

**INTERNATIONAL TRAINING  
PROGRAM**

**ON**

**“GENERIC DRUGS”**

**(A VIRTUAL EVENT)  
19<sup>th</sup> November 2020**

**ORGANISED BY:**



CSIR-INDIAN INSTITUTE OF CHEMICAL TECHNOLOGY  
(CSIR-IICT)  
TARNAKA – UPPAL ROAD, HYDERABAD- 500007  
TELANGANA, INDIA



CENTRE FOR SCIENCE & TECHNOLOGY OF THE NON-  
ALIGNED AND OTHER DEVELOPING COUNTRIES  
(NAM S&T CENTRE)  
NEW DELHI, INDIA

## INTRODUCTION

A generic drug is a pharmaceutical substance that contains the same qualitative and quantitative composition as an Active Pharmaceutical Ingredient (API) which was originally covered in patent by its inventor and whose bioequivalence with the reference drug has already been demonstrated. A generic medicine works in the same way and provides the same clinical benefit as its brand-name version, and may vary only in some aspects such as the process in which they are manufactured, formulations, excipients, color, taste, packaging, etc. In most cases, generic drugs are allowed to be manufactured or sold by other companies after the patent on the original drug expires. Although the profitability of branded generics is undeniable, but it is not the sole reason drug makers have for creating such products - more often, it is to increase the products' recognisability.

Generic pharmaceutical industry plays a key role in the health care of a country by providing affordable medicines. The generic drug industry is involved in development of manufacturing processes at reduced cost thereby increasing the affordability of drugs to common people. The generic drug thus produced should have exact therapeutic efficacy, safety and performance like a branded drug. In other words, this industry helps in managing the health of people under poverty line, which is an important factor for a developing nation. Development of generic industry can effectively reduce the country's dependence on imports, saves foreign exchange, and importantly secures their medicines, especially in medical emergencies and pandemic situations like present COVID, thereby, increasing a country's self reliance on pharmaceuticals, an important factor of National Health Security.

With the increase in spending on health care and rising costs of medicines, there is a need to encourage the use of generics. However, maximizing generic drug use is not possible without the public's positive perception and meeting their informational needs about generic drugs. Thus, improving the public's confidence and knowledge of generic drugs in the market is critical.

Therefore, in order to impart basic knowledge in the area of generic drug industries for scientists and professionals; and to encourage acceptability of generic drugs for facilitating

access to healthcare in NAM and other Developing Countries, **the Centre for Science & Technology of the Non-Aligned and Other Developing Countries (NAM S&T Centre)**, New Delhi, India jointly with the **CSIR-Indian Institute of Chemical Technology (CSIR-IICT)**, Hyderabad, India announces an International Training Program on “**Generic Drugs**” on **19<sup>th</sup> August 2020**. The event will be hosted by the Department of Organic Synthesis and Process Chemistry, CSIR-IICT and will be organized in Virtual Mode.

## **OBJECTIVES**

The training program intends to provide its attendees with basic knowledge about the generic drugs and their use as well as different aspects involved in the logistics and manufacturing of generic drugs. The program will cover some key aspects such as challenges involved in manufacturing of generic drugs, quality control, impurity profiling, regulatory aspects, bio-equivalence, formulations, etc. that may help guide policy, education and practice interventions supporting the use of generic drugs.

## **TOPICS TO BE COVERED**

- **Modalities in Technology Transfer and Establishment of Generic Drug Industry**  
Dr. K. V. S. Ram Rao, CEO, PI Industries
- **Challenges involved in the Manufacturing of Generic Drugs:**  
Dr. T. Rajamannar, Executive Vice President, Sun Pharma Pvt. Ltd &  
Dr. Veera Reddy, Vice President, Suven Life Sciences
- **Formulation/Polymorphism:**  
Dr. Srividya Ramakrishnan , Head, API Process Engineering, Dr. Reddy's Laboratory
- **Regulatory Aspects**  
Dr. A. Kalyan Chakravarthy, Head, Regulatory Affairs, Dr. Reddy's Laboratory
- **Key Aspects Pertaining to Generic Drugs Industry - Case Studies**  
Dr. Srinivas Lanka, Chairman, Elixir Global
- **Impurity Profiling**  
Dr. C. S. Venkatesan, Senior Vice President, Gland Pharma Ltd.

- **Bioequivalence**  
Dr. G. Venkata Ramana, Principal Scientist, Drug discovery & Clinical Research, NATCO Pharma Ltd
- **Role of R & D in Synthesis of API's**  
Dr. Ch. Raji Reddy, Senior Principal Scientist, OSPC, CSIR-IICT

## IMPORTANT DATES

<b>Date of the Program</b>	<b>19<sup>th</sup> November 2020</b>
<b>Submission of Application Starts</b>	21 <sup>st</sup> September 2020
<b>Last Date for Submission of Application</b>	16 <sup>th</sup> October 2020
<b>Confirmation to Selected Applicants</b>	30 <sup>th</sup> October 2020

## PROGRAMME

A tentative program of the event is given below:

<b>Date of Program: 19<sup>th</sup> November 2020</b>		
<b>Time</b>	<b>Theme of Training Lecture</b>	<b>Resource Person</b>
1030 - 1100	Inaugural and Introduction	Dr. S. Chandrasekhar /Dr. Amitava Bandopadhyay
1100 - 1130	Modalities in technology transfer and establishment of generic drug industry	Dr. K. V. S. Ram Rao
1130 - 1200	Challenges involved in the Manufacturing of Generic Drugs -1	Dr. T. Rajamannar
1200 - 1230	Challenges involved in the Manufacturing of Generic Drugs -2	Dr. Veera Reddy
1230 - 1300	Formulation/Polymorphism	Dr. Srividya Ramakrishnan
1300 - 1330	Regulatory Aspects	Dr. A. Kalyan Chakravarthy
1330 - 1430	BREAK	
1500 - 1530	Impurity Profiling/Analytical	Dr. C. S. Venkatesan
1530 - 1600	Bioequivalence	Dr. G. Venkata Ramana

**Date of Program: 19<sup>th</sup> November 2020**

<b>Time</b>	<b>Theme of Training Lecture</b>	<b>Resource Person</b>
1600 – 1630	Key aspects pertaining to Generic Drugs – Case studies	Dr. Srinivas Lanka
1630 – 1700	Role of R & D in Syntheses of API's	Dr. Ch. Raji Reddy
1700– 1730	Discussion and Concluding Remarks	Chaired by: Dr. B. V. Rao/ Dr. Prathama Mainkar (Panel of all Speakers)

*The Participants of the Virtual Training Program will receive a Participation Certificate electronically.*

## **ABOUT THE ORGANISERS**

### **NAM S&T CENTRE**

*The Centre for Science and Technology of the Non-Aligned and Other Developing Countries (NAM S&T Centre; [www.namstct.org](http://www.namstct.org)) is an Inter-governmental Organisation with a Membership of 47 countries spread over Asia, Africa, Middle East and Latin America. The Centre was set up in 1989 in New Delhi, India to undertake a variety of programmes, including organisation of workshops, symposiums and training courses and implementation of collaborative projects. It also offers short-term *Research Fellowships* to scientists from developing countries in association with the *Centres of Excellence* in various countries. The Centre also brings out technical books and other scientific publications in different subjects of interest to developing countries. The Centre's activities provide opportunity for scientist-to-scientist contact and interactions; familiarising participants on the latest developments and techniques in the subject areas; identification of the requirements of training and expert assistance; locating technologies for transfer between the Members and other Developing Countries, and dissemination of S&T information etc. In addition, the Centre encourages Academic-R&D-Industry interactions in the developing countries through its *NAM S&T-Industry Network*.*

### **CSIR-Indian Institute of Chemical Technology (CSIR-IICT)**

CSIR-Indian Institute of Chemical Technology, Hyderabad, established in 1944, is a constituent laboratory of the Council of Scientific and Industrial Research (CSIR), New Delhi. With its expertise in chemistry and chemical technology, it provides solutions to challenges faced by Industry, Government Departments and Entrepreneurs through basic and applied research, and process development. It is internationally recognized for its contributions to chemistry research and is an ideal place for taking ideas to commercialization through state of the art research and development.

**Vision:** To serve society by creating an outstanding knowledge base in chemistry and chemical technology.

**Mission:** CSIR-IICT will strive towards knowledge intensive translational research in chemistry to meet the country's expectations with novel technologies.

The **Organic Synthesis & Process Chemistry (OSPC) Department** is a leading research centre in CSIR-IICT with over 50 years experience in the area of synthetic organic chemistry encompassing natural product synthesis and innovative synthetic approaches aimed at offering sustainable chemical solutions and technologies. The department has around 40 personnel including academic experts, specialists and support staff as well as a large number of research students. The department is decorated by professionals with wide spectrum of expertise in organic synthesis such as natural products, carbohydrates, peptides, polymers, heterocycles, etc. The quest for new innovations witnessed the development of several novel technologies. The department is committed to providing safe and sustainable technologies with maximum economical viability and compatibility. Recently, OSPC played a key role in transferring process know-how's on repurposed antiviral API's and intermediates to Indian Pharma companies for mitigation of Covid-19.

## **PARTICIPANTS**

Young researchers, scientists, government officials and policy makers, and representatives from industry and non-government organizations - who are engaged in pharmaceuticals and healthcare sector are invited to participate in this *Virtual Training Program*. The combination of participants from various developing countries will allow for exchange of knowledge, ideas and experiences as well as opportunities for global networking and collaboration.

## **RESOURCE PERSONS**

The Training Programme would be designed and coordinated by Dr. D. Shailaja, Chief Scientist, CSIR- IICT. Other resource persons for the Virtual Training Program will comprise eminent experts and professionals from CSIR-IICT and reputed industries from India with expertise in the relevant fields.

## **SUBMISSION OF APPLICATION**

Scientists, researchers and other professionals desirous of participating in the Virtual Training Program should submit their filled-in application **electronically** directly to the NAM S&T Centre (E-Mail: [namstcentre@gmail.com](mailto:namstcentre@gmail.com)) as early as possible, but latest by **Friday, 16<sup>th</sup> October 2020**.

The following documents must be submitted as e-mail attachments:

- i. Filled in Application Form (Blank form **enclosed**)
- ii. A short CV (**maximum two pages; in MS-Word format**) [Format **Enclosed**]
- iii. Opinion (**a short para; in MS-Word format**) how you qualify to participate in the Training Program.

## **SELECTION OF APPLICANTS**

Selection of applicants will be made based on their academic and professional background, and relevance of their current engagements in the field of pharmaceutical and medical industry. Only a limited number of participants will be selected from various countries in order to ensure organized deliberations and exchange of information and expertise among the participants. Successful applicants will be electronically informed about their selection by **30<sup>th</sup> October 2020**. The details about the *Virtual Platform* that will be used for the Training Program and *log-in details* for joining the program will also be communicated to the selected applicants. Other details and terms & conditions for the participation of scientists from various countries will be given to the individual candidates on receipt of their applications.

### **CONTACT DETAILS**

#### **NAM S&T CENTRE**

##### **Dr. Amitava Bandopadhyay**

Director General

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#### **CSIR-IICT**

##### **Dr. D. Shailaja**

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