

## **MINUTES OF THE 213<sup>th</sup> MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 19.08.2021 BY VIDEO CONFERENCING**

The Chairman, RCGM extended a formal welcome to the members of the RCGM for the **213<sup>th</sup>** meeting and initiated the process of the meeting. The list of participants is given at Annexure-I.

**2.** The Committee adopted the minutes and recommendations of the **212<sup>th</sup>** meeting of the RCGM held on **05.08.2021**

**3.** On action taken report, the Member-Secretary informed that during the **212<sup>th</sup>** meeting of the RCGM, a total of 22 applications including information items were considered and the Secretariat is in the process of issuing requisite permit letters based on the recommendations of the RCGM.

### **4. Proposals considered**

#### **4.1 Applications in the area of pharmaceuticals**

The committee considered applications to export Gam-COVID-Vac combined vector vaccine drug product; to conduct pre-clinical toxicity study of candidate Vaccine as VLP preparation against SARS CoV-2 virus, Tocilizumab biosimilar, *Varicella Zoster Virus* vaccine; pre-clinical toxicity study reports on Protein subunit vaccine of the SARS-CoV-2, Tocilizumab biosimilar, Bevacizumab biosimilar; extension for submission of preclinical toxicity studies data of Pertuzumab; progress report on change in Required Biosafety Level from Enhanced BSL-2 to BSL-2 for Handling of live attenuated SARS-CoV-2 strain CDX-005 during vaccine manufacturing and characterization. After deliberation on each application including information items, appropriate decisions were taken by the RCGM.

#### **4.2 Applications in the area of Agriculture**

The Committee considered application to receive GE banana lines; transfer GE banana lines. After deliberation on each application including information items, appropriate decisions were taken by the RCGM.

### **5. IBSC Reports**

The Committee considered minutes submitted by six IBSCs, nil annual compliance report and one medical surveillance report, and appropriate decisions were taken by the RCGM.

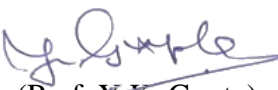
### **6. Other items**

The Committee deliberated on requirement of GEAC approval for bioreactors scale of more than 100 L for the Biosimilars/ IND product development related to organisms falling under RG -1 and RG-2. The committee also deliberated on the draft list of microorganisms finalized by the Expert Committee constituted, vide OM dated 22.05.2020, to review & update risk groups of microorganisms under Risk Groups 1-4 of "Regulations and Guidelines on Biosafety of Recombinant DNA Research & Biocontainment, 2017". Appropriate decisions were taken by the RCGM.

No other transaction took place and the meeting ended with vote of thanks to the chair.



The Minutes are approved.



(Prof. Y.K. Gupta)  
Chairman, RCGM

## Annexure-I

<b>List of Participants:</b>		
1.	Prof. Y.K. Gupta, Former Director IITR, Lucknow and President, AIIMS, Bhopal	Chairman
2.	Dr. Amita Aggarwal, Professor, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow	Co-Chair (Biopharma)
3.	Dr. Kuldeep Singh, Director, ICAR- NBPGR, New Delhi	Co-Chair (Agri)
4.	Dr. Alka Sharma, Scientist 'G' & Head Regulation, DBT	Member
5.	Dr. Anand Kumar Kondapi, School of Life Science, University of Hyderabad, Hyderabad	Member
6.	Dr. Gururaj Katti, Former Principal Scientist & Head, ICAR- IIRR, Hyderabad	Member
7.	Dr. Chandish R. Ballal, Former Director, National Bureau of Agricultural Insect Resources, Bangalore	Member
8.	Dr. P. V. Mohanan, Scientist 'G', SCTIMST, Thiruvananthapuram	Member
9.	Dr. R. Uma Shaanker, University of Agricultural Sciences, Bengaluru	Member
10.	Dr. Neelam S. Sangwan, Head, Department of Biochemistry, Central University of Haryana, Mahendergarh	Member
11.	Dr. S.K. Rath, Principal Scientist, CSIR- CDRI, Lucknow	Member
12.	Dr. Rajnish Kumar Chaturvedi, CSIR-Indian Institute of Toxicology Research, Lucknow	Member
13.	Dr. K.G. Tirumurugan, Professor, TANUVAS, Chennai	Member
14.	Dr. Vinay Nandicoori, Director, CSIR-CCMB, Hyderabad	Member
15.	Dr. Rajesh Gokhale, National Institute of Immunology, New Delhi	Member
16.	Dr. Pradyumna Kumar Singh, CSIR-National Botanical Research Institute, Lucknow	Member
17.	Dr. Kavita Lole, Scientist, National Institute of Virology, Pune. Nominee- ICMR	Member
18.	Dr. Ajit Kumar Shasany, Director, ICAR-National Institute for Plant Biotechnology, New Delhi. Nominee-ICAR	Member
19.	Sh. Jayant Ganga Khedkar, Asst Drugs Controller (India), CDSCO. Nominee-CDSCO	Member
20.	Sh. Tarun Kathula, Director Biosafety & Member Secretary-GEAC, Ministry of Environment, Forest and Climate Change, Government of India. Nominee-MoEF& CC	Member
21.	Dr. Ashish Kumar, Scientist D, Ministry of Environment, Forest and Climate Change, Government of India. Nominee-MoEF& CC	Member
22.	Dr. Naryanam Srikanth, Deputy Director General, Central Council For Research In Ayurvedic Sciences, Ministry Of Ayush. Nominee- Ministry of Ayush	Member
23.	Dr. Neelima Mishra, Scientist 'G', Science and Engineering Research Board, New Delhi. Nominee-DST	Member



24.	Sh. Sanjeev Arora, Deputy Director, Ministry of Home Affairs. Nominee-MHA	Member
25.	Dr. Nitin K. Jain, Scientist 'F', DBT, New Delhi	Member Secretary
26.	Dr. Sangeeta Agarrwal, CSO, BSU, New Delhi	Special Invitee
27.	Dr. Gandharva Nagpal, Scientist 'C', DBT, New Delhi	Secretariat Member
<b>Biosafety Support Unit:</b>		
28.	Dr. Poonam Vishwakarma, Scientist	
29.	Dr. Govind Kumar Rai, Scientist	
30.	Dr. Manpreet Kaur, Scientist	
<b>Others:</b>		
31.	Dr. Ramnath RL., M/s. Reliance Bio, Mumba	
32.	Mr. Girish Masand, M/s. Reliance Bio, Mumbai	
33.	Dr. Praveen Rao, M/s. Reliance Life Sciences Pvt. Ltd., Mumbai	
34.	Dr. Venkata Ramana, M/s. Reliance Life Sciences Pvt. Ltd., Mumbai	
35.	Dr. Harinarayana Rao, M/s. Reliance Life Sciences Pvt. Ltd., Mumbai	
36.	Dr. Prasad Krishnamurthy, M/s. CuraTeQ Biologics Private Limited, Hyderabad	
37.	Dr. Disha Dhadke, M/s. CuraTeQ Biologics Pvt. Limited, Hyderabad	
38.	Mr. Ankireddy Sivakesava Reddy, M/s. CuraTeQ Biologics Pvt. Limited, Hyderabad	
39.	Mr. Janaki Raghu Ram, M/s. CuraTeQ Biologics Private Limited, Hyderabad	
40.	Dr. Narendra Deshmukh, M/s. Intox Pvt. Ltd., Pune	

