN updates
### PSPT wP Project

#### Gantt Chart

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**What is happening now**

**Labs Get Ready!**
DCVMN 3Rs Paper

Work ongoing

• Integrate findings from the DCVMN Survey on animal use and 3Rs implementation

• Authors and contributions from the 3Rs WG
  • 3Rs WG members are welcome to work with DCVMN on the draft
  • Volunteers?
Updates on 3Rs initiatives & opportunities

• Abnormal Toxicity Test
  • Animal Free Safety Assessment Collaboration + EFPIA plans half a day discussion (first half of October) with industry and regulatory stakeholders to speed up deletion of the test
  • Invitation to DCVMN and all its members will come in the next weeks

• Rabies – replacement of NIH with ELISA
  • EDQM/EPAA BSP148 phase 2 started – protocol distributed, vaccines samples distribution
Updates on 3Rs initiatives & opportunities

• Polio Vaccines – NGS to replace MAPRECT+Monkey NVT
  • PATH is looking for interested manufacturers to join FDA/NIBSC phase 2 international collaborative study. If interested contact Kutub Mahmood - kmahmood@path.org

• HSI Working Group “Accelerating 3Rs methods in vaccine testing in China”
  • Promotion of the WG activities at Symposium on Regulatory Science Issues Related to Vaccine R&D and Registration" (疫苗研发注册有关的监管科学问题座谈会), May 15th, 2021.
Updates on 3Rs initiatives & opportunities

• NC3Rs: Reviewing animal use requirements in WHO biologics guidelines – opportunities for the 3Rs – [https://nc3rs.org.uk/review-animal-use-requirements-who-biologics-guidelines](https://nc3rs.org.uk/review-animal-use-requirements-who-biologics-guidelines)
  • Review work ongoing.
  • Survey to manufacturers and regulators will be shared
DCVMN 3Rs Training opportunities

• MAT
  • E-learning module (DCVMN moodle) (end of Q2)

• DT
  • E-learning module (DCVMN moodle) (Q3)

• Statistical analysis of the stability testing
  • E-learning module available in June
Key 3Rs publications

• Characterisation of tetanus monoclonal antibodies as a first step towards the development of an \textit{in vitro} vaccine potency immunoassay. \url{https://doi.org/10.1016/j.biologicals.2021.04.002}

• Characterisation of diphtheria monoclonal antibodies as a first step towards the development of an \textit{in vitro} vaccine potency immunoassay. \url{https://doi.org/10.1016/j.biologicals.2020.12.002}

• Variability of \textit{in vivo} potency tests of Diphtheria, Tetanus and acellular Pertussis (DTaP) vaccines. \url{https://doi.org/10.1016/j.vaccine.2021.03.078}
Next Meeting: Q3 doodle poll will follow