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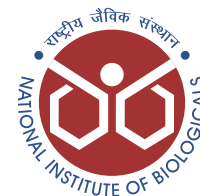
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भारत 2023 INDIA

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ONE EARTH • ONE FAMILY • ONE FUTURE



# NATIONAL INSTITUTE OF BIOLOGICALS NEWSLETTER

January – March, 2023

Issue #1



## Director's Desk



Another year has elapsed and we plan to move forward with a strong commitment for quality of Biologicals, public health and academic excellence. With continuous adhering to the spirit of sharing knowledge and to contribute in evaluating new products, we sincerely hope that in terms of progress and prosperity year 2023 shall live up to all our expectations.

NIB organized the National Summit on Quality of Biologicals on 27<sup>th</sup> January 2023, to celebrate the 31<sup>st</sup> Foundation day of NIB, at Vigyan Bhawan, New Delhi, which was virtually inaugurated by Dr. Mansukh Mandaviya, Hon'ble Union Minister of Health & Family Welfare.

The Summit provided an integrated platform to different stakeholders, regulators, industry, academia and researchers for the exchange of ideas that can potentially circumvent the present bottlenecks of the Quality regulation of Biologicals. A coffee table book about NIB was also launched by the dignitaries at the event.

I congratulate NIB on receipt of the award for exemplary work in Rajbhasha by Nagar Rajbhasha Karyanvayan Samiti, NOIDA at V.V. Giri National Labour Institute, Noida (UP).

Enduring with the Mandate of Training, NIB in collaboration with the Blood Cell-National Health Mission, conducted a six-day residential Hands-on training programme from 09<sup>th</sup> – 14<sup>th</sup> January 2023 on "Training of Trainers for Strengthening of Blood Services" for 41 Blood Bank Officials from Chhattisgarh state.

I am immensely proud of our Institute's progress for moving to new ways of working in the area of Quality Control of Biologicals.

I wish Good Luck to All!!

Anup Anvikar  
Director

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## EDITORIAL TEAM

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## ENSURING QUALITY OF BEVACIZUMAB: A BLOCKBUSTER DRUG FOR TARGETED CANCER THERAPY

*Dr. Ratnesh Shrama, Scientist Grade-II, NIB*

Monoclonal antibodies (mAbs) have emerged as a promising tool in the field of therapeutics. They are produced by cloning a single type of immune cell that produces a specific antibody that can bind to a specific target. The high specificity, low toxicity and long half-life of mAbs make them an attractive option for many patients and healthcare providers.



It is known that vascular endothelial growth factor (VEGF) plays a key role in the growth of blood vessels. In case of cancer disease, VEGF is often overproduced, leading to the growth of new blood vessels that provide nutrients and oxygen to cancer cells, allowing them to grow and spread over the body.

Bevacizumab is a US FDA approved humanized recombinant monoclonal antibody which specifically binds to VEGF and prevents it from binding to its receptors on the surface of blood vessel cells. This blocks the signalling pathway that stimulates the growth of new blood vessels, a process known as angiogenesis. By inhibiting angiogenesis, Bevacizumab can help to starve cancer cells of the nutrients and oxygen they need to grow and spread. This can slow the growth of tumours and may also make them more sensitive to other treatments, such as chemotherapy and radiation therapy.

In recent years the angiogenesis inhibitor Bevacizumab has changed the treatment paradigm and became a standard of care in the treatment of advanced cancers including colorectal cancer, renal cell carcinoma, non-small-cell lung cancer, breast cancer, ovarian cancer and Glioblastoma Multiforme.

It is a rDNA-derived bio therapeutic and manufactured through a highly complex process with a number of critical process parameters which determine the critical quality attributes of the final product. Due to the complex structural and process intricacies the product variability could affect clinical efficacy and may have serious patient safety consequences.

Therefore, implementation of current good laboratory practices (cGMP) guideline that are set for the



industry by National regulatory authority is of utmost importance. Quality control of therapeutic mAbs including Bevacizumab involves a combination of analytical and biological testing to ensure that the drug is safe and effective for use in patients.

To fulfil the regulatory objectives, National Institute of Biologicals (NIB) has established the Therapeutic Antibodies Laboratory to undertake the quality control evaluation of various therapeutic mAbs received from CDSCO or from the manufacturers for their market authorization. The laboratory has state of art infrastructure and expertise for quality evaluation of several non-pharmacopeial/ pharmacopeial therapeutic monoclonal antibodies. The laboratory is NABL accredited accordance with ISO/IEC 17025:2017 and regularly participates in proficiency testing programme and inter laboratory comparisons with international organizations like EDQM, NIBSC etc.

The scientists of the laboratory are constantly devoted for the cause of public health safety and actively involved in the preparation of Monographs of various non pharmacopeial mAbs to be incorporated in Indian Pharmacopeia and research activities as per the mandates of NIB.

In addition of this, the scientists of the laboratory also extend their technical expertise during joint inspections of indigenous mAbs manufacturing premises with the officials of CDSCO to ensure the quality of biologicals and contributing significantly to promote the make in India campaign of government of India.

#### References:

1. M.Rajabi, S.A.Mousa; The Role of Angiogenesis in Cancer Treatment; Biomedicines,5(2) (2017)
2. J. Garcia, H. I. Hurwitz et al; Bevacizumab (Avastin®) in cancer treatment: A review of 15 years of clinical experience and outlook; Cancer Treatment Review; 86 (2020).

#### AWARDS:

- NIB received the award for exemplary work in Rajbhasha by Nagar Rajbhasha Karyanvayan Samiti, NOIDA at V.V. Giri National Labour Institute, Noida (UP).
- Two NIB scientists-one each for क and ग क्षेत्र - were awarded 1st prize (हिन्दी भाषी और हिन्दी तर) in 'Hindi Essay writing competition' held on 16.12.2022 organized by 'Nagar Rajbhasha Karyanvayan Samiti (Karyalay), Noida', Rajbhasha Vibhag, Ministry of Home Affairs, Government of India during the year 2022-23 at V.V. Giri National Labour Institute, Noida (UP).

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

- Biochemical Kit Laboratory 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 and the generated results were uploaded on the CMC-EQAS website.
- The Molecular Diagnostics Laboratory has participated in External Quality Assessment Scheme (EQAS) conducted by NRL-Australia for Event-1 2023 NAT Proficiency Testing. The lab put up the tests for viral load monitoring of HBV, HCV, HIV and Qualitative Multimarker blood donor screening in the month of March 2023 and the generated results were uploaded on the NRL-EQAS website.

## NATIONAL SUMMIT - 2023

NIB organised the first National Summit on Quality of Biologicals on 27<sup>th</sup> January 2023, on the occasion of its 31<sup>st</sup> Foundation day at Vigyan Bhawan, New Delhi. The Summit was virtually inaugurated by Dr. Mansukh Mandaviya, Hon'ble Union Minister of Health & Family Welfare. Dr Bharati Pravin Pawar, Union Minister of State for Health & Family Welfare also addressed the Summit through a video message. Shri Rajesh Bhushan, Secretary, Ministry of Health & Family Welfare addressed the gathering sharing his views on the current practices and future prospects in the field of Quality Control of Biologicals. He emphasized the necessity of active collaboration and support among industry, regulation, research, and academia verticals with respect to Quality of Biologicals in the interest of Public Health. Dr Atul Goel, DGHS, Dr V.K. Paul, Member, NITI Aayog, and Ms S. Aparna, Secretary, Department of Pharmaceuticals, chaired the three Sessions. Several other eminent dignitaries namely Prof. Y. K. Gupta, President, AIIMS, Bhopal and Dr Pramod Kumar Garg, Executive Director, THSTI along with participation from manufacturers of various Biologicals, medical procurement agencies, IPC, CDSCO etc. also graced the occasion. The Summit provided an integrated platform to different stakeholders, regulators, industry, academia and researchers for the exchange of ideas that can potentially circumvent the present bottlenecks of the Quality regulation of Biologicals. A Coffee Table Book about NIB was also launched by the dignitaries at the event.



Session 1: Assuring Quality of Biologicals in India: Current Scenario & Future Perspective



Session 2: Biologicals: Regulatory Aspects



Session 3: Step towards Aatmanirbharta: Connecting Industry with Academia

## TECHNICAL EXPERT COMMITTEE MEETINGS:

- Dr. Shikha Yadav, Scientist Grade-I & Head, In Vivo Bioassay Lab and Animal Facility participated as Adhoc Specialist for assistance in conducting a site visit to an institutional animal care and use program for AAALAC accreditation purposes from 1<sup>st</sup> -3<sup>rd</sup> February 2023 at Ahmedabad, Gujarat.
- Dr. Gauri Misra, Scientist Grade-II & Head, CKTL attended as an expert in the virtual meeting on FIRST HUB held on 03<sup>rd</sup> February 2023.
- Dr. Gauri Misra, Scientist Grade-II & Head, CKTL attended a virtual meeting as an external expert to review and revise the technical specification of Tab. Buprenorphine used for the OST programme under NACP on 06<sup>th</sup> February 2023.
- Dr. Meena Kumari, Scientist Grade-II & Head, BPL attended the 7<sup>th</sup> Meeting of the Expert Working Group- Blood and Blood-Related Products through Video conferencing conducted by IPC, Ghaziabad on 20<sup>th</sup> February 2023, along with Ms. Y. Madhu (Scientist-III), Dr. Manoj Kumar (Scientist-III) & Mr. Tara Chand (Scientist-III) from Blood Products Laboratory.
- Dr. Meena Kumari, Scientist Grade-II & Head, BPL attended the meeting on the Board of Studies in Biotechnology UIET KUK held on 25<sup>th</sup> February 2023 in online mode.
- Dr. Gauri Misra, Scientist Grade-II & Head, CKTL nominated by DBT as an ethical committee member for an interaction meeting with foreign delegates held on 1<sup>st</sup> March 2023 at MedTherapy India Pvt. Ltd., Noida.
- Dr. Gauri Misra, Scientist Grade-II & Head CKTL attended “Chintan Shivir” organized by the Quality Council of India (QCI) held on 23<sup>rd</sup> March 2023 at Lucknow (U.P.).
- Dr. Charu Kamal Mehra, Scientist Grade-I & Head, Recombinant Product Laboratory and Enzymes & Hormones Laboratory along with Scientists of the laboratories attended 13<sup>th</sup> Meeting of the Expert Working Group for Biologicals and rDNA Derived Therapeutic Products organized by IPC, Ghaziabad held on 28<sup>th</sup> March 2023 through video conferencing at NIB.
- Dr. Gauri Misra, Scientist Grade-II & Head CKTL attended the Eleventh Meeting of Medical Biotechnology and Nanotechnology Sectional Committee, MHD 20 on 29<sup>th</sup> March 2023 organised by the Bureau of Indian Standards.

## WORKSHOPS/ CONFERENCES/ SEMINARS:

- Mrs. Apoorva Anand Talwar, Junior Scientist, Blood Products Laboratory attended Sun Pharma Science Foundation’s International Symposia entitled “Cell Therapy Comes of Age in India” in collaboration with Tata Memorial Centre, Mumbai, held on 7<sup>th</sup> & 8<sup>th</sup> January 2023 in online mode.
- Ms. Sudha V Gopinath- Scientist Grade-II & Dr. Sanjay Mendiratta, Scientist Grade-III participated in a training program on ISO 17034:2016 “General Requirements for the Competence of Reference Material Producers” from 2<sup>nd</sup> to 4<sup>th</sup> Feb 2023 at Mumbai conducted by NABL.
- Dr. Gauri Misra, Scientist Grade-II & Head, CKTL along with Scientist of CKTL attended the ICMR-Cochrane Affiliate Centre Workshop on “Methodology for Writing a Systematic Review” held on 14<sup>th</sup> February 2023 on virtual mode.
- Dr. Harish Chander, Deputy Director (QC), Mr. Harit Kasana, Scientist Grade-II & Head, VAL, Dr. Pankaj K. Sharma, Scientist Grade-III, BPL, Mr. Subhash Chand, Scientist Grade-III, TAL have participated in Bodoland International Festival at Bodoland University, Kokrajhar, Assam, held from 27<sup>th</sup> February to 2<sup>nd</sup> March 2023.

- NIB has organised a Training cum-Orientation Programme on “Building Effective Teams” on 23<sup>rd</sup> February 2023 for Senior Scientists at NIB. The training was imparted by two officials: Dr. Nidhi Phutela (Officiating Director) and Dr. Priya Grover (Associate Professor) from the Symbiosis Centre for Management Studies (SCMS), Noida, U.P.
- Dr. Gauri Misra, Scientist Grade-II & Head, CKTL and Dr. Hemant Kumar Verma, Scientist Grade-II & Head, CFB, attended as an invited guest, one day Conference on “Pharma Anveshan-2023” Organized by Pharmacy Council of India, New Delhi, held on 6<sup>th</sup> March 2023 in New Delhi.



### INVITED TALKS/ LECTURES DELIVERED:

- Dr. Shikha Yadav, Scientist Grade-I & Head In Vivo Bioassay Laboratory and Animal Facility delivered scientific talk on “Perioperative care & Analgesia” on 8<sup>th</sup> February, 2023 in a 2 weeks Certificate Course in Laboratory Animal Science (CCLAS), organized by National Brain Research Centre (Under Department of Biotechnology), Ministry of Science & Technology, Manesar, Haryana.
- Dr. Shikha Yadav, Scientist Grade-I & Head In Vivo Bioassay Laboratory and Animal Facility delivered lecture on “Perioperative Care, Anesthesia, Surgical Techniques; Analgesia and Pain: Its Causes, Category Monitoring and Distress in Laboratory Animals” on 22<sup>nd</sup> February 2023 in a 4 days’ Workshop on Handling and Care of Laboratory Animals organized by the School of Life Sciences (SLS) Jawaharlal Nehru University (JNU), Delhi.
- Dr. Anoop Kumar, Junior Scientist, In Vivo Bioassay Laboratory and Animal Facility delivered a lecture on “Real Time PCR & Its application in disease diagnosis” on 22<sup>nd</sup> March 2023 in a Workshop on "Hands-on-training on Biological and Molecular Techniques" in the Department of Zoology, MMV, Banaras Hindu University, Varanasi, held from 20<sup>th</sup> -23<sup>rd</sup> March 2023.

### TRAININGS/VISITS:



Delegates from 17 countries who are participants of the 13<sup>th</sup> International Training Programme on “Competence and Management systems of Laboratories” for developing Countries conducted at NITS, Noida, India, on 14<sup>th</sup> February 2023. The delegates were given a basic overview of NIB and visited various Laboratories, and interacted with Scientists. The said delegates are

NIB in collaboration with the Blood Cell-National Health Mission, conducted a six-day residential Hands-on training programme from 09<sup>th</sup> – 14<sup>th</sup> January 2023 on “Training of Trainers for Strengthening of Blood Services” for 41 Blood Bank Officials (including 17 Doctors and 24 Lab Technicians) from Chhattisgarh.

NIB hosted a Laboratory visit to 33 International



## PUBLICATIONS

- Shruthi Padavu, Ballamoole Krishna Kumar, Anoop Kumar\*, and Praveen Rai\*, In silico analysis of Human papillomavirus-45 E6, E7 & L1 proteins as potential immunogens, Journal of Pure and Applied Microbiology (JPAM).
- Shruthi Padavu, Pooja Aichpure, Ballamoole Krishna Kumar, Anoop Kumar, Radha Kanta Ratho, Shipra Sonkusare, Indrani Karunasagar, Iddya Karunasagar, Praveen Rai. (2023) An insight into clinical and laboratory detections for screening and diagnosis of cervical cancer. Expert Review in Molecular Diagnostics 2023 Jan 25. doi: 10.1080/14737159.2023.2173580.
- Manoj Kumar, Sangeeta Pahuja, Prashant Khare, Anoop Kumar\*, Current challenges and future perspectives of diagnosis of Hepatitis B virus, Diagnostics 2023, 13(3), 368.
- Swati Shalini, Anu Sharma, Nripendra N. Mishra, Ratnesh K. Sharma, Harish Chander, Anupkumar R. Anvikar, Subhash Chand. Cost-effective and reliable cell-based ELISA as an alternative method of flow cytometry for assessment of binding activity of Vedolizumab. Heliyon. Issue 2, Vol 9. DOI: <https://doi.org/10.1016/j.heliyon.2023.e13570> (9 Feb 2023).
- Surekha, Anoop Kumar, Harit Kasana, Jaipal Meena, Archana Sayal, Comparative evaluation of HEP-2 (Cincinnati) & Vero cell lines sensitivity to Bivalent Oral Polio Virus Vaccine (Type 1 & Type 3) by using in-vitro microtitration potency assay, Research Journal of Pharmacy and Technology, 2023, Vol: 16, Issue: 8.
- Kumar Anand, Vijay Kumar, Indu Bhushan Prasher, Megha Sethi, Harsh Raj, Himanshu Ranjan, Subhash Chand, Gaurav Kumar Pandey. Bioactive molecules from fungal endophytes and their applications in pharmaceutical industries: challenges and future scope. Journal of Basic Microbiology <https://doi.org/10.1002/jobm.202200696> (I.F. 2.6)

## WOMEN'S DAY CELEBRATIONS

NIB celebrated International Women's Day with a great enthusiasm and spirit by organizing various competitions and cultural activities on 13th March, 2023.



## ACKNOWLEDGEMENT:

Newsletter Editorial Team acknowledges the contribution of all the staff members of NIB.



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