NATIONAL INSTITUTE OF BIOLOGICALS

NEWSLETTER

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Visit of Dr. Ira Ray, Founder Director of NIB on 1st April, 2025 for an interaction with NIB officials

Director's Desk

The second quarter of 2025 was graced by the memorable visit of Dr. Ira Ray, the visionary founder director of the National Institute of Biologicals (NIB), on 1st April 2025. Even after 33 years since the institute's inception, her presence filled us with pride and inspiration. Dr. Ray shared heartfelt insights into the institute's founding journey and expressed her joy at witnessing its remarkable progress and vital role in safeguarding public health.

The National Institute of Biologicals continues to be a cornerstone in India's healthcare landscape, demonstrating unwavering commitment to quality assurance, regulatory science, and capacity building in the field of biologicals and in-vitro diagnostics. In alignment with global health priorities, the institute commemorated World Malaria Day on 25th April, 2025 themed 'Malaria Ends With Us: Reinvest, Reimagine, Reignite,' featuring an insightful lecture on IVD kits for malaria diagnosis.

This report highlights NIB's continued excellence in external quality assessments, regulatory inspections, and its active participation in national and international collaborations. The engagement of NIB scientists in expert committees, workshops, and inter-agency dialogues underscores the institute's pivotal role as a key technical stakeholder in India's drug and diagnostic regulatory ecosystem. Notably, during this quarter, the institute expanded its testing capabilities to include eight new biological products.

Further strengthening its commitment to capacity building, the Training Unit successfully coordinated a visit and orientation for six Assistant Secretaries (IAS Officers, 2023 batch) from the Ministry of Health and Family Welfare on 6th May, 2025. The officials were acquainted with quality control testing of biologicals through comprehensive laboratory visits at NIB.

As we look forward, this edition stands as both a reflection of our achievements and a reaffirmation of our dedication to enhancing regulatory frameworks, fostering scientific innovation, and upholding the highest standards of quality in healthcare products for the benefit of public health.

Warm regards
Dr. Neelima Mishra

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p53 and Drug Regulatory System: Guardians of Genome & Guardian of Public Health

Ms. Rashmi Shrivastava, Scientist Grade - III has over 24 years of rich and varied experience in Research and Development, Application industry, Regulatory and QA/QC area of Life Science. In NIB, since 2009, she has been involved in Quality evaluation of Hormones, Vaccines, Monoclonal Antibodies and Blood Products and headed Central departments like SRRDU & IT cell. She is currently engaged with Quality Assurance and Management of laboratories with respect to ISO/IEC 17025:2017, is a qualified NABL Assesor and a registered PhD Scholar.

The human body, like a nation, operates under strict regulations to ensure survival and stability. At the cellular level, one of the most vital regulatory mechanisms is controlled by the p53 protein, which plays a central role in monitoring the cell cycle and preventing tumor formation. Analogous to p53's function in maintaining cellular health, a country's drug regulatory system acts as the guardian of public health, ensuring that medicines and therapies are safe, effective, and of high quality. This article draws parallels between the p53; the guardian of genome and Drug regulatory system; guardian of public health.

p53: The Cellular Guardian

p53, often referred to as the "guardian of the genome," is a tumor suppressor protein that monitors and regulates the cell cycle. Its primary function is to maintain genomic stability by preventing the proliferation of cells with damaged DNA. When a cell encounters stress, such as DNA damage, p53 is activated and acts in various ways to prevent the development of cancer. Depending on the severity of the damage, p53 can initiate DNA repair mechanisms, induce cell cycle arrest, or trigger apoptosis (programmed cell death) to eliminate the potentially harmful cell.

This multifaceted regulation is essential for the system to prevent uncontrolled cell division, which can lead to the development of tumors. Without p53's oversight, damaged cells could proliferate, leading to the accumulation of mutations and ultimately resulting in cancer.

Drug Regulatory System: The Public Health Guardian

Just as p53 regulates cellular activity to prevent harm, a country's drug regulatory system oversees the development, approval, and monitoring of drugs and medical products to ensure public safety. This system is composed of several institutions, such as the Food and Drug Administration (FDA) in the United States, the European Medicines Agency (EMA) in Europe and CDSCO in India.

These regulatory bodies are responsible for evaluating the safety, efficacy, and quality of new drugs before they can be marketed to the public. They achieve this by reviewing clinical trial data, inspecting manufacturing facilities and continuously monitoring drugs after they have been approved for public use. The drug regulatory system acts as a gatekeeper, ensuring that only safe and effective treatments reach patients. Institutions like the National Institute of Biologicals (NIB) are instrumental in pre-market quality testing of various biologicals in the field of therapeutics, diagnostics and prophylactics. Just as p53 checks for genetic fidelity before allowing a cell to divide, NIB's prime mandate is to ensures a medicine's biological integrity before it reaches a hospital shelf.

Parallel Functions and Mechanisms

Both p53 and drug regulatory agencies share similar functions in their respective systems:

Sr. No.	Function	P53	Drug Regulation
I.	Surveillance and Monitoring	p53 continuously monitors cellular DNA for any signs of damage and acts immediately to correct or contain the problem.	Drug regulatory agencies continuously oversee the drug development process, ensuring that clinical trials adhere to safety and regulatory standards and that drugs are free from harmful side effects before they are made available to the public.
II.	Decision-Making Under Stress	When DNA damage is detected, p53 decides whether to repair the damage, halt cell division, or initiate apoptosis based on the severity of the threat.	Similarly, when a new drug is presented, regulatory agencies must decide whether to approve, reject, or request further data based on the balance of benefits and risks.
III.	Prevention of Harm	p53 Activates checkpoints (G1/S, G2/M) prevents damaged cells from multiplying, thereby reducing the risk of tumor development, hence Prevents tumor formation	Regulatory agencies prevent unsafe or ineffective drugs from entering the market, thereby protecting public health from drug related drug-related public health disasters. Central labs act as checkpoints (NIB, CDTLs)
IV.	Adaptability	p53 can respond to different types of cellular stress, from DNA damage to oxidative stress, adapting its response to the specific threat	Drug regulatory systems are flexible, updating their guidelines and practices in response to new scientific evidence, emerging diseases, or innovations in drug development, such as biotechnology and gene therapy
V.	Post-Surveillance and Repair	p53 continues to monitor the cell function after a repair, ensuring the cell cycle resumes only when it is safe to do so	Drug regulatory agencies perform post-marketing surveillance, tracking drugs for any long-term adverse effects and issuing recalls or safety warnings if necessary.

Failures and Consequences

When p53 is mutated or fails to function properly, cells can begin to divide uncontrollably, leading to cancer. Similarly, if a drug regulatory system fails—due to corruption, inadequate oversight, or lack of resources—unsafe drugs can enter the market, leading to widespread public health crises.

For instance, the thalidomide tragedy in the 1960s, where a drug approved without sufficient testing caused severe birth defects, highlighted the need for rigorous drug regulation. This event led to reforms in drug regulatory systems worldwide, much like how discoveries of p53's critical role in cancer prevention led to a deeper understanding of cellular regulation and the importance of maintaining its integrity.

Conclusion: Guardians of Health

The p53 protein and drug regulatory systems serve as essential guardians in their respective spheres. Just as p53 protects cells from becoming cancerous, drug regulatory systems protect the public from unsafe and ineffective medications. Both systems are indispensable in maintaining the health and well-being of individuals and society at large.

Failures in either system can have dire consequences—cancer at the cellular level or public health crises at the societal level. Therefore, maintaining the integrity and functionality of both is crucial. As we continue to advance in medicine and biology, strengthening these regulatory mechanisms will be key to ensuring a healthier future for all. Whether within a cell or a country, oversight systems are crucial for long-term survival. p53 ensures cellular homeostasis through strict control of the cell cycle, while drug regulatory bodies like CDSCO, with checkpoints like NIB, ensure that medicines and biologicals are trustworthy.

So, these systems— national and cellular—are not merely bureaucratic or biological entities; they are the frontline defenders of life and health. Their robustness determines whether we can trust the cells in our bodies—or the medicines in our hands.

References :

1. Indore Institute of Pharmacy. Pharmaceutical Regulation: Ensuring Safety and Efficacy in Global Markets [Internet]. Indore Institute; [cited 2025 Oct 3]. Available from: https://iip.indoreinstitute.com/blog-post

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4. Kim JH, Scialli AR. Thalidomide: The tragedy of birth defects and the effective treatment of disease. Toxicol Sci. 2011 Jul;122(1):1-6. doi:10.1093/toxsci/kfr088. Erratum in: Toxicol Sci. 2012 Feb;125(2):613. PMID: 21507989.

Awards

1. Ms. Rashmi Shrivastava, Scientist Grade - III, participated and received second prize in स्वरचित हिन्दी काव्य पाठ प्रतियोगिता organized by Nagar Rajbhasa Karyanvyan Samiti on 29th April, 2025 at राष्ट्रीय मध्यम अवधि मौसम पूर्वानुमान केंद्र, सेक्टर 62 नोएडा.

Quality Assurance / Quality Control of Bio-Therapeutics, Prophylactics and In-Vitro Diagnostics

1. The Biochemical Kit laboratory is enrolled with External Quality Assessment Scheme (EQAS) for Chemistry II (Glucose, Cholesterol, Triglycerides, Creatinine, Uric acid & albumin), conducted by the Department of Clinical Biochemistry, Christian Medical College, Vellore. The laboratory during the period April – June, 2025 has achieved a Z score $\leqslant \pm 1.0$ (Excellent) for all the six parameters.

2. Dr. Hemant Kumar Verma, Scientist Grade - II & Mr. N. Nanda Gopal, Scientist Grade-III conducted Joint Inspection along with North Zone officials of CDSCO, for the Grant of permission in Form CT-11 of M/s Mankind Pharma Ltd., Manesar, Gurugram on 3rd April, 2025.

3. Dr. Charu Mehra Kamal, Scientist Grade - I, Dr. Hemant Kumar Verma, Scientist Grade - II and Mr. N. Nanda Gopal, Scientist Grade-III conducted Joint Virtual Inspection of M/s Gufic Biosciences Limited, Navsari, Gujarat to verify the adequacy of the facility for the applied drugs for purpose of test / analysis from 29th-30th April, 2025

4. Recombinant Products Laboratory has received results for Inter laboratory Comparison (ILC-2025) study conducted by IPC, Ghaziabad for Teriparatide (Assay Parameter) and has scored satisfactory results.

5. QMU facilitated the onsite re-assessment of NIB laboratories/units as per ISO/IEC 17025:2017 From 17th to 18th May, 2025 by a team of NABL assessors for renewal of accreditation.

Nomination/ Participation of NIB Scientists in various Meetings/ Workshops

1. Dr. Subhash Chand, Scientist Grade-III participated in the workshop on In vitro models for toxicology assessment at the Institute for In Vitro Sciences (IIVS) in Gaithersburg, Maryland, USA sponsored by the PETA Science Consortium International from 12th -15th May, 2025.

2. Dr. Pankaj K. Sharma, Scientist Grade-III and Ms. Vandana Tandasi, Junior Scientist virtually participated in the Expert committee meeting with respect to exemption in lot testing of high risk IVD kits at CDSCO port offices on 8th April, 2025 at NIB.

3. Dr. Gauri Misra, Scientist Grade-I as an expert virtually attended the '30th Technical Advisory Committee Meeting of MedTech Mitra' organized by ICMR(HQ) on 9th April, 2025.

4. Ms. Kanchan Ahuja, Scientist Grade-II virtually attended 18th meeting of In-vitro Diagnostic Medical Devices and Biological evaluation of Medical Devices Technical Committee, MHD 19 organized by Bureau of Indian Standards on 17th April, 2025.

5. Recombinant Products Lab members attended a meeting with M/s Eli Lilly Global team at NIB for discussion on proposed "Dulaglutide Monograph for Drug Substance and Drug Product and other collaboration activities" on 24th April, 2025.

6. Dr. Rajesh Kumar Sharma, Scientist Grade – III attended an Expert committee meeting with respect to quality control testing of Biochemical Kits and rapid HbA1c Test Kits under Medical Devices Rules, 2017 at Central Drugs & Standards Control Organization Head Quarters in New Delhi on 28th and 29th April, 2025 respectively.

7. Dr. Rajesh Kumar Sharma, Scientist Grade-III was nominated from NIB to attend Technical Committee Meeting w.r.t. Technical Specification of TTI kits under Chairpersonship of DGHS through online mode on 15th May, 2025 and 12th June, 2025 at Nirman Bhawan, New Delhi.

8. Dr. Gauri Misra, Scientist Grade – I virtually attended hybrid meeting of committee on "contract to open and evaluate the bids received for retender for implementing of N A T technology in IRCS, NHQ, Blood Centre" on 15th May, 2025.

9. Ms. Rashmi Shrivastava, Scientist Grade - III virtually attended a meeting as an external expert for ICMR-ICMAI on IVD cost evaluation activities across ICMR institutes on 15th May, 2025.

10. Dr. Gauri Misra, Scientist Grade - I delivered an invited talk on "Standards Testing and calibration requirements for ensuring quality assurance of medical devices" under MedTech Mitra: A NITI Ayog-ICMR-CDSCO Initiative, held on 15th May, 2025 at ICMR, New Delhi.

11. Dr. Gauri Misra, Scientist Grade - I was invited as expert speaker to deliver a lecture on "Regulatory perspective for transition of discoveries to in-vitro molecular diagnostics products" on 9th June, 2025 at CSTD Seminar Hall, CSIR-NIST, Kerala.

12. Mr. N. Nanda Gopal, Scientist Grade-III, attended "World Accreditation Day" at New Delhi conducted by Quality Council of India (QCI-NABL) on 9th June, 2025.

13. Dr. Rajesh Kumar Sharma, Scientist Grade-III was nominated from NIB to attend expert committee meeting on "To conduct clinical performance evaluation of in-vitro diagnostics medical device to ensure safety, essentiality, desirability, effectiveness and clinical performance of new in-vitro diagnostic product i.e. Lords Med ShapeDx Point -of-care Sickle Cell Test" through video conferencing on 20th June, 2025 organized by Central Drugs Standard Control Organization, New Delhi.

14. A virtual meeting was held between CDSCO and NIB officials regarding the expansion of testing of Rabies vaccine on 25th June, 2025.

Trainings

1. The Training Unit of NIB along with IIPA-Delhi organized an interactive session-cum-laboratory visit of 48 Drug Inspectors from CDSCO, Government of Bihar on 3rd April, 2025.

2. NIB's scientific and technical staff attended an online lecture on the topic "What You Must Learn, Which They Do Not Teach You in the University," delivered by Dr. Swaminathan Sivaram, an eminent polymer chemist and former Director of CSIR-NCL on 4th April, 2025.

3. A lecture on "Research and Development of IVD Kits for Infectious Diseases and the Challenges in Regulatory Compliance was delivered by Dr. Manoj Chugh, Vice President, Research & Development, TransAsia Bio-Medicals Ltd., to NIB officials on 4th April, 2025.

4. A lecture session to commemorate World Malaria Day on 25th April, 2025 was delivered by Dr. Umesh Kaushik, Head of the Research and Development Department, Medsource Ozone Biomedical Pvt. Ltd., Faridabad on the topic "Recent Trends in Manufacturing of Various IVD Kits for Diagnosis of Malaria and Challenges in Pre- and Post-Validation Internal Quality Control".

5. Ms. Sudha V. Gopinath, Scientist Grade-I attended Five Days Offline Training Workshop entitled under "Lead Trainer training of Rashtriya Karmayogi Jan Seva Program", held from 05th-09th May, 2025.

6. The Training Unit coordinated the visit cum-orientation of 6 Assistant Secretaries (IAS Officers of 2023 batch) from Ministry of Health and Family Welfare (MoHFW), Govt. of India on 6th May, 2025. The concerned officials were familiarized to the Quality Control testing of biologicals including visit to various laboratories of NIB.

7. Training unit organized a Lecture Session for NIB officials on "Biomedical waste management Regulations and Best practices" by Dr. Suresh Kumar, Scientist Grade – III on 28th May 2025.

8. Sh. PK Mohapatra, Administrative Officer (Finance) and Dr. Suresh Kumar, Scientist Grade-III, attended two days offline Workshop on "Handling RTI Matters (H-RTIM-02)" held from 09th to 10th June, 2025 at ISTM (Institute of Secretariat Training and Management), Delhi.

9. Training unit organized a Lecture Session on "Recombinant LAL Method Implementation and Regulatory Compliance", on 23rd June, 2025 governed with a special talk by Mr. Alan Hoffmeister (Senior Scientific Portfolio Specialist) Charles River Laboratories India Pvt. Ltd. New Delhi

Publications

- Jia H, et al. World Health Organization, Expert Committee on Biological Standardization. Report on a Collaborative Study for Proposed 1st WHO International Standard for Ranibizumab. WHO; 2025. WHO/BS/2026.2486. Participant of the Collaborative study from NIB: Subhash Chand, Ajay Kumar Ade, Nidhi Solanki, Sabiha Aaysha, Charu M Kamal, Harish Chander.

- Misra G, et al. Strategic approach to enhancing diagnostic precision: optimizing panel size for HBV and HCV viral load monitoring kits. J Med Virol. 2025 Jun;97(6):e70437. doi: 10.1002/jmv.70437.

- Singh P, et al. Development and validation of novel RT-PCR assay for molecular diagnostic of viral variants using SARS-CoV-2 as a case study. Methods. 2025 Aug;240:54-62. doi: 10.1016/j.ymeth.2025.04.006.

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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!!!