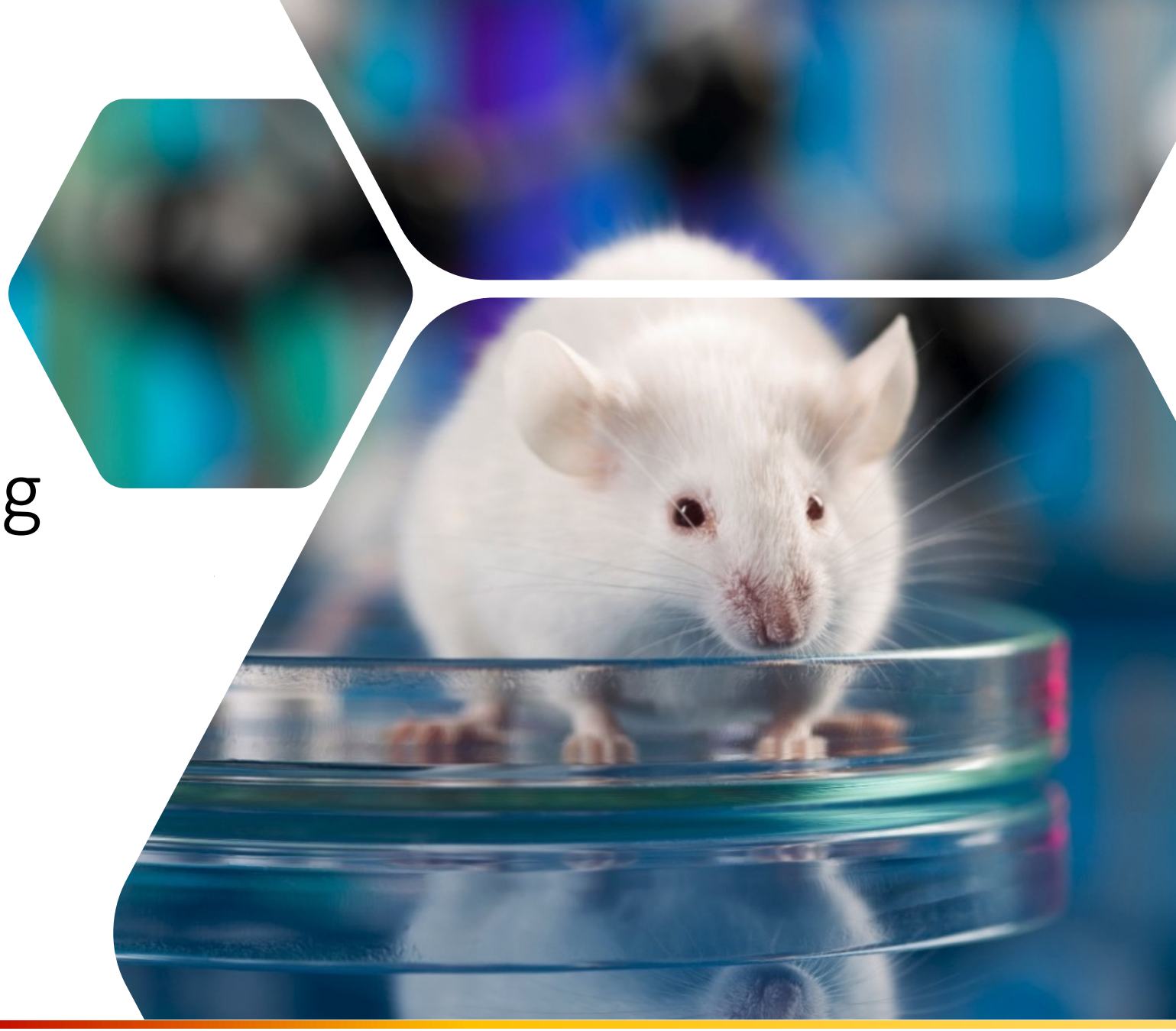
3Rs WG – Q3 Meeting

July 20th, 2021



dcvmn
Developing Countries Vaccine Manufacturers Network

1. Agenda

- Welcome

1. Deletion of the Abnormal Toxicity Test
2. 3Rs Case studies from D. Mahesh (Indian Immunologicals, Human Biologicals Institute)
3. 3Rs Case studies from P. Das (Biological E)
4. Update on 3Rs Initiatives and Opportunities

1. Deletion of Abnormal Toxicity Test

- DCVMN companies invited to participate to the multi-stakeholders workshop organized by AFSA and EFPIA in collaboration with IABS:

“Accelerating Global Deletion of the Abnormal Toxicity Test. Planning common next steps”
on October 14th, 2021 at 12:30 CEST via Zoom

- DCVMN represented by Indian Immunological in one roundtable.
- DCVMN companies invited to participate in a special country specific session to share their experience – if intersted contact L. Viviani
- Registration link soon to be shared by organizers

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

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

2. Do you still experience the following barriers?

- Limited expertise;
- Lack of business case to adequately inform relevant managers (QA, RA and production) of advantages;
- Hesitation due to the absence of regulatory/pharmacopoeia acceptance and guidance on 3Rs methods;
- Regulatory's hesitation on new methods;
- Lack of global harmonization of release requirements;
- Difficulties in in-house validation of the new methods;
- Need for establishment of new working Standard materials;
- Reagents availability;
- How to apply the alternative methodologies to evaluate vaccine stability.

2. Sharing case studies on successful 3Rs implementation

- D. Mahesh presentation
- P. Das presentation

3. DCVMN updates

PSPT wP Project

What is happening now

	Gantt Chart																	
	Month																	
	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb
Establish Consortium																		
Definition of the Study Design																		
Kick off meeting /Workshops																		
CMO Coating Antigen Production																		
Characterization of the Coating Antigen																		
Shipment of the Coating Antigen						preparation												
Technical Workshops																		
Preparation for the testing phase																		
Testing phase																		
Data Collection (online platform)																		
Statistical Analysis																		
Reporting																		
Final meeting (presentationof the																		

DCVMN 3Rs Paper – writing ongoing

- Integrated 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
  - **“Accelerating Global Deletion of the Abnormal Toxicity Test. Planning common next steps”**
    on October 14th, 2021 at 12:30 CEST via Zoom
  - Invitation to DCVMN and all its members sent – registration link will follow

HSI Working Group “Accelerating 3Rs methods in vaccine testing in China”

- Preparation of a summary document of all 3Rs accepted methods to be compared with current Chinese Pharmacopoeia (2020) requirements

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
  - Survey to manufacturers is going to be distributed soon to all DCVMN members
  - Please fill it in by Friday August 20th

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

- World Congress on Alternative to Animal testing
  - 23 August – 2 September – online - https://www.wc11maastricht.org/
  - S21 dedicated to ATT deletion

2021 3Rs in transition From development to application VIRTUAL CONGRESS - AUGUST 2021

Next Meeting: Q4 doodle poll will follow