



NATIONAL INSTITUTE OF BIOLOGICALS

Ministry of Health & Family Welfare

Government of India



NEWSLETTER

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A meeting on non-animal testing approaches, under a collaborative initiative of the National Institute of Biologicals (NIB), PETA Science Consortium International e.V. (PSCI), and the Institute for In Vitro Sciences (IIVS), USA held on 12th December 2025 at NIB, Noida.



Director's Desk



It gives me great pleasure to present this edition of the Newsletter of the National Institute of Biologicals, covering the period October to December 2025. This quarter reflects our sustained commitment towards excellence in quality assurance of biologicals, alongside a strong emphasis on capacity building, institutional development, and national service.



Dr. Neelima Mishra

NIB continues to play a vital role in ensuring the quality, and safety of vaccines, biotherapeutics, blood products, and in-vitro diagnostics. The diverse activities highlighted in this issue underscore our ongoing efforts to strengthen laboratory systems, expand technical capabilities, and align with evolving national and global regulatory frameworks.

A notable highlight of this quarter has been the successful implementation of the Rashtriya Karmayogi – Large Scale Jan Seva Programme (Phase-II) at NIB. This initiative reflects our commitment not only to scientific excellence but also to fostering a culture of public service, accountability, and citizen-centric governance. Through active participation and internal capacity building, our officers have further strengthened their competencies in service delivery, reinforcing the core values of efficiency, transparency, and responsiveness in public institutions.

I am pleased to observe the active engagement of our scientists in national and international platforms, contributing as experts, trainers, and thought leaders. These interactions enhance NIB's visibility and play a crucial role in shaping regulatory science, policy development, and adoption of innovative approaches in biological standardization.

The institute has also made significant progress in organizing collaborative initiatives, including those focused on emerging areas such as non-animal testing methods and Reference Standards Development. These efforts are aligned with our vision of positioning NIB as a centre of excellence in biological quality control & regulatory science.

I would also like to place on record my appreciation for the outstanding achievements of our scientists. During this period, our colleagues have been recognized with prestigious awards at national scientific forums, including accolades at Immunocon 2025. Such recognitions reflect the high standards of scientific excellence and innovation upheld at NIB and serve as an inspiration for the entire institution.

I extend my heartfelt congratulations to all awardees, contributors, and staff members for their dedication and commitment. Their achievements continue to strengthen the reputation of NIB as a leading scientific institution in the country.

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Nourishing the Gut Microbiome : Dietary Strategies for Better Health

Dr. Suresh Kumar is serving as Scientist Grade-II at the National Institute of Biologicals, Ministry of Health & Family Welfare, Government of India, with over 20 years of research experience. He possesses specialized expertise in the quality control of biologicals, particularly vaccines and therapeutics, with a strong focus on in vivo evaluation models. He has extensive experience in laboratory animal science, including CCSEA-compliant facility management, biosafety, and biomedical waste management. His research interests encompass epidemiology, neurobehavioral science, and gut microbiota in metabolic disorders.



Introduction

The human gut harbours a dynamic ecosystem comprising trillions of microorganisms including bacteria, fungi, viruses, and archaea that coexist symbiotically with the host and play crucial roles in digestion, metabolism, immune regulation, and overall health. Recently the advancing in sequencing and metabolomics have firmly established the gut microbiome as a central regulator of human physiology rather than a passive inhabitant of the gastrointestinal tract. Diet stands out as the most direct, modifiable, and impactful factor influencing gut microbial composition and function across the life. However interestingly a recent study indicates that microbial assembly, particularly during early life, is not governed by diet alone. Notably, social and environmental interactions play a crucial complementary role in microbial transmission and ecosystem development highlighting the importance of early-life exposures in shaping the gut microbiome. This article highlights how targeted nutritional strategies can shape the gut microbiome, boost beneficial microbial metabolites, and support long-term health.

Role of the Gut Microbiome in Human Health

A primary function of the gut microbiome is to ferment dietary components that escape digestion in the upper gastrointestinal tract. In the gut, complex carbohydrates and dietary fibers are converted into short-chain fatty acids (SCFAs), mainly acetate, propionate, and butyrate. A variety of microbial metabolites serve a variety of functions, including providing energy to intestinal epithelial cells, enhancing gut barrier integrity, regulating glucose and lipid metabolism, and exerting anti-inflammatory properties. As one of the SCFAs, butyrate plays a crucial role in maintaining intestinal homeostasis and immune tolerance. In these processes, beneficial gut bacteria, such as *Faecalibacterium prausnitzii*, *Roseburia* species, *Bifidobacterium* species, *Lactobacillus* species, and *Akkermansia muciniphila* species, play critical roles. There is also emerging evidence that *Christensenella minuta* is a keystone bacterium associated with leanness and improved metabolic outcomes.

Dietary Fiber and Plant-Based Foods

Dietary fibre is crucial for gut health because it enters the colon largely intact, where it is fermented by beneficial microorganisms into short-chain fatty acids (SCFAs). A plant-based diet has been consistently linked to greater microbial diversity in the gut, which is considered a key indicator of gut health. A wide variety of whole grains (barley, brown rice, oats), legumes (chickpeas, beans, lentils), fruits (berries, apples, bananas), and vegetables (carrots, broccoli, leafy greens) are rich sources of dietary fibre. Resistant starch, found in vegetables, green bananas, and cooled potatoes, promotes the growth of butyrate-producing bacteria such as *Faecalibacterium* and *Roseburia*.

Prebiotics and Selective Microbial Stimulation

Prebiotics such as inulin, fructooligosaccharides, and galactooligosaccharides selectively stimulate the growth of beneficial gut bacteria, particularly *Bifidobacterium* and *Lactobacillus*, thereby enhancing immune function, strengthening the gut barrier, and reducing intestinal inflammation. These prebiotics are non-digestible dietary fibres naturally present in foods such as garlic, onions, leeks, asparagus, chicory root, bananas, and whole wheat. Regular consumption of these foods supports microbial balance and contributes to long-term gut health by preferentially nourishing beneficial gut microorganisms.

Fermented Foods as Natural Probiotics

Fermented foods contain live beneficial microorganisms, commonly referred to as probiotics, which exert positive effects not only on digestive health but also on overall immune function. Many traditional fermented foods, including yoghurt, kefir, curd, kimchi, sauerkraut, miso, tempeh, and other fermented vegetables, are rich sources of lactic acid producing bacteria. Several studies have demonstrated that regular consumption of fermented foods can enhance gut microbial diversity, suppress pathogenic bacteria, and reduce markers of both systemic and intestinal inflammation. Among these, yoghurt and kefir are particularly well recognized for their health benefits, especially in improving lactose digestion and supporting immune health.

Polyphenols and Healthy Fats

Polyphenols are complex phytochemicals abundant in plant-based diets and fruits that interact closely with the gut microbiota. Although polyphenols are poorly absorbed in the small intestine, they are extensively metabolized by gut bacteria into more bioactive compounds, including phenolic metabolites and urolithins, which exhibit potent antioxidant and anti-inflammatory properties. Rich dietary sources of polyphenols include apples, berries, grapes, green tea, coffee, cocoa, olives etc. These compounds selectively promote the growth of beneficial gut microbes, particularly *Akkermansia muciniphila*, a bacterium strongly associated with improved metabolic health and reduced inflammation. In addition, omega-3 fatty acids—found in fatty fish, flaxseeds, chia seeds, walnuts, and plant-based oils support an anti-inflammatory gut microbial profile. In contrast, excessive intake of saturated and trans fats disrupts gut microbial balance, leading to dysbiosis and the development of metabolic inflammation.

Overall, the gut microbiome plays a crucial role in human health, and diet is considered as one of most driving factors in shaping of its composition and function. In this context, the Ministry of Health and Family Welfare (MoHFW), in collaboration with the Food Safety and Standards Authority of India (FSSAI), implements several programmes and national campaigns to promote nutrition security, prevent non-communicable diseases (NCDs), and support gut health through dietary interventions, in alignment with the “*Viksit Bharat*” vision for a healthier nation. Government led initiatives encouraging the revival of traditional fermented foods, promotion of millet-based diets (*Shree Anna*), development of probiotic research and standards, and advancement of microbiome-focused biotechnology, bioengineering, and startups—supported by agencies such as the Department of Biotechnology (DBT), Indian Council of Medical Research (ICMR), Ministry of AYUSH, and Biotechnology Industry Research Assistance Council (BIRAC) reflect the growing recognition of the gut microbiota as remarkable societal asset for improving population-level health outcomes.

AWARDS / CONFERNCES

Dr. Priya Sharma, Junior Scientist, was honored with both the G.P. Talwar Young Scientist Award and the Best Poster Award at Immunocon 2025-the 52nd Annual Meeting of the Indian Immunology Society, themed “Immunology Meets Technology: Improving the Effectiveness and Reach of Diagnostics and Therapeutics,” held at MNNIT, Prayagraj, from 19th to 22th November, 2025.

Dr. Swati Shalini, Junior Scientist, was awarded First Prize in an essay contest on the occasion of “Swasth Nari Sashakt Pariwar” and also secured First Prize in the essay competition held during Hindi Pakhwada 2025.

Mr. Pushpendra Kumar received a Consolation Prize in the Shrutlekh competition as part of Hindi Pakhwada 2025.

10th National Official Language Rajbhasha Conference

The 10th National Rajbhasha Conference (10^{वाँ} राष्ट्रीय राज भाषा सम्मेलन), themed “*India, Indianness, and IndianLanguages*,” was successfully organized by the National Institute of Biologicals under the Ministry of Health & Family Welfare, Government of India, at the National Institute of Open Schooling (NIOS), Sector-62, Noida, from 29th to 30th December 2025. The conference brought together officials, experts, and stakeholders to deliberate on the promotion and effective implementation of Hindi and other Indian languages in official work. It featured thematic sessions, discussions, and interactive activities aimed at strengthening the use of Rajbhasha in governance and day-to-day functioning, while reinforcing the cultural and linguistic diversity of the country.

Rashtriya Karmayogi Large Scale Jan Seva Programme-Phase II (RKLSJSP)

National Institute of Biologicals (NIB), Noida organized a training programme under the Rashtriya Karmayogi Large Scale Jan Seva Programme – Phase II to strengthen a citizen-centric and performance-driven work culture. Conducted in multiple batches (28th, 29th, 30th October, 2025 and on 18th November, 2025), the programme ensured wide participation across all staff categories, with 96% of regular employees participating. It promoted the core value of “Seva Bhav” through interactive sessions, group exercises, and discussions, reinforcing commitment to continuous learning, accountability, and service excellence in line with Mission Karmayogi. The sessions were facilitated by Ms. Rashmi Srivastava and Mr. N. Nanda Gopal, the Master Trainers for the programme at NIB, under the guidance of Ms. Sudha V Gopinath- Lead Trainer, conducted by the Department of Clinical Biochemistry, Christian Medical College, Vellore. The laboratory achieved an “Excellent” Z score for all six parameters during the period from October to December 2025.

QUALITY ASSURANCE / QUALITY CONTROL OF BIO-THERAPEUTICS, PROPHYLACTICS AND IN-VITRO DIAGNOSTICS

- The Biochemical Kit Laboratory (BKL) is enrolled in the CMC External Quality Assessment Scheme (EQAS) for Chemistry II encompassing Glucose, Cholesterol, Triglycerides, Creatinine, Uric Acid, and Albumin conducted by the Department of Clinical Biochemistry, Christian Medical College, Vellore. The laboratory achieved an “Excellent” Z score for all six parameters during the period from October to December 2025.

NOMINATION/ PARTICIPATION OF NIB SCIENTISTS IN VARIOUS MEETINGS/ WORKSHOPS

- An Expert Committee Meeting has been organized on 6th October, 2025 at NIB, NOIDA under the Chairmanship of **Dr. V. M. Katoch**, former Secretary DHR and Director General (D.G.), Indian Council of Medical Research (ICMR), to review the Protocols for Quality Control Evaluation/ Performance Validation of Various Malaria In-vitro Diagnostics (IVDs).
- Dr. Gauri Misra, Scientist Grade- I and Head, attended the 7th Project Review Group (PRG) Meeting as an expert, held virtually at ICMR Headquarter, New Delhi on 7th October, 2025.
- Dr. Shikha Yadav, Scientist Grade-I and Head, received invitation from AAALAC International as a Council member, for conducting site visit and assessed two units in India on 3rd and 6th October, 2025 to evaluate their institutional animal care and use program for accreditation purposes.
- Dr. Manoj Kumar Rajput, Scientist Grade-III, attended one day Brainstorming Workshop on Need of Exascale Computing for Life Science Applications, organized by DST, Government of India on 9th October, 2025.
- Dr. Gauri Misra, Scientist Grade- I and Head, attended the Technical Advisory Committee (TAC) meeting of MedTech Mitra as an expert, held virtually at the ICMR Headquarter, New Delhi on 14th October, 27th November, 17th & 18th December, 2025.
- Dr. Gauri Misra, Scientist Grade- I and Head, as an external expert, virtually attended a meeting organized by CDSCO concerning a clinical performance application for a new *In-vitro* Diagnostics Medical Device in form MD-24 on 4th November, 2025.
- Dr. Harit Kasana, Scientist Grade-II and Head, attended CDSCO-WHO Workshop on Regulatory Performance Indicators (RPIs) at Delhi from 6th to 8th November, 2025.
- Mrs. Kanchan Ahuja Scientist Grade-II and Head, participated virtually in the National webinar on “Blood and Blood Components”: Ensuring Quality and Safety through Indian Pharmacopoeia' on 7th November, 2025 organized by Indian Pharmacopoeia Commission, Ghaziabad.
- Dr. Gauri Misra, Scientist Grade- I and Head, virtually participated in the third meeting of the Technical Working Group (TWG) on the Diagnostics Landscape Review, organized by the Centre for One Health, National Centre for Disease Control (NCDC), New Delhi on 10th November, 2025.
- Reference Standard Unit, NIB organized a meeting with officials from WHO-SEARO on 12th November 2025 at NIB, Noida to explore potential collaborations with the South-East Asia Regulatory Network (SEARN)
- Dr. Gauri Misra, Scientist Grade- I and Head, delivered a lecture as an invited speaker at the InBix-2025 Conference: "Action Towards Genomics & Community Health (ATGC-Health)", hosted at the ICMR-National Institute of Research in Tribal Health (NIRTH) in Jabalpur, Madhya Pradesh scheduled from 13th to 15th November, 2025.



- The Central Bioassay Facility, NIB organized a meeting with officials from PETA India on 14th November, 2025. The meeting brought together regulators, policymakers, scientists, and industry experts to discuss regulatory pathways and the adoption of the Monocyte Activation Test (MAT) for biopharmaceuticals in India.
- An Expert Committee Meeting has been organized online on 18th November 2025 under the Chairmanship of **Dr. V. M. Katoch**, former Secretary DHR and Director General (D.G.), Indian Council of Medical Research (ICMR), in continuation to the discussion held during the previous Expert Committee Meeting on Quality Control testing of different In Vitro Diagnostics (IVDs) for malaria, held on 6th October, 2025 at NIB, NOIDA, to deliberate further on the panel size required for Quality Control testing of malaria Rapid Diagnostic Test (RDT) kits, at NIB, Noida.
- Dr. Gauri Misra, Scientist Grade-I and Head, attended the National CDSCO Mission Assembly 2025 Conclave, titled "Translating knowledge to practice-One Earth one Health one future," organized under the National One Health Muhim (NOHM) at Bharat Mandapam, New Delhi on 20th to 21st November, 2025.



- Dr. Charu Mehra Kamal, Scientist Grade-I and Head, attended the Interaction and Briefing Session by Dr. Sankarshan Sahoo, Statistical Advisor, Department of Biotechnology, Ministry of Science and Technology, Government of India at NIB, Noida, on 21st November, 2025.
- Dr. Harit Kasana, Scientist Grade-II and Head, delivered a guest lecture on Quality control evaluation of Rabies vaccine during 27th National Conference on One Health, virtually held on 21st November, 2025.
- Dr. Charu Mehra Kamal, Scientist Grade-I and Head, as a QCI empaneled speaker conducted a session as part of the Orientation Training for ICMR Technical Assistants at ICMR-Centre for Research, Management and Control of Haemoglobinopathies, Chandrapur on "Quality Control of Biosimilars and Recombinant Products" on 26th November, 2025.



- Dr. Suresh Kumar, Scientist Grade-III, participated as a Resource Person at LASAICON-2025, an International Conference titled "From Preclinical to Clinical: Connecting the Dots of Research, Animal Welfare, Drug Discovery, and Pharma Innovation for Viksit Bharat", jointly organized by CSIR-Institute of Microbial Technology (IMTECH), Chandigarh, and the Laboratory Animal Science Association of India (LASAI), held from 30th November to 2nd December, 2025.
- Dr. Jyoti Sharma, Scientist Grade -III, attended 'International Conference on Navigating Cell Therapy in India: Regulatory Pathways, Market Dynamics and Opportunities' organized by The Indian Pharmaceutical Association on 6th December, 2025 at India Habitat Center, New Delhi.
- Dr. Gauri Misra, Scientist Grade-I and Head, delivered an invited talk titled "Advancing Viral Variant Surveillance through In-house Developed RT-PCR Diagnostic Assay" at India International Sciences Festival (IISF-2025)-Young Scientist Conclave (YSC) co-organised by DST, DBT, DOS, DAE (Gov. of India) and coordinated by Indian Institute of Tropical Meteorology, Pune, on 9th December 2025.
- Dr. Gauri Misra, Scientist Grade-I and Head, virtually organised a review meeting of 7th Technical Expert Committee of MDL for initiation of Performance Evaluation of HIV molecular kits on 9th December, 2025.
- Dr. Shikha Yadav, Scientist Grade-I and Head, delivered a lecture on "Laboratory Animals Pain Assessment and Management" in the 7th Certificate Course on Laboratory Animal Experimentation organized by Institute of Liver & Biliary Sciences (ILBS), Delhi on 12th December, 2025.

- The Centralized Facility for Bioassay (CFB) organized a meeting to discuss a potential collaboration between NIB and PETA Science Consortium International e.V. (PSCI) & Institute for In Vitro Sciences (IIVS), US, to provide training on non-animal testing approaches held on 12th December, 2025 at the National Institute of Biologicals, Noida. Dr. Harish Chander, Dr. Charu M. Kamal, Sudha V Gopinath, Dr. Subhash Chand & Dr. Suresh Kumar participated in the meeting.



- Dr. Harit Kasana, Scientist Grade-II and Head, attended WHO Advanced In-country Workshop on Good Manufacturing Practices (GMP) Regulatory Inspection using the Risk based approach in India from 8th to 12th December, 2025 at Ahmedabad. Organized by Central Drugs standard Organization (CDSCO) and World Health Organization (WHO).
- Dr. Gauri Misra, Scientist Grade- I and Head delivered an invited talk on “MASTL Inhibition: A Promising Strategy for Breast Cancer Therapeutics” at the International Conference on Advances in Biotechnology, Bioprocessing and Structural Biology (ICABSB-2025) held at IIT Roorkee on 14th December 2025.
- Dr Charu Mehra Kamal, Scientist Grade-I, Head, Divisional Head (Biotherapeutics) and Ms. Gurminder Bindra, Scientist Grade-III, carried out Joint Inspection with CDSCO and State FDA of M/s Eris Bionxt Private Ltd, Raisen, Madhya Pradesh on 16th to 17th December, 2025.
- Dr. Shikha Yadav, Scientist Grade-I, and Head, delivered a talk on “Common issues found in India during accreditation of animal care and use program and AAALAC expectations” in Pre-Conference workshop on 18th December, 2025 and attended the 13th LASA International Conference on “Preclinical Insights from Animal Studies on Drug Discovery & Translational Research, from 19th to 20th December, 2025 that was organized by Gandhi Institute of Technology & Management (GITAM), Visakhapatnam.
- Dr. Gauri Misra, Scientist Grade- I & Dr. Harit Kasana, Scientist Grade-II attended the Influenza Chintan Shivir organised by National Centre for Disease Control (NCDC), Ministry of Health & Family Welfare (MoHFW) in collaboration with WHO Country office for India on 22nd & 23rd December, 2025.

EVENTS UNDER ANNUAL CAPACITY BUILDING PLAN-2025-26 FOR NIB OFFICIALS

- **Lecture session on “Procurement in Government Offices; A Vigilance Perspective**
As part of National Vigilance Week (27th October to 2nd November, 2025), NIB Noida organized a scientific session titled “Procurement in Government Offices: A Vigilance Perspective” on 31st October, 2025. The session featured an invited talk by Dr. Sagar Deshpande and saw active participation from senior officials and scientists.
- **India International Science Festival (IISF) 2025**
India International Science Festival (IISF) 2025– Curtain Raiser Programme was organized at NIB, Noida on 26th November, 2025 under its Annual Capacity Building Plan. The event, held from 10:00 AM to 1:00 PM, was graced by Hon'ble Central and UP State Government Ministers and featured engaging sessions by experts and scientists. It aimed to enhance scientific outreach, strengthen collaboration with stakeholders, and mark the IISF curtain raiser. The event was further enriched by multiple lecture sessions covering Cyber Security & Data Privacy (by Mr. Naveen Mathur, NIC Delhi), AI/ML and Blockchain in Biologicals (by Dr. Abhinesh Kaushik, IIIT Lucknow), and an online session on Mass Spectrometry in Biopharmaceuticals in coordination with Thermo Fisher Scientific.
- **Lecture Session on “Basics of Protein Purification Techniques** held on 18th December, 2025 governed with a special talk by Dr. Nupur Postdoctoral Fellow, NIB.
- **Lecture Session on “Ethics in Use of Animals in Research** held on 24th December, 2025 governed with special talk by Dr. Farha Deebea Postdoctoral Fellow, NIB.

SHORT-TERM STRUCTURED LAB BASED CUSTOMIZED TRAINING PROGRAMMES

- **Five days training on Quality Control Testing of Immunodiagnostic Kits** held from 24th to 28th November 2025 in the Immunodiagnostic Kit Laboratory-NIB. A total of 02 participants (01 MBBS Student of GIMS-Greater Noida and 01 Assistant Drugs Controller, Govt. of NCT of Delhi) attended this training course
- **CDSCO officials Training at VAL:** NIB, Noida organized a two-day training programme for 16 officials from the Vaccine Division of CDSCO at the Vaccine & Antisera Laboratory (VAL), NIB on 27th to 28th November, 2025, as part of CDSCO's annual refresher training activities.



- Five days training course on Basics of Cell Culture & Bioassays was conducted from 01st to 05th December, 2025 in Central Bioassay Facility Lab. A total of 06 participants (01 MBBS Student, 01 NIB Scientist, 03 Industry- Pfizer Healthcare, & 01 Lab Technologist GIMS Greater Noida) attended this training course.



PUBLICATIONS

- Shalini S, Fatima A, Gowri B, et al. Establishment of method validation criteria and internal quality control system for measurement of glucose in accredited laboratory. *Proc Natl Acad Sci India Sect B Biol Sci.* 2026;96: 193–200. doi:10.1007/s40011-025-01746-0.
- Karpe SC, Kiran M, Sayal A, Meena J, Joshi K, Kumar R, Chander H, Anvikar AR, Kasana H. Current quality evaluation landscape of rotavirus vaccines: a comprehensive review. *J Pure Appl Microbiol.* Accepted for publication.
- Kumar A, Lata S, Yadav IS, Misra G. Targeting G and F proteins of human metapneumovirus: an in-silico strategy for multiepitope vaccine design. *In Silico Res Biomed.* 2025 Dec 26:100167.



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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!!!

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