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# NATIONAL INSTITUTE OF BIOLOGICALS NEWSLETTER

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## Director's Desk

As we bid farewell to another year, we find ourselves on the brink of advancing our endeavors to enhance the quality of our Biologicals, champion public health, and cultivate academic excellence. Our steadfast commitment for collaborative knowledge sharing remains unwavering, and NIB Scientists are wholeheartedly contributing to the assessment of new products. With great anticipation for progress and prosperity, we hold high expectations that 2024 will surpass our aspirations.



The scientists from the National Institute of Biologicals (NIB) were notably active in significant events during the past year. They played pivotal roles in the "XVIII Annual Congress of the Asian Association of Transfusion Medicine & 4th Joint Meeting of AABB-AATM2023" held on December 1st and 2nd, 2023, in New Delhi. This active engagement underscores our dedication to stay at the forefront of advancements in transfusion medicine. Furthermore, NIB scientists actively contributed to a panel discussion during the first hub session (BIRAC) on December 5<sup>th</sup>, 2023, as part of the Global Bio-India event at Bharat Mandapam, Pragati Maidan, New Delhi, organized by DBT-BIRAC, Government of India. This participation highlights our commitment to fostering discussions and collaborations within the scientific community.

I am very proud that Trainings imparted by NIB in different areas like Total Quality management, Diganostyics, Therapeutics, Transfusion and Haemovigilance are significantly contributing in facilitating skilled manpower in the area of Biopharmaceuticals Industry and Quality Control of Biologicals. I am enthusiastic about the opportunities that lie ahead, and I am confident that our active involvement in these events will further solidify our position as contributors to the advancement of scientific knowledge and innovation. I eagerly look forward to the continued progress and success in the coming year.

**I wish Good Luck to All!!**

**Anup Anvikar**

Director

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## CONTRIBUTION OF NATIONAL INSTITUTE OF BIOLOGICALS (NIB) TOWARDS NATIONAL SKILL DEVELOPMENT AND CAPACITY BUILDING IN THE FIELD OF BIOLOGICALS

The Indian pharmaceutical industry is the third largest in terms of volume globally. India has significantly contributed in shaping the healthcare outcomes of patients around the world. The Biopharmaceutical industry has immense potential in the coming years and is a knowledge-driven sector that demands highly skilled professionals. The impact of human performance cuts across the entire industry, whether for a manufacturing operator, a scientist or engineer in a highly technical role such as product development, process evaluation or assuring the quality of such lifesaving drugs.

Further, new technologies are creating potentially disruptive changes within the industry, including applying single-use technologies, continuous processing; implementing Quality by Design (QbD) principles, Process Analytical Technology (PAT); and introducing new therapies and personalized medicine. In response, education and technical professional development are critical to ensure that the competency level of today's biopharmaceutical manufacturing workforce grows as the industry evolve.



**Ms. Sudha V Gopinath,**  
*Scientist Grade II, NIB*

In today's globally competitive job market, developing a workforce pipeline for the bioprocess industry requires academic programs that equip students with knowledge, skills, and theory surrounding the equipment, methodologies, processes, and regulatory requirements specific to it. Skilled manpower will be key for the Indian Pharma industry to achieve Vision 2030, which aims to grow to \$120 -130 bn by 2030 from the current \$50 bn in 2022. Investment in skill and knowledge development of the workforce will be essential.

As per various surveys and symposia<sup>[1,2]</sup> involving experts from academia, government institutes, industry professionals and policy makers, the following recommendations have been put forward to identify potential domains that has to be considered for adequate capacity building in the field of biopharmaceutical / diagnostic industries in India:

1. Explore possibilities for establishing few Centres of Excellence for biopharmaceutical training. Biopharmaceutical industry would show interest in contributing to such training platforms. These training institutes could be housed within existing educational/ National institutes and could be funded through the CSR of industries.
2. Focus on skills needed for biologics manufacturing would be beneficial.
3. Other aspects to be focussed are good manufacturing process and quality management, documentation, regulatory, digitalization, and big data analysis
4. Continuous and up-to-date education for regulators in alignment with emerging technology requirements.
5. Update biotechnology curriculum in alignment with industry requirements with a focus on drug discovery and translational research.
6. Skills development in emerging technologies, management, and entrepreneurship and support for interdisciplinary skill-sets aligned with global standards.
7. Provision for industry training or internship for graduate/post-graduate students to enhance R&D skills. Industry may take initiative to send their staff to academia for such teaching/training.
8. Shared resources or high-end R&D centres to promote accessibility of latest technologies to start-ups and small-scale industries.
9. Enhanced engagement and collaboration with Indian diaspora scientists from top universities and companies to leverage their experience.



National Institute of Biologicals (NIB) considering few aspects mentioned above, for Skill Development and capacity building, has been organizing various training programs in the field of “Quality Control of Biologicals”.

### **1. National Skill Development & Hands-on Training Program on Quality Control of Biologicals**

The objective of this two weeks residential training program is to disseminate knowledge and enhance technical capabilities in the field of Biologicals amongst PG Students from Hill Universities, North Eastern states, tribal region and other far flung regions of our nation. The participants are fully supported by NIB for their travel boarding and lodging, and training activities. The training covers techniques used in quality evaluation like HPLC, Electrophoresis, ELISA, Bacterial Endotoxin testing, Transfusion Transmitted Infection testing, Blood group Serology, Cell culture aseptic handling, sub culturing and maintenance, cell line based potency assays, animal handling, use of laboratory animals etc. applicable in Quality Control testing of Biologicals and to create awareness about Global scenario of biological testing. The feedback remarks from the students, who have undergone this two-weeks training at NIB revealed that the training has ignited their minds for research career in the area of Biologicals and Bio-therapeutic studies.

### **2. Training of Trainers for Strengthening of Blood Services for Blood Bank Officials**

With an aim to strengthen the blood services in the country NIB in collaboration with National Health Mission (NHM), Ministry of Health and Family Welfare, Govt. of India, is organizing Six days Residential hands-on Training Programme for Blood Bank officials from various parts of the country. The training bestows technical support in strengthening blood services in the areas of EQAS for transfusion-transmissible diseases, Blood Group serology, Transfusion Transmitted infection testing, Haemovigilance programme of India, Analysis of Gaps in Blood Bank Management, Total Quality Management Systems etc. The objective of the training to develop trained manpower to improve quality, safety and efficacy of blood and blood products, meeting the requirements of current good laboratory practices (cGLP) and strengthen Total Quality Management System in the Blood banking system of the country.

### **3. Six weeks Summer Training**

The focus of this training program is to sensitize the students on best practices in quality control and quality management system in Biologicals and enhance their technical capabilities. The program is organized annually usually during June-July.

### **4. Six Months Project work**

NIB imparts 04-06 months Project Work to Post Graduate Students of various Universities and Institutes on Quality Control of Biologicals in state-of-the-art Laboratories of NIB. The training on various analytical platforms for a period of 4-6 months helps them in understanding the related principles, procedures, regulatory requirements which would makes them proficient in the specific field, and help in their future research endeavors as well as enable them to get good job opportunities. These programs are intended to encourage students from Government Institute/Government aided Institutes and specifically from those regions who have resource limited infrastructure at their educational institution, to enhance their knowledge on basic techniques used in biological Testing. The Program is organized annually from January-June.

### **5. Customized short term Structured Training Course launched in the year 2022**

NIB has launched a panel of customized short-term structured training courses in the field of Biopharmaceuticals, In-vitro Diagnostics, and Vaccines. The program targets students and employees, professionals from Government & Private labs/Institutes, Hospitals, Medical Colleges, Industries, and Regulatory Officials. The training courses have been designed to develop skills of aspirants as per present needs of the Biotechnology and Pharmaceutical Industries by providing skilled professionals with hands-on experience in various facets of techniques. In this regard, Application form, Guidelines along with the respective course modules are available on the NIB website. For updated schedule and training fee, please refer to our website: [www.nib.gov.in](http://www.nib.gov.in)

### **6. New Initiatives**

Further the institute is in the process of developing a dedicated Research and Training facility that will support in R&D activities related to improving the quality and safety of biologicals. A Certificate Course on Quality Assurance of Biologicals is also in pipeline which offers intense practical exposure in various disciplines relevant to the present industrial needs & hence putting efforts to bridge the gap between the industry and academia, thereby generating immediately employable work force.





## 7. References :

1. Excerpts from the Biosimilar Workshop organized by Institute of Chemical Technology (ICT) Mumbai held from 29<sup>th</sup> November to 1<sup>st</sup> December 2018 and published “The growing Indian biopharmaceutical industry: its requirements and endeavours”, Ibani Kapur & Navodita Jain, Posted on Feb 15, 2019 in Health & Medicine, Pharmacology, Teaching and Undergraduate
2. Biopharmaceutical Industry Capability Building in India: Report from a Symposium-outcomes of a symposium conducted by US Pharmacopeia (USP), Department of Biotechnology (DBT) India, and the Confederation of Indian Industry (CII)-Journal of Pharmaceutical Innovation, November 2021.

## VISITS :

- 33 M Tech Biotechnology students and Ph.D scholars from Jaypee Institute of Information Technology (JIIT) Noida, along with their faculty members visited NIB Laboratories on 20<sup>th</sup> November 2023.

## AWARDS :

- Ms Saroj Verma, Assistant-I, NIB was declared as winner of First Consolation Prize in the 'Self-Written Story Competition' held on 06<sup>th</sup> November, 2023 by NOIDA Special Economic Zone, NOIDA under the aegis of Town Official Language Implementation Committee for the officials of its Member Offices. The said award was given away to Ms Saroj Verma by the Chairman of TOLIC in its 46<sup>th</sup> meeting held on 29<sup>th</sup> January, 2024.



## PROFICIENCY TESTING (PT)/EXTERNAL QUALITY ASSURANCE SCHEME (EQAS)

- Biochemical Kit Lab is enrolled into the Association of Clinical Biochemists of India/ Christian Medical College (ACBI/CMC) External Quality Assessment Scheme (EQAS)-2023 for Chemistry II (Glucose, Cholesterol, Triglyceride, Creatinine, Uric acid & Albumin), conducted by the Department of Clinical Biochemistry, Christian Medical College, Vellore. The test was put up and the generated results were uploaded on the CMC-EQAS website.



- Blood Reagent Laboratory successfully participated in the IRCS PT program wherein 6 coded samples of Anti-A, Anti-B, Anti-D (IgM), and Anti-AB were tested for all test parameters.
- The Immunodiagnostic kit Laboratory IDKL participated in 3rd Round of EQAS 2023 from NRL Australia (a designated World Health Organization Centre for Diagnostics and Laboratory Support for HIV, AIDS and Blood borne Infections and Fully accredited Proficiency testing provider under ISO 17043:2010) for the Multi-marker Blood Screening Serology Programme. The test results were uploaded on the portal of NRL Australia.

## TECHNICAL EXPERT COMMITTEE MEETINGS:

- Dr. Meena Kumari, Head, Blood Products Laboratory, attended the “Meeting of Expert Working Group (EWG)-Biological Impurities” conducted by Indian Pharmacopoeia Commission, Ghaziabad on 26.10.2023.
- Dr Charu Mehra Kamal, Head, RPL & EHL virtually attended 14<sup>th</sup> Meeting of the Expert Working Group - Biologicals and DNA Products, organized by Indian Pharmacopoeia Commission, Ghaziabad, as an expert member along with Dr Sanjay Mendiratta, Scientist Grade-III on 7.11.2023.
- Dr. Gauri Misra, Head, CKTL - MDL & SRRDU attended virtually special meeting of Medical Biotechnology and Nanotechnology sectional committee, MHD 20 as an external expert for development of Indian standard on the 'Development of Standard for Nanopore Sensors' on 14.11.2023 organized by Bureau of Indian Standards (BIS).
- Dr. Charu Kamal Mehra, Head, RPL & EHL and Ms. Y. Madhu, Scientist Grade-III, BPL attended “USP South Asia 4<sup>th</sup> regional chapter meeting, part of USP Convention Cycle 2020-2025”, on 15.11.2023 at Delhi, organised by USP.



- Dr. Gauri Misra, Head, CKTL - MDL & SRRDU attended virtually the diagnostics meeting organized by CDSCO to discuss “Clinical performance evaluation of in-vitro diagnostic medical device to ensure safety essentiality desirability, effectiveness and clinically performance of new in-vitro diagnostic medical device i.e. assured plus rapid diagnostic kit for detection of dengue, chikungunya and malaria in a single cassette” on 07.12.2023 as an external expert.
- Dr. Gauri Misra, Head, CKTL - MDL & SRRDU as an external expert have virtually attended the fourteenth sectional committee meeting of Medical Biotechnology and Medical Nanotechnology MHD20, on 13.12.2023 at New Delhi.





- Dr. Gauri Misra, Head, CKTL - MDL & SRRDU has participated as an external expert in the panel discussion for the first hub session (BIRAC) on 05.12.2023 in Global Bio-India at Bharat Mandapam, Pragati Maidan, New Delhi organized by DBT-BIRAC, Govt. of India.
- Dr. Gauri Misra, Head, CKTL - MDL & SRRDU participated virtually as technical expert for discussion on modalities for strategic ICMR-MDMS & Niti Aayog handholding support for MedTech innovators on 12.12.2023.
- Dr. Gauri Misra, Head, CKTL - MDL & SRRDU as an expert have virtually attended “2nd Malaria Expert Working Group Meeting” on 19.12.2023.
- Dr. Shikha Yadav, Head, In-Vivo Bioassay Laboratory & Animal Facility has been nominated as the main CPCSEA Nominee in the IAEC of Bio- Med Private Limited, Ghaziabad, UP. She attended their IAEC meeting and also conducted annual inspection of their Animal Facility on 20.12.23

## INVITED TALKS/LECTURES:

- Dr. Gauri Misra, Head, CKTL - MDL & SRRDU presented an invited talk at the International Conference on 'Structural Biology & Drug Discovery' on topic “Natural compounds mediated inhibition of mastl kinase preventing breast cancer proliferation” during 11.10.2023 to 12.10.2023 at School of Biotechnology, Gautam Buddha University, Greater Noida.
- Dr. Shikha Yadav, Head, In-Vivo Bioassay Laboratory & Animal Facility delivered talk on “Laboratory Animals Pain Assessment and Management” on 3.11.2023 in the Workshop on Basic Training in Animal Handling & Experimentation, organized by Institute of Liver and Biliary Sciences (ILBS), Delhi.
- Dr. Shikha Yadav, Head, In-Vivo Bioassay Laboratory & Animal Facility was invited as Resource Person in “Workshop for Handling and Care of Laboratory Animals” at CLAR, School of Life Sciences, JNU, Delhi organized from 28.11.23 to 2.12.23.
- Dr. Suresh Kumar, Scientist Grade-III delivered a talk on “ABSL-3 biosafety guidelines, CCSEA rules, laboratory animal handling and care” at the Valedictory session of Hands-on Training course on BSL3 training, biosafety practices and TB research protocols at Department of Biochemistry, University of Delhi, South Campus, Delhi on 15.12.2023.





## WORKSHOPS/ CONFERENCES/ SEMINARS :

- Dr. Rajesh Kumar Sharma, Scientist-III & Dr. Pankaj Kumar Sharma, Scientist Grade-III attended TRANSCON 2023 at King George's Medical University, Lucknow from 06<sup>th</sup>-08<sup>th</sup> October 2023.
- Mr. Harit Kasana, Head, VAL, Mr. Jaipal Meena, Scientist Grade-III and Ms. Archana Sayal, Junior Scientist of Vaccine and Antisera Lab attended two days' discussions & training on "Lot Release procedure of Vaccines" from 12.10.2023 to 13.10.2023 at CDL, Kasauli.
- Dr. Shikha Yadav, Head and Dr. Suresh Kumar, Scientist Grade-III (Vet), In-Vivo Bioassay Laboratory & Animal Facility attended the 11<sup>th</sup> International Conference (LASACON-2023) of Laboratory Animal Scientists' Association (LASA) India on "Advancements of 3R's in Biomedical Research and Laboratory Animal Science and Welfare: International Perspectives" organised by Laboratory Animal Scientist Association (LASA) India from 6<sup>th</sup> to 8<sup>th</sup> November 2023 at IISc, Bengaluru.
- Dr. Charu Mehra Kamal, Head, RPL & EHL and Mr. Nanda Gopal, Scientist Grade-III, EHL, attended the 5<sup>th</sup> Confederation of Indian Industry (CII) Life Sciences Summit 2023 on 17<sup>th</sup> November, 2023 at New Delhi.
- Dr. Gauri Misra, Head, CKTL - MDL & SRRDU attended the 50th National Seminar on Crystallography (NSC50) CSIR-Institute of Microbial Technology (CSIR-IMTECH), Chandigarh, during 22nd to 24th November, 2023.
- Dr. Meena Kumari, Head and Ms. Y. Madhu, Scientist-III, BPL attended the "XVIII Annual Congress of Asian Association of Transfusion Medicine & 4<sup>th</sup> Joint Meeting of AABB-AATM2023", held on 1<sup>st</sup> and 2<sup>nd</sup> December, 2023 at New Delhi.
- Md. Daud Ali, Junior Scientist, Ms. Girija L.V., Lab Technician & Mr. Ritesh Prajapati, Lab Technician attended the 8<sup>th</sup> Annual CBT Course Series at Centre of Excellence, Biopharmaceutical Technology, Indian Institute of Technology (IIT), Delhi from 11<sup>th</sup>-13<sup>th</sup> December 2023.



## TRAININGS :

- Five-day structured training on "Quality Control testing of Biologicals, using Cell Culture & In-vitro Bioassays" has been organized from 09<sup>th</sup>-13<sup>th</sup> October 2023 in Centralized Facility for Bioassay Laboratory, NIB. The training comprised of demonstration and Hands-on practice.
- Training on "Analytical techniques related to Blood & Blood related products" organized from 04<sup>th</sup>-15<sup>th</sup> December 2023 in the Blood Products Laboratory, NIB. The training course comprised introduction to QC testing of blood products, ISO 17025 application in quality control laboratory, overview of Monograph development and validation, demonstration and Hands-on practice.



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Please feel free to share your valuable thoughts & feedback for the betterment of the edition. We look forward to hear from you!!!