In the next issue:
- e-rakikosh training
- WHO workshop
- LQMS Diagnostics

Release of Blue & Green Book on Laboratory Quality Management System (Diagnostics) Workshop from 08th-10th Feb, 2017 organized by NIB in collaboration with Clinical Development Services Agency (CDSA), DBT.

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NATIONAL INSTITUTE OF BIOLOGICALS
NEWSLETTER

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Director’s Message

It gives me great pleasure to bring out this NIB newsletter after successful completion of 25 years of the institute. In addition to the Quality Control testing of different biologicals, NIB is gearing up for Research & Development activities which are in concurrence to mandate of the institute in the areas of biologicals viz. preparation of reference standards, proteomics, genomics, glycobiology, molecular & immunodiagnostics and new platform technologies. A committee comprising many eminent scientists and experts has already been formed in order to further widen the wings of R&D activities.

South African National Control Laboratory (SANCL) had invited two scientists from NIB, to assist the South African accreditation body, SANAS to be a part of their audit team and with an indication that the expert should not be a part of prequalification testing for the WHO.

NIB is to undertake the forthcoming training on HPAECPAD in NIB Vaccine and 2nd WHO Global Network of National Vaccine Control Laboratories (GNVCL) meeting, under the direction of Dr. Ute Roskopf, Scientist, WHO and Dr. Christina Van Hulstein, Director, Biological Vaccine Unit CRVI-BSS Rome, Italy.

Dr. Gaby Vercauteren, Senior Advisor (Essential Medicines & Health Products), WHO-HQ and Dr. Madhur Gupta, Technical Officer (Pharmaceuticals), WHO-India, during their visit to NIB, deliberated on the opportunities for establishing NIB as WHO Collaborating Center (WCC).

A National Workshop for Laboratory Quality Management System (Diagnosics), for stakeholders, researchers etc. was organized to enhance the quality deliverables while working in the area of diagnostics. Major focus of the workshop was the Management and Technical requirements as per global standards of ISO.

Institute is also extending its services to Bhutan for establishment of their Haemovigilance system. NIB’s support in building institution and capacity of their health professionals on Haemovigilance Programme has also been appreciated by Royal Government of Bhutan. Further, NIB has also been requested to extend technical support to setup a Transfusion Transmitted Infection (TTI) test kits evaluation capacity at Royal Centre for Disease Control, Thimphu, Bhutan.

With great pride, I wish to share that three more laboratories of NIB viz. Viral Vaccine, Bacterial Vaccine and Enzymes & Hormones have been notified as CDL for the Quality Control testing vide Gazette Notification No: G.S.R. 250 (E) - Part-II - Section 3 - Sub-Section (i) dated 15th March, 2017 by Government of India.

With Best Regards
Dr. Suninder Singh
Director, NIB

About NIB
National Institute of Biologicals, has successfully completed its 25 years of contribution in the field of Quality Control of Biologicals to protect public health. The glorious journey was celebrated in NIB amphitheatre on 27th January, 2017. During this span of 25 years, NIB has established Quality Control testing of various biologicals in the area of biotherapeutics, diagnostics, vaccines with the state-of-art laboratories and animal facility. The testing laboratories are ISO/IEC 17025:2005 accredited since 2011. Till date, NIB has contributed for the development of 65 monographs for biological testing in Indian Pharmacopoeia. To strengthen indigenous manufacturers for diagnostic kits, NIB also provides Sera Panel for viral markers like HIV, HBV & HCV. In addition to this, a National Reference Standard for Insulin has also been developed by NIB for indigenous manufacturers. Preparation of more Reference Standards for different biologicals is in progress.

As a result of national and international linkages developed over the period, NIB will soon be declared as WHO Collaborating Centre (WCC) and a center for 2nd WHO Global Network of National Vaccine Control Laboratories (GNVCL) meeting.

Three more laboratories of NIB viz. Viral Vaccine Lab, Bacterial Vaccine Lab and Enzymes & Hormones Lab have received the CDL notification for the Quality Control testing vide Gazette Notification No: G.S.R. 250 (E)-Part-II-Section 3-Sub-Section (i) dated 15th March, 2017.

Allergen Testing Laboratory is the first lab in the country to undertake Quality Control testing & analysis of allergen products and contributing significantly towards improving modalities for the same. To achieve this, the lab has written the first ever General Chapter for the Allergen Products, to be published in Indian Pharmacopoeia 2018.
Visits of International Dignitaries

Dr. Ute Rosskopf, Scientist, WHO and Dr. Christina Von Hunoistein, Director, Bacterial Vaccine Unit CRIVIB-1SS Rome, Italy visited NIB from 21st-23rd Feb, 2017, to discuss, oversee and finalize the arrangements to be made for the forthcoming training on HPEAC-PAD in Hib vaccine and 2nd WHO Global Network of National Vaccine Control Laboratories (GNVCL) meeting to be held at NIB.

Ms. Gaby Vercauteren, WHO-HQ along with Dr. Madhur Gupta, WHO-India, visited the institute on 05th April, 2017 and discussed concrete training opportunities and the roadmap for NIB to become a WHO Collaborating Centre (WCC) and also discussed the logistics for hosting the annual meeting for regulators.

Hon’ble High Commissioner of Embassy of Zambia visited NIB on 15th March, 2017 to identify the areas of cooperation between Health Agencies in Zambia and NIB.

Indo-Bhutan Bonds

Institute is extending its services to Bhutan for establishment of Haemovigilance system. Further, Secretary (MoHFW) Govt. of India, has received a proposal from Secretary Health, Royal Government of Bhutan, appreciating NIB’s support in building institution and capacity of their health professional on Haemovigilance Programme. NIB has also been requested to extend technical support to setup a Transfusion Transmitted Infection (TTI) test kits evaluation capacity at Royal Centre for Disease Control, Thimphu, Bhutan.

A delegation comprising Drug Controller of Royal Government of Bhutan and Regulatory Officer visited the institute on 24th May, 2017 with an objective “To Explore Possibilities for Testing of Biologics and TTI Test Kits” and to identify areas of institutional linkages between Drug Regulatory Authority of Bhutan and NIB, Ministry of Health & Family Welfare, Government of India.

Hands on training to two officials of the Royal Centre for Disease Control, Department of Public Health, Ministry of Health, Thimphu, BHUTAN on Transfusion Transmitted Infection (TTIs) Kits and Blood Grouping at NIB from 12th-16th June, 2017.

Special Achievements

➢ Government of J&K Health and Medical Education Department, has notified five NB scientists (Dr. Reba Chhabra, Dr. Renu Jain, Dr. J P Prasad, Ms. Ajanta Sircar and Ms. Kanchan Ahuja) as Government Analysts for whole of the state for inspection of various classes of drugs.

➢ NIBSC, UK has invited Recombinant Product Laboratory to participate in the establishment of a replacement WHO International standard for rhPTH 1-34. Laboratory has completed the ILC study programme for PTH reference preparation with NIBSC for content and purity. Final report is yet to be communicated from NIBSC to NIB.

➢ Immunodiagnostic Kit Laboratory of the Institute has participated in the International EQAS, conducted by NRL, Australia for Hepatitis, HIV and Syphilis Serology with 100% score.

➢ Molecular Diagnostic Laboratory participated in Proficiency Testing, conducted by EDQM, France for HCV-NAT. The performance of the lab has been declared “Excellent” by EDQM.
Assessment of South African National Control Laboratory (SANCL) by NIB Scientists as Technical Experts

Two scientists from NIB, Dr. Renu Jain (S-I & DDQC I/c Biotherapeutics) and Sh. Jaipal Meena (S-III & Head, VVL) were deputed as Technical Expert to assist the South African accreditation body, SANAS, for the audit.

Three days on-site audit (4th-6th April, 2017) for SANCL at Bloemfontein, located in the University of Free States (UFS), was designed as per the requirements of ISO/IEC 17025 accreditation from SANAS for the testing of Yellow Fever Vaccine, Measles Vaccine and Oral Polio Vaccine.

SANCL Director gave an appreciative feedback on the Technical assessment of their facility conducted by NIB scientists.

R & D Committee Meeting

First Expert Committee Meeting to guide R&D and academic activities, including preparation of Reference Standards was held on 04th Feb. 2017, at NIB, under the Chairmanship of Prof. N. K. Ganguly, Former DG, ICMR and distinguished Biotechnology Research Professor, NII, New Delhi. The meeting with the committee consisting of five eminent external experts was convened by the Director, NIB.

A blue print prepared with the research proposals of the institute in thrust areas of biologicals viz. proteomics, genomics, glyco-biology, molecular & immunodiagnostics and new platform technologies along with preparation of reference standards, was taken up by the committee. The Research & Development activities which are in concurrence to the mandate of the institute were sensitized by a laboratory guided tour to the experts for various emerging thrust areas. This will strengthen capacity building initiative with manpower, equipment along with the skill development at NIB. The purpose of the meeting was to deliberate the progress in order to make NIB a Centre of Excellence for research in the area of Biologicals.

The committee suggested that the R & D activities envisaged at NIB should be targeted to strengthen the current regulatory framework. Since no university on the globe is providing degree in discipline of Regulation of Biologicals, NIB can be first of its type to do so.

Collaboration with other organizations

Dr. Shikha Yadav (S-II & Head, Animal Facility):

i. Collaborated with
   a) Dr. Archana Chugh, Associate Professor, IIT, Delhi for the project entitled “Corneal delivery of antifungal-peptide conjugate encapsulated nanoparticle formulation in an experimental animal model of Fusarium solani”.
   b) Dr. Vijay Pal Singh, IGB, Delhi for the project entitled “Evaluation of A1 and A2 variants of α-casein in cow milk as a factor causing allergic disease in murine model.”

ii. Invited by Technology Development Board (TDB), Department of Science & Technology, Government of India, as an expert member of Initial Screening Committee (ISC) for screening a project proposal on “Establishment of Specific Pathogen Free Laboratory Animal Breeding & Testing Facility” from ICC Laboratories India Pvt Ltd, Hyderabad on 23rd May 2017.

iii. Selected by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC)-International Council on Accreditation, as an Ad hoc Specialist (Site Visitor) wherein she will be assisting AAALAC International in conducting and evaluating site visits/audits of Animal Facilities for accreditation purposes.
Laboratory Quality Management system (LQMS) in Diagnostics

NIB in collaboration with Clinical Development Services Agency (CDSA), DBT, conducted 2nd National Workshop for 38 participants from 08th-10th Feb, 2017, at NIB, in the area of Diagnostics with an objective to make the participants aware about the basics of LQMS, so as to enhance their quality deliverables while working in the area of diagnostics. The participants selected belonged to various manufacturing, quality control and quality assurance departments, academic institutions and regulatory bodies from all over the nation.

Hands-on training was also provided to the participants in Immunodiagnostic Kit lab, Molecular Diagnostic Lab, Blood Reagent Lab and Biochemical Kit Lab.

Scientific Presentations & Participations

2nd JK Medical Science Congress and 1st Annual Conference of Metabolic Syndrome-Prediabetes-PCOS Society held from 10th-13th May at Sher-i-Kashmir International Conference Centre, Srinagar, J&K.

Mr. Tara Chand (S-III, BKJ): *Overview of self-monitoring of blood glucose systems evaluated at NIB*

Mr. Subhash Chand (S-III & Head, TMA): *Change Heterogeneity pattern of Trastuzumab: Targeted therapy for metastatic Breast Cancer*

Ms. Gurminder Bindra (S-III): *Role of NIB in connecting science to patients by assuring safe and quality anti diabetic products*

Dr. J. P. Prasad (S-I & Head, BPL): *Quality Control Testing of Various Plasma Derived Products* and Ms. Sudha V. Gopinath (S-I) represented NIB in interactive panel discussion session at Initiative on Hemophilia Care III held on 11th April, 2017 at IHC, New Delhi.

Dr. Renu Jain (S-I & DDQC i/c Biotherapeutics): *Role of testing laboratories in current regulation for biopharmaceuticals in India* at BIRAC-CDSA Regulatory Workshop on Biopharmaceuticals at Venture Center, Pune on 15th Mar, 2017.

Establishment of ICMR-NARFBR at Hyderabad and visit to Animal Facility, NIB

Dr. Suresh Pothani, Director i/c, National Animal Resource Facility for Bio-Medical Research (NARFBR), being established in Hyderabad under ICMR, DHR MoHFW along with Dr. R. S. Sharma, Senior Deputy Director General, ICMR and team of 6 CPWD engineers visited Animal Facility, NIB on 22nd May 2017 as it is one of the best animal facility in the country under the Ministry of Health & Family Welfare.
Skill Development of NIB Employees

'Enhancing Performance for Global Organizational Success' lecture delivered by Mr. R. N. Kumar, Faculty (Behavior Science), Administrative Training Institute, Mysore on 3rd April, 2017.


'Data Integrity & Analytical Platforms' lecture given by team of M/s Waters India, on 3rd June, 2017.

International Day of Yoga (21st June) observed at NIB, where the entire staff became a part of the programme and enthusiastically performed the yoga asanas taught by Yoga Guru Sh. Amit Ranjan Sr from Universal Yoga Group, Gurugram, Haryana.

Trainings

In view of the Hon’ble Prime Minister of India, Shri Narendra Modi’s, “Pradhan Mantri Kaushal Vikas Yojana (PMKVY)” which emphasizes on Skill Development, the institute conducted “National Skill Development and Hands-on Training in Quality Control of Biologicals” for 164 postgraduate students from Universities of Gauhati, Jammu, Himachal Pradesh, Uttarakhand and Students from institutes like CRI Kasauli, NIPER Kolkata, Mohali and Guwahati. The students were trained for various techniques like HPLC, Electrophoresis, ELISA, Bacterial Endotoxin Testing, Cell Culture Handling. They were also trained for use of laboratory animals in QC testing of Biotherapeutics and Vaccines.

The institute has also provided 04-08 weeks/03-06 months dissertation/project work to 54 Under Graduate/Post Graduate Students of various universities in Quality Control of Biologicals. The hands-on training on various analytical platform makes them proficient, help in their future research endeavors and enable them to get better future opportunities.

Two students from Iraq pursuing their M.Sc. (Microbiology) from Acharya Nagajuna University, Andhra Pradesh and one Indian student of Georgia-Gwinett University have also been trained at the institute.
Meetings

2nd Meeting of NIB-Scientific Expert Committee for DNA products & mAbs held on 27th Jan, 2017 at Biosafety Unit-DBT (RCGM), New Delhi

Scientific Meeting for discussion on preliminary report on Reference Standard Preparation on Insulin Lispro held on 26th May, 2017 at NIB

First scientific meeting for Revision of Monograph on Peg Filgrastim on 2nd Feb, 2017

1st meeting for the preparation of National Reference Standard for Anti-A (Monoclonal) and Anti-B (Monoclonal) on 12th May, 2017

Meeting regarding setting up R & D at NIB, 23rd - 24th Jan, 2017

1st Core Committee meeting on Allergens on 20th Apr, 2017

Second meeting of the Scientific Expert Committee for Blood Products on 2nd Feb, 2017

1st meeting of Expert committee for R & D Project and Preparation of National Reference Standard for Enzymes & Hormones Lab on 31st Jan 2017

Meeting on development of National Reference Standards for Total Protein estimation in human albumin and potency assay for Human Coagulation Factor VIII on 12th Apr, 2017

- Development of Filgrastim Reference Standard (RS) on 06th Apr, 2017 at IPC, Ghaziabad
- Meeting to discuss technical issues related to specification of HIV test kit on 09th Jan, 2017 at NACO, New Delhi
- Meeting for revision of Pediatric ARV drugs as per the availability of the formulation in market on 29th March, 2017 at Nirman Bhawan, New Delhi.
- Apex Lab Meeting on 23rd Mar, 2017 at NARI, Pune.
- Technical Specification committee meeting for procurement of equipment on 02nd June, 2017 at Nirman Bhawan, New Delhi.
Haemovigilance

Two Days National Workshop on ‘Voluntary Blood Donation for Preparing Road Map for Achieving 90-100% True Voluntary Blood Donation in India’ organized by NIB in collaboration with Federation of Blood Donor Organizations of India, West Bengal from 4th-5th Mar, 2017.

Two Days National Workshop on Haemovigilance, Donor Vigilance & Voluntary Blood Donation at Kalimpong, West Bengal organized by NIB, in collaboration with Federation of Blood Donor Organizations of India (FBDOI) from 14th-15th June, 2017 at Kalimpong, West Bengal.

Two Days Workshop on Haemovigilance, Donor Vigilance & Voluntary Blood Donation held from 24th-25th Mar, 2017 at Agartala in collaboration with FBDOI, West Bengal & Tripura State Blood Transfusion Council. Shri Manik Sarkar, Hon’ble Finance Minister, Govt. of Tripura had inaugurated the workshop. Shri Manik Sarkar, Hon’ble Chief Minister of Tripura had graced the workshop as Chief Guest on the closing day.

Silver Jubilee Celebrations of NIB

Superannuation of Mr. P. C. P. Mohapatra, Administrative Officer

Mr. P.C.P. Mohapatra, Administrative Officer, superannuated from NIB on 31st May, 2017 after rendering 12 years of service since 2005. NIB will always be indebted for his extensive contribution as the Administrative Officer.

NIB wishes him a happy and healthy life.