

3Rs WG – Q4 Meeting

December 9th, 2021





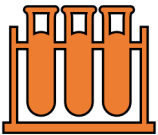
1. Agenda

- Welcome
- 1. Internal and External 3Rs initiatives and opportunities
 - Agree on DCVMN members further engagement
- 2. Share 3Rs-related cost savings data
 - Agree on what can be publicly reported
- 3. Nomination of new chair and co-chair for 2022
 - Introduce the process
- 4. ABO and wrap-up

1. Internal 3Rs initiatives and opportunities

- DCVMN/NIIMBL Pertussis Serological Potency Test (PSPT) Project

- Laboratories' testing phase almost complete
- Statistical Analysis by independent consultant to be initiated
- DCVMN's request to NIIMBL for project extension to be submitted
 - Complete statistical analysis
 - Workshop(s) on results review and support full validation studies' planning
 - Documentation review; peer-reviewed publication; communication materials to promote project's outcomes
 - Final meeting



1. Internal 3Rs initiatives and opportunities

- DCVMN Workshop on DT Single Dilution Assay on January 27th, 2022
 - DCVMN only participants
 - Facilitated by 3Rs and Regulatory WG Chairs and co-chairs, in collaboration with the Italian Institute of Health/ISS.
 - Share laboratories' experience in implementing the assay from quality control and regulatory perspective
 - *Live* discuss opportunities for DCVMN members to implement the assay
 - Registrations will be open soon - <https://dcvmn.org/DCVMN-3Rs-Workshop-Implementing-the-Diphtheria-Tetanus-Single-Dilution-Assay>



1. Internal 3Rs initiatives and opportunities

- DCVMN New training materials:

- Monocyte Activation Test

- Introductory course on moodle
 - VR experience to be available soon

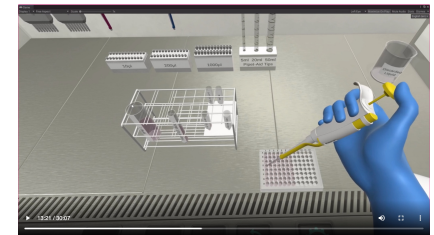
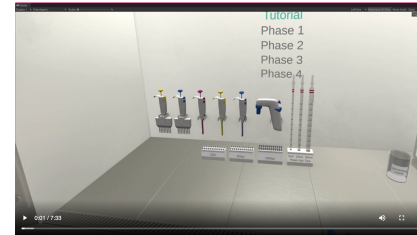
- You can watch the videos of the VR experience here:

Phase1: <https://drive.switch.ch/index.php/s/sgHz6X5JG8nWTkP>

Phase2: <https://drive.switch.ch/index.php/s/qDAy9VoGleJlpLJ>

Phase3: <https://drive.switch.ch/index.php/s/rhfbzIDbXgiUCCh>

Phase4: <https://drive.switch.ch/index.php/s/cTjtfrYbSB3J9XV>



1. Internal 3Rs initiatives and opportunities

- DCVMN 3Rs Planning for 2022



	Quarter											
	Q1			Q2			Q3			Q4		
	1	2	3	4	5	6	7	8	9	10	11	12
Increase WG membership and encourage quite members to contribute (change Chair and co-chair in Q1)	█	█	█	█	█							
Positioning DCVMN is all key ongoing 3Rs projects, collaborations, partnership	█	█	█	█	█	█	█	█	█	█	█	█
3R WG Calls		█			█				█		█	
Project to support implementation of single dilution assay for potency test (DT)	█	█	█	█	█	█	█	█	█			
2 workshops (members only) on other 3Rs opportunities				█					█			

1. External 3Rs initiatives and opportunities



- DCVMN participated to the multi-stakeholders workshop organized by HSI/AFSA and EFPIA in collaboration with IABS:

“Accelerating Global Deletion of the Abnormal Toxicity Test. Planning common next steps” on October 14th, 2021

All materials available here: <https://www.afsacollaboration.org/biologicals/att-deletion-workshop/>

- Importance of DCVMN’s engagement in the discussion at the global and local level carried out individually by both companies and DCVMN
- **Further dialogue opportunities will be advanced by HSI/AFSA, EFPIA and IABS and DCVMN will be involved**
- **HSI/AFSA in collaboration with some IPFMA companies will create a map on the status of ATT deletion and waiver. Consolidate data will show where ATT deletion has occurred and if and how regulatory requirements has changes or are changing. DCVMN contribution is more than welcome!**

1. External 3Rs initiatives and opportunities



- VAC2VAC project - Vaccine batch to vaccine batch comparison by consistency testing – sustainability plan aims to secure:
 - Access to new validated assays for safety and potency testing (not animal based or with important reduction and refinement opportunities)
 - Secure key critical reagent availability
 - Industry and regulatory engagement to promote implementation and acceptance – series of local webinars (2022-2023) and final conference (2024)
 - **DCVMN will be involved and engaged into the local webinars and into the final conference activities**

www.vac2vac.eu - www.iabs.org - www.afsacollaboration.org - www.euvaccine.eu

1. External 3Rs initiatives and opportunities



- NC3Rs/WHO Project
 - To learn more about it: DCVMN webinar on September 8th, 2021 - <https://dcvmn.org/-Webinar-materials-13->
 - European workshop on March 2nd, 2022. Register here: <https://www.nc3rs.org.uk/events/nc3rs-workshop-implementing-3rs-who-guidelines-understanding-impact-quality-control-and>
 - Asian region workshop – current draft agenda includes DCVMN contribution on:
 - Keynote: Collaborating across the region on advancing 3Rs methods – **Who?**
 - A manufacturers perspective on the adoption of non-animal approaches in quality control & batch release testing of **biologicals – Joint presentation between DCVMN 3Rs WG and other manufacturers**

1. External 3Rs initiatives and opportunities



- WHO-National Control Laboratory Network for Biologicals
 - 4th Meeting held on November 22-24, online.
 - DCVMN presented its ongoing 3Rs Activities
 - Opportunities for DCVMN members to join the network and share batch release data (under NDA)
 - The network aims to facilitate best practices exchanges and training among laboratories (inc. 3Rs), and promote alignment.
 - Watch the video: <https://www.dropbox.com/s/yvpni8s9vp9ankm/WHO-NNB-1280x720.mp4?dl=0>

1. External 3Rs initiatives and opportunities

Updates from the European Pharmacopoeia

- Histamine sensitisation test in mice (acellular Pertussis vaccines)
 - Residual toxin by standardised* cell-based (CHO) test performed on non-adsorbed purified pertussis components (validated detoxification procedure), irreversibility of toxoid test deleted, no toxicity test on final lot – effective 01/01/2020
- Toxicity for tetanus vaccines
 - Removal of test for specific toxicity (process validation guinea-pig test), removal of test for irreversibility of toxoid (guinea-pig test), (test for residual toxin (in guinea-pig@) retained on bulk purified toxoid) – effective 01/01/21
- Toxicity for Diphtheria vaccines
 - Removal of test for specific toxicity (process validation guinea-pig test) (test for residual toxin retained on bulk purified toxoid (vero cell assay)) – effective 01/01/22 (publication date 01/07/2022)
- Strategic plan to delete Rabbit Pyrogenicity Test from all monographs by 2026

* EDQM Biological Standardisation Program (BSP) study BSP114

@ EDQM Biological Standardisation Program study BSP136 BINACLE assay for in vitro replacement ongoing

1. External 3Rs initiatives and opportunities

- **Any other initiative or opportunity you wish to share with the group?**

2. Share 3Rs-related cost savings data



- Why?
 - Business aspect of the 3Rs implementation might provide with key information to companies and regulators and increase adoption
- What?
 - Number of not-used animals per batch
 - Reduction of batch production overall cost – in %?
 - Cost of the implementation – investment done vs cost reduction?
 - Other?
- When and Where?
 - 3Rs publications (in general and on specific projects)
 - DCVMN external presentations in conferences/workshops/webinars
 - Company internal presentations

3. Nomination of new chair and co-chair for 2022

- DCVMN 3Rs Working Group Terms of Reference requires nomination of new chair and co-chair every year with possibility to confirm the chair and co-chair for 2 consequent years.
- They will be responsible, in collaboration with the facilitator, for drafting the WG workplan, developing meeting's agenda and chairing meetings or teleconferences, approving the minutes of the meetings and supporting the facilitator and the Secretariat to fundraise to ensure the sustainability of the working group activities.

3. Nomination of new chair and co-chair for 2022

- New Nomination Process as recently approved by the DCVMN Board:
 - **Please submit your nominations by December 15th, 2021 to the DCVMN Secretariat (Mr. Suri, cc: Laura Viviani)**
 - The secretariat will share the names, qualification, experience, publications etc of all group members as also the suggested names for Chair & Co-Chair who will be met by 2 Board members and CEO before finalising their candidature.
- Profiles:
 - Expertise in implementing quality control related changes (from in-process control to final batch release with good understanding of the regulatory requirements and processes)
 - Specific expertise in implementation of Reduction, Refinement and Replacement opportunities (recognized by local regulatory authorities and/or WHO or other authorities; not yet recognized methodologies);
 - Experience in participating in international collaborative studies, projects, expert groups, committees or similar (country-specific or international or both) for the 3Rs implementation.

4. ABO and wrap up

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- DCVMN thanks very much Dr. Sunil Gairola and Dr. Pradip Das for all their support and guidance to the 3Rs WG!
- DCVMN thanks you all very much for your participation and wishes to see you all becoming even more active and engaged in promoting 3Rs!

Next Meeting: Q1 2022 doodle poll will
follow

THANK YOU!