



INDIAN PHARMACOPOEIA COMMISSION

(Ministry of Health and Family Welfare,
Government of India)

1st IPC Workshop on Therapeutic Proteins: Regulatory and Quality Considerations February 23, 2018

Organised By

Indian Pharmacopoeia Commission
Sector 23, Raj Nagar,
Ghaziabad 201 002

Workshop Venue

IPC Regional Office, CDSCO Zonal Office
CDSCO Bhawan, Beside T.B. & Demonstration Centre
S.R. Nagar, Hyderabad 500 038

ABOUT INDIAN PHARMACOPOEIA COMMISSION

Indian Pharmacopoeia Commission (IPC) was created on 1st January, 2009 as an autonomous Institution of the Ministry of Health and Family Welfare, Govt. of India to set standards of drugs in the country with a vision 'to promote the highest standards of drugs for use in human and animals' and mission 'to promote public health in India by bringing out authoritative and officially accepted standard for quality of drugs'. It has basic function to update regularly the standards of drugs by publishing official written standard in the form of Indian Pharmacopoeia (IP). IPC also provides measurement standards in the form of IPRS which act as a finger print for identification of an article under test and its purity as prescribed in IP. The IP, or any part of it, has got legal status under the Second Schedule of the Drugs & Cosmetics Act, 1940 and Rules 1945 there under. IP standards are authoritative in nature and are enforced by the regulatory authorities for quality control of medicines in India. During quality assurance and at the time of dispute in the court of law the IP standards are legally acceptable.

ABOUT WORKSHOP

Therapeutic proteins are an imperative part of the pharmaceutical industry and are among the fastest-growing segments in the biopharmaceutical market. The current progress in the field of pharmaceutical biotechnology has increased the value and number of protein-based therapeutics in the market. The CDSCO is the Central Drug Authority in India for discharging functions assigned under the Drugs and Cosmetics Act and has functions of regulatory control over the import of drugs, approval of new drugs and approval of clinical trials. CDSCO has approved many recombinant proteins as biotechnology medicines for therapeutic use including various peptides, cytokines, enzymes and interferons. Although therapeutic proteins have taken centre stage in drug discovery and development with enhanced safety profiles for human use, there are certain challenges that still need to be addressed.

In order to address the regulatory and quality related challenges in the area of therapeutic proteins, IPC is organizing "1st IPC Workshop on Therapeutic Proteins: Regulatory and Quality Considerations" on February 23, 2018 at IPC Regional Office, Hyderabad. This workshop is expected to:

- ◆ Create awareness about the IP standards among the stakeholders
- ◆ Better understand regulatory pathways for the approval of therapeutic protein products in India
- ◆ Discuss the issues related to post-marketing pharmacovigilance
- ◆ Understand modern analytical approaches for characterization of therapeutic proteins and biosimilars
- ◆ Provide common platform for regulatory understanding between CDSCO, IPC and industry

Target Audience

- ◆ QC Analysts of Manufacturing and Regulatory Labs
- ◆ R&D Scientists of Manufacturing and Academic Labs
- ◆ Regulatory Affairs Professionals
- ◆ Contract Research Organization Scientists & Managers
- ◆ Contract Manufacturing Organizations Professionals

REGISTRATIONS

Registration Fee Before 15th February, 2018	Registration Fee After 15th February, 2018	On-spot Registration (Subject to availability of seats)
Rs. 2000 + 18% GST per participant	Rs. 2500+ 18% GST per participant	Rs. 3000 + 18% GST per participant

No refunds will be issued for any cancellation requests or failure to attend the workshop. However, we may consider request for substitute registrant from the same organization and request for substitutions must be sent to ipclab@vsnl.net before 20th February, 2018.

Registration Enquiries

Dr. M. Kalaivani/ Dr. Gaurav Pratap Singh

Email: ipclab@vsnl.net, biologics.ipc@gmail.com

Phone: +91-120-2783400, 2783401, 2783392

Website: www.ipc.gov.in



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**1st IPC Workshop on Therapeutic
Proteins: Regulatory and Quality
Considerations**
February 23, 2018

REGISTRATION FORM

PARTICIPANT DETAILS		INVOICING DETAILS	
Name		Name	
Company/Institution		Company/Institution	
Address (with pin code)		Address (with pin code)	
Telephone		Telephone	
Fax		Fax	
Email		Email	
Purchase Order Reference (If any) (To be mentioned on the invoice)			

PAYMENT DETAILS

Amount	
NEFT ID/DD No.	
Date	

TERMS AND CONDITIONS OF PARTICIPATION

1. Payment shall be made either by Demand Draft in favour of 'INDIAN PHARMACOPOEIA COMMISSION' payable at Ghaziabad or NEFT to 'Indian Pharmacopoeia Commission, Bank of Baroda, Raj Nagar, Ghaziabad; Bank Account No.: **21860100013540**, Branch IFSC Code: **BARBOSANGHA** (Fifth corrector is 0=zero), Type of Account: Super Saving account, MICR Code of Bank: **110012204**
2. Scanned copy of duly filled and signed registration form may be sent to biologics.ipc@gmail.com.
3. Seats are limited and registrations will be accepted based on first come first served basis.
4. No refunds will be issued for any cancellation requests or failure to attend the workshop. However, we may consider request for substitute registrant from the same organization. Request for substitutions must be send to ipclab@vsnl.net.
5. In case of any dispute, decision of IPC will be final and accepted by one and all.

Date: _____

Signature of Participant: _____

Place: _____



1st IPC Workshop on Therapeutic Proteins: Regulatory and Quality Considerations

Date: February 23, 2018

Venue: IPC Regional Office, CDSCO Zonal Office, CDSCO Bhawan, Beside T.B. & Demonstration Centre, S.R. Nagar, Hyderabad 500 038

TENTATIVE SCHEDULE

8:15 AM – 9:00 AM Registration

Inaugural Session

9:00 AM – 9:10 AM Welcome Address

9:10 AM – 9:30 AM Introduction to Participants

9:30 AM – 9:40 AM Vote of Thanks

9:40 AM – 10:00 AM Tea Break

Session I: Therapeutic Proteins-Regulatory Considerations in India

10:00 AM – 10:45 AM Regulatory Framework for Therapeutic Proteins in India
Speaker: Dr. A. Visala, DDC(I), CDSCO-Hyderabad

10:45 AM – 11:15 AM Role of Indian Pharmacopoeia in Setting Standards for Therapeutic Proteins
Speaker: Dr. Jai Prakash, IPC-Ghaziabad

11:15 AM – 11:30 AM Tea Break

Session II: Pharmacovigilance Issues of Therapeutic Proteins

11:30 AM – 12:15 PM Post-marketing Pharmacovigilance of Therapeutic Proteins
Speaker: Dr. Subhadeep Sinha, Hetero Labs Ltd.

12:15 PM – 1:00 PM Post-marketing Data and ADR Reporting for Biosimilars in India
Speaker: Dr. Nitu Sinha, Dr. Reddy's Lab.

1:00 PM – 1:45 PM Lunch Break

Session III: Analytical Characterization of Therapeutic Proteins

1:45 PM – 2:30 PM Analytical Characterization of Biosimilars
Speaker: Dr. Rajesh Singh, Gennova Biopharmaceuticals

2:30 PM – 3:15 PM Bioassays for Biosimilar Characterization
Speaker: Dr. Sushobhan Das, Bioneds India Pvt. Ltd.

3:15 PM – 3:30 PM Tea Break

3:30 PM – 4:15 PM Role of LCMS in Characterization of Biosimilars
Speaker: Dr. VadiBhat, Agilent Technologies

4:15 PM – 5:00 PM Electrophoretic Techniques for Characterization of Biosimilars
Speaker: Dr. Prashant Dour, SCIEX

5:00 PM – 5:15 PM Workshop Concludes