BIRAC - CDSA Regulatory Meet: Demystifying Indian Drug Regulations for New Product Approvals

Magnolia, Indian Habitat Centre, Lodhi Road, New Delhi

About The Work Shop

Biotechnology Industry Research Assistance Council (BIRAC), in collaboration with Clinical Development Services Agency (CDSA) is organizing a set of **four** workshops:-

Demystifying Indian regulations for new Drug	2 Days
Current Regulation for Vaccines and Biopharmaceuticals - Indian Perspectives	2 Days
Regulatory Framework for Medical Devices, Diagnostics, GLP and GMP in India	2 Days
Understanding Herbal / Phyto-Pharmaceuticals Regulations in India	1 Day

The First Workshop is on "**Demystifying Indian regulations for New Drugs**".

The proposed workshops shall bring together the experts from Central Drugs Standard Control Organization (CDSCO), Indian Council of Medical Research (ICMR), Academic Institutes and Industries engaged in new product development. The goal of these workshops is to provide direct, relevant and valuable information on the key aspects of Regulations governing new product approvals in India.

The Regulatory Workshop will focus on topics like :

1. Updates on Indian Regulations, guidance and Laws in India
2. Understanding the Drugs and Cosmetic Act
3. The format and content of IND submissions, including regulatory and scientific requirements
4. Pre-Clinical and Clinical Documentation Needs
5. Review & Approval Process
6. Real time Experience in Filing and seeking Approvals for INDs

Demystifying Indian Regulations for New Drugs

When 11th and 12th February 2013.

Where Magnolia, Indian Habitat Centre

Faculty The faculty comprises of top level speakers from CDSCO, ICMR Medical Institution and Industry

Workshop Format

The proposed workshops will feature several cross-cutting sessions addressing the issues and needs common to new drugs, biological – biopharmaceuticals, medical device approval as well as break-out sessions which focus on the unique issues of filing applications for new drugs, biological – biopharmaceuticals and medical device to the regulatory authority for approval. There will be ample opportunity for Q & A and networking throughout the workshop.

What you will receive

Each participant will receive the course material for use during the workshop and for future reference, which will comprise of:

i. A compact CD on Indian Drug Regulations

ii. A Booklet of Various applicable Guidelines

Registration

The participation is only by Invitation and interested candidates can write for invitation to Sonia Gandhi, Program Manager, BIRAC at **sgandhi.birac@nic.in**

Workshop Fee

There will be no fee for attending the workshop.

Who Should Attend?

- Our intended Audience will be Small and Medium Enterprises (SMEs), Young Entrepreneurs, Academic Institutions related to the area of new drugs, biological – biopharmaceuticals and medical devices who want to learn about how CDSCO approaches the regulation in India.

Contact

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11th & 12th February, 2013

PROGRAMME STRUCTURE

Day I : 11th February 2013

0900 - 0930 hrs	**Registration**
0930 - 0945 hrs	**Welcome Remarks** **Dr. Harmeet Sidhu, Program Director, CDSA** Welcome address and CDSA Overview
0945 - 1000 hrs	**Key Note Address** **Dr. Renu Swarup, Managing Director, BIRAC** BIRAC overview – Vision and Meeting purpose and outcomes anticipated
1000 - 1100 hrs	**Introduction to CDSCO** **M. Mitra, Ex. DDC (I)** This session aims to capture brief about, CDSCO, Brief about different divisions at CDSCO (Zonal, Sub-zonal Offices and its Role, Central Laboratories, Role of State Licensing Authorities, etc). including role of RCGM, GEAC, DBT, ICMR, NIB
1100 – 1115 hrs	**Networking Tea**
1115 – 1215 hrs	**Demystifying the Drugs and Cosmetic Act** **Dr. A.B. Ramteke, CDSA** What is a Considered as a New Drug, Current Applicable Rules & Guidances, including Schedule Y that one should be aware of
1215 – 1315 hrs	**New Drug IND** **TBD** During this presentation, we will discuss the format and content of IND submissions, including regulatory and scientific requirements
1315 – 1330 hrs	**Q&A - Interactive Discussion**
1330 – 1430 hrs	**Lunch Break**
1430 – 1600 hrs	**Drug Development CMC Needs** **Dr. Praveen Khullar, Sanofi Aventis** Drug development is a term used to define the entire process of bringing a new drug to the market. It is an integrated, multi-disciplinary endeavor. This presentation is an overview of what information one needs to include pertaining to drug discovery, chemistry, pharmacology and manufacturing in an IND application and some of the challenges that can arise.
1600 – 1615 hrs	**Networking Tea**
1615 – 1745 hrs	**Drug Development Animal Toxicology Needs** **Dr. Siddangouda Patil, Clinigene International Ltd.** This presentation is an overview of what information one needs to include pertaining to animal pharmacology/toxicity in an IND application and some of the challenges that can arise.
1745 – 1815 hrs	**Q&A - Interactive Discussion**

PROGRAMME STRUCTURE

Day II : 12th February 2013

0930 - 1130 hrs	**Drug Development Clinical Needs** **Dr. Arun Bhatt - Clininvent** This presentation is an overview of what information one needs to include pertaining to clinical information during various phases of clinical development in an IND application and some of the challenges that can arise.
1130 - 1145 hrs	**Networking Tea**
1145 - 1230 hrs	**New Drug Review & Approval Process** **Asim Sahu, Technical Officer, CDSCO** New Drug approvl Process for review at CDSCO and other interlinked agencies including NDAC.
1230 - 1300 hrs	**Q&A - Interactive Discussion**
1300 - 1400 hrs	**Lunch Break**
1400 - 1530 hrs	**Panel Discussion:** **Real time Experience in Filing and seeking Approvals for New Drug/ INDs** **Moderator:** M. Mitra, Ex. DDC (I) **Panelists:** Mr. Arvind Kukreti, ADC (I) - CDSCO Dr. Y. K. Gupta, AIIMS TBD Dr. A. B. Ramteke, CDSA Dr. Satish Bhatia, CDSA **Experiences at CDSCO** Mr. Arvind Kukreti, ADC (I) - CDSCO **Experiences of Invited Industry Representatives** (e.g. Ranbaxy, Zydus Cadilla, Cipla, Torrent Pharma, Sun Pharma, Piramal, etc.) and Participants (5-10min Presentation by each representative followed by brainstorming and recommendations)
1530 - 1545 hrs	**Networking Tea**
1545 - 1715 hrs	**Panel Discussion Contd.**
1715 - 1730 hrs	**Wrap Up and Concluding Remarks** **Sonia Gandhi** Program Manager, BIRAC

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About BIRAC

Biotechnology Industry Research Assistance Council (BIRAC), a Not-for- Profit Company as DBT's interface agency, Government of India.

Biotechnology Industry Research Assistance Council (BIRAC), a Not-for-Profit Company of Government of India, has been set up as DBT's interface agency, which serves as a single window for emerging biotech Industry. BIRAC aims to strengthen and empower the emerging biotech enterprise to undertake strategic research and innovation, addressing nationally relevant product development needs.

Vision

"To stimulate, foster and enhance the strategic research and innovation capabilities of the Indian biotech industry particularly SME's, to make India globally competitive in biotech innovation and entrepreneurship, for creation of affordable products addressing the needs of the largest section of society."

Mission

"Facilitate and mentor the generation and translation of innovative ideas into biotech products and services by the industry, promote academia - industry collaboration, international linkages and encourage techno-entrepreneurship and enable creation and sustainability of viable bio-enterprises."

Biotechnology Industry Research Assistance Council

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About CDSA

Clinical Development Services Agency (CDSA), an extramural unit of Translational Health Science & Technology Institute (THSTI), Department of Biotechnology, Govt. of India.

Clinical Development Services Agency (CDSA) has been created recently by the Department of Biotechnology, Govt. of India as an extramural unit of Translational Health Science & Technology Institute (THSTI) to enhance the capacity of clinical trials in India and bring it at par with international level. A very important aspect of CDSA is to provide very high quality training to establish and aspiring researchers and SMEs to equip them with skills and knowledge about drug regulation and to make them good in filing their applications to the regulatory authority in the country.

Mission

To create and nurture clinical trials capability and capacity in India for developing affordable clinical products for public health diseases.

Clinical Development Services Agency

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