

3Rs WG Meeting Teleconference

8th October, 2020

Developing Countries Vaccine Manufacturers
Network International

Agenda

1. NC3Rs/WHO project: Decision on DCVMN nominations
2. Presentation of external WG China 3Rs (for DCVMN members)
3. MoU with ISS: signature and activities
4. Brief update on the PSPT project
5. wP-aP training available on DCVMN Moodle
6. 3Rs paper and survey on animal use
7. aob

1. Invitation from NC3Rs received on 27.95 circulated to members: 6 nominations received.

NC3Rs query to Review of WHO Biologicals Guidelines Working Group

1. How much animal testing is recommended within the Biologicals Guidelines for the batch release testing of biologicals.
2. What opportunities exist for the integration of the 3Rs and to make recommendations for how this could be best achieved.
3. What barriers prevent 3Rs approaches from being implemented by manufacturers and the national authorities responsible for the testing and release of biologicals.

DCVMN expectation on the potential representation (criteria):

1. Person with experience in QC/batch release testing and 3Rs
2. Company member with a broad portfolio of vaccines (types and volume of doses)
3. Company member that is not over-represented in DCVMN activities
4. Geographical representation (NC3Rs has already one DCVMN Indian company participating)

Received and shortlisted CVs

	DCVMN Member volunteered (geographical location)	Current Role of the Representative	Other DCVMN related roles covered by the member	Company' vaccines in house lot release testing	Median to high volume of doses supplied (1 low- 5 high)	Recommendation from DCVMN secretariat
1	Incepta (Bangladesh) ✓	Manager Quality Control ✓	<ul style="list-style-type: none"> Member of 3Rs WG ✓ 	6 ✓	3 ✓	<ul style="list-style-type: none"> High number of vaccines with In-house lot release testing Middle-High volume capacity Only one role in DCVMN Geographical representation complementary to NC3Rs WG)
2	Indian Immunological (India)	Deputy General Manager Quality Control ✓	<ul style="list-style-type: none"> Member of 3Rs WG ✓ 	2	4 ✓	
3	Zydus Cadila (India)	Head of Vaccine Analytical team ✓	<ul style="list-style-type: none"> Member of 3Rs WG Chair of regulatory WG lead of PIP discussions 	3	2	
4	Panacea Biotec (India)	General Manager QA ✓	<ul style="list-style-type: none"> Member of 3Rs WG ✓ 	6	4	
5	BioNet-Asia (Thailand) ✓	Senior Quality Control Manager ✓	<ul style="list-style-type: none"> Member of 3Rs WG ✓ 	2	2	
6	Biological E (India)	Assistant General Manager QC ✓	<ul style="list-style-type: none"> Co-chair of 3Rs WG Member of PSPT Consortium, Gavi Board representative, COVAX Committee representative 	6 ✓	5 ✓	
7	Pasteur Institute (India)	Director, Head of Institute	<ul style="list-style-type: none"> Member of 3Rs WG, Member of PSPT Consortium 	n.a.	1	

Decision

- Is the 3Rs WG endorse the nomination of the candidate from Incepta?

2. Invitation from HSI received on 07.07 circulated to members: 2 nominations received.

HSI request for DCVMN nomination for an ad-hoc 3Rs WG in China

- engage DCVMN International and its Members from China in an *ad hoc* working group to discuss about the implementation of 3Rs and the removal of obsolete *in vivo* testing in Chinese vaccine regulations and requirements.
- The working group will have representatives from industry and regulators from China, the Bill & Melinda Gates Foundation, and a representative from NC3Rs

DCVMN expectation on the potential representation (criteria):

- minimum of 2 members,
- one from a private and one from a public manufacturer,
- manufacturers that have more than 2 products registered and available in the local market,
- the expertise of the nominated members should be in the quality control testing and in the regulatory affairs.

Received CV

	DCVMN Member volunteered	Current Role of the Representative	Company ownership	Company' vaccines in house lot release testing	Recommendation from DCVMN secretariat
1	IMCAMBS ✓	Vice President of Quality Management and Principal Investigator of Joint Lab ✓	Government ✓	3 ✓	<ul style="list-style-type: none"> • Good number of vaccines with In-house lot release testing

Decision

- Is the 3Rs WG endorse the nomination of the candidate from IMBCAMS?

3. MoU with ISS (Italy)

- Signed on August 8th
- Agreed activities

DTP	MAT
Support in the PSPT project	Webinar
Webinar	Moodle
Moodle	Virtual Reality training

4. PSPT Project

- DCVMN/NIIMBL award agreement signature on Sept 1st
- Consortium Agreement MoU – 11 Laboratories + 1 pending
- Steering Group appointed – first call Sept 2nd
- Contract signed with BioLyo on Sept 11th - Coating Antigen production. B. Pertussis strain on its way to BioLyo.
- PSPT Consortium kick-off meeting on Sept 29th
- Contract signed with Intravacc on Oct 5th for coating antigen characterization

5. Pertussis moodle

- Soon to be available a training in 2 parts about Pertussis vaccines and their 3Rs opportunities
- Get a certificate for the 3Rs general e-learning module (DCVMN Moodle) by Prof. Coenraad Hendriksen:
<https://moodle.dcvmn.net/course/view.php?id=22>

6. 3Rs DCVMN Paper

- Focus on the 3Rs opportunities already taken by DCVMN members and on the opportunities to explore.
- We would like to propose a survey to all DCVMN to collect data from the network about:
 - animal use
 - ...

7. AoB/ Key updates and events about 3Rs

Any updates from your countries?

Pharmacopoeias' update?

Industry/Regulators meetings?

Conferences?

THANK
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