



Technical Workshops Series – 2018

**Beyond the Chemistry:**  
**How does a Pharmaceutical Molecule reach the Market?**  
 - Organized by NIDHI-CoE at Venture Center and NCL Technology and Entrepreneurship Club --

<b>Purpose</b>	<ul style="list-style-type: none"> <li>Learn about the steps in taking a molecule from the lab to market (for generics and new molecules) from an experienced chemical engineer and pharma business professional.</li> <li>This workshop is specially aimed at chemists, chemical technologists/ engineers, pharmaceuticals graduates and others interested in the pharma industry.</li> </ul>								
<b>Organized by</b>	<ul style="list-style-type: none"> <li>NIDHI-Centre of Excellence (CoE) at Venture Center supported by Department of Science and Technology, Government of India.</li> <li>NCL-TEC club</li> </ul>								
<b>Supported by</b>	<ul style="list-style-type: none"> <li>Venture Center</li> <li>NCL Innovations, CSIR-National Chemical Laboratory</li> </ul>								
<b>For whom</b>	<ul style="list-style-type: none"> <li>Students of Chemistry, Chemical Technology/Engineering, Pharmaceuticals and related subjects</li> <li>Students with interest in technology development, industry careers, entrepreneurship in pharma and related industries</li> <li>Startups, Micro/small companies with a pharma focus</li> <li>Technology developers and translators with a pharma focus</li> </ul>								
<b>When</b>	<b>Friday   14 December 2018   Time: 9 am – 6 pm</b> <b>Saturday   15 December 2018   Time: 9 am – 2.00 pm</b>								
<b>Where</b>	Lecture Theatre, Venture Center, 100 NCL Innovation Park, Dr. Homi Bhabha Road, Pashan, Pune-411008								
<b>Contact</b>	<b>Technical queries:</b> Smita Kale   020-25865877/75/76   7410045652   <a href="mailto:smita@venturecenter.co.in">smita@venturecenter.co.in</a> <b>Registration queries:</b> Lipika   020-25865877/75/76   <a href="mailto:eventsdesk@venturecenter.co.in">eventsdesk@venturecenter.co.in</a>								
<b>Registration</b>	<p><b>Limited seats: 25; First-come-First -Serve</b></p> <table border="1" style="width: 100%;"> <thead> <tr> <th style="background-color: #0070C0; color: white;">Category</th> <th style="background-color: #0070C0; color: white;">Fees</th> </tr> </thead> <tbody> <tr> <td>Registered NCL-TEC members/ IISER-Pune-EIC members (recommended by President, NCL-TEC or IISER-Pune-EIC)</td> <td>Rs. 200/-</td> </tr> <tr> <td>VC affiliated resident incubatees/ associate incubatees/ grantees/ fellows; Students with valid ID cards.</td> <td>Rs 900/-</td> </tr> <tr> <td>Individuals; Micro, Small &amp; medium enterprises; Others</td> <td>Rs 4000/-</td> </tr> </tbody> </table> <p><b>Register here:</b> <a href="http://bit.ly/14-15decbeyonchemistry">http://bit.ly/14-15decbeyonchemistry</a>  <b>Registration closes once 25 seats are full or 11 Dec 2018 (whichever comes sooner)</b>  <b>Note:- Fees paid is not refundable and non transferable under any circumstances.</b></p>	Category	Fees	Registered NCL-TEC members/ IISER-Pune-EIC members (recommended by President, NCL-TEC or IISER-Pune-EIC)	Rs. 200/-	VC affiliated resident incubatees/ associate incubatees/ grantees/ fellows; Students with valid ID cards.	Rs 900/-	Individuals; Micro, Small & medium enterprises; Others	Rs 4000/-
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## Introduction

This workshop aims to inform and teach the participant about the journey of a pharma molecule from the lab (as a molecule) to the market (as a formulated product). The workshop shall focus on the process of drug development - for both Generics and New Chemical Entities (NCEs) - with an emphasis on practical and hands-on insights on how the pharma industry works (i.e., what are the critical decisions for companies in the generics and NCE segments). To this end it will provide details such as market size, therapy area segmentation, and success factors for Generics and NCE companies. The organization structure of a typical company with different functions and skills required to work in the functions will also be discussed. The US market will be used as the primary market for discussion of NCEs

This workshop is specially aimed at chemists, chemical technologists/ engineers, pharmaceuticals graduates and other interested in the pharma industry. This workshop will be of interest to students/ researchers/ technology developers involved in pharmaceutical (drug) molecule/ process development who wish to understand how this one activity forms a part of the whole in a company for introducing new treatments to the market.

Key goals:

- Provide an overview of the Global Pharma Industry including market sizing, segmentation into different therapies.
- Explain the differences between Generics and NCE markets and the requirements it places on the organizations.
- Provide details on how a molecule developed in the Lab can be launched in the market as a formulated dose (tablet, syrup) for treatment of a disease condition (based on US regulatory framework).
- Explain how Pharma Companies (PharmaCos) are organized to fulfill the above goal
  - What are the different functions/ groups in a PharmaCo and their responsibilities?
  - What skills and knowledge are required to work in the different groups?
- Explain how critical decisions such as product/ therapy area selection and marketing messaging for NCEs are reached at companies (includes hands-on work with Industry data by participants to analyze real-world scenarios)
- **Not covered - Clinical trials**

## Workshop outline

1. Global Pharma Market
  - a. Market Sizing
  - b. Size of different therapy area segments
  - c. Generics, NCEs (patented), and branded (Overlaps and Differences)
2. Generics Market
  - a. Key differences with Patented/ NCE market
  - b. How to decide which molecule/ market to enter? – workshop to use Industry data for decision-making
  - c. A typical Generics Company structure (for generic bulk drugs and for formulations)
3. NCEs - Before any Chemistry can begin:
  - a. Which therapy area to target?
  - b. A general introduction about marketing approvals for drugs in a typical country
  - c. A Case Study to understand market opportunity in therapy areas
4. Overview of Steps in Drug Development
  - a. Steps in Finalizing the Molecule (Chemical Entity)
  - b. Steps in Finalizing a Formulation (the Sold Entity)
  - c. Steps in Finalizing the Therapy (the APPROVED Entity)
  - d. Understand the FINAL APPROVED ENTITY and link to marketing claims
5. Overview of Requirements for Launch:
  - a. Description of the molecule and the formulation
  - b. Analytical methods used to assess the final compounds, intermediates and RM
  - c. Manufacturing process validation and Impurities characterization



- d. Stability data to support the shelf-life (expiry date)
  - e. Therapy details and Clinical trials(covered a high-level)
  - f. Other requirements such as current Good Manufacturing Process (cGMP) practices
6. A Typical PharmaCo
- a. Organization structure and responsibilities for different groups/ functions
  - b. Skills and knowledge required in different functions

**Workshop includes**

- Certificate of Participation issued by Venture Center
- Lunch and Tea at Venture Center cafeteria
- Free reference membership of Venture Center Library for 1 year

**Please note, the participants will have to arrange for their own travel/local transport and accommodation and dinners. For more information and options, you can see <http://www.venturecenter.co.in/puneguide/>**

**Workshop faculty**



**Tushar Gore**

Dr. Gore completed his B.Tech. in Chemical Engineering from the Indian Institute of Technology (IIT) Bombay. He graduated at the top of his class and joined the Ph.D. program at the University of Minnesota. Tushar worked at McKinsey & Company in the US and subsequently headed the marketing strategy group at Novo Nordisk, US, for the Diabetes, Growth Hormone, and Clotting factors businesses. He started and managed the US office of Resonance Laboratories - a niche, private, generic API manufacturer - for 4 years before moving to India to manage the operations in Bangalore till Mar 2018. Presently, he is a Director on the company's board.



## Schedule

**Friday | 14 December 2018 | Time: 9 am – 6 pm**

Time (hrs)	Topic and Contents	Venue	Faculty
0830-0900	Registration	Foyer area	900 NIP
0900-0915	Introduction to Venture Center, the Workshop and the Faculty	Lecture Theatre	Smita Kale
0915-0930	Overview of the Workshop	Lecture Theatre	Tushar Gore
0930-1100 (90 min)	Session 1: <ul style="list-style-type: none"> <li>Global Pharma Industry Overview including segmentation</li> </ul>	Lecture Theatre	Tushar Gore
1100-1130	Tea break	Foyer area	
1130-1300 (90 min)	Session 2: <ul style="list-style-type: none"> <li>Competing in the Generics space</li> <li>Case/ Workshop to shortlist molecule/markets to target (bulk and formulations)</li> </ul>	Lecture Theatre	Tushar Gore
1300-1400	Lunch Break	Cafeteria	
1400-1530 (90 min)	Session 3: <ul style="list-style-type: none"> <li>NCEs <ul style="list-style-type: none"> <li>Before Chemistry – which area to enter? Case/ workshop to use actual market data</li> <li>Requirements for launch? Workshop to study the approval license of approved drugs and figure out the requirements</li> </ul> </li> </ul>	Lecture Theatre	Tushar Gore
1530-1600	Tea Break	Foyer area	
1600-1630	Venture Center Tour and Group Photo		
1630-1800 (90 min)	Session 4: <ul style="list-style-type: none"> <li>Steps in Drug Development based on requirements from Session 3 above</li> <li>Other requirements in launching products</li> </ul>	Lecture Theatre	Tushar Gore

**Saturday | 15 December 2018 | Time: 9 am – 2.00 pm**

Time (hrs)	Topic and Contents	Venue	Faculty
0900-1030 (90 min)	Session 5: <ul style="list-style-type: none"> <li>The Challenge in Pharma: Needle in a haystack</li> <li>Marketing the needle: workshop to develop marketing claims for NCE</li> </ul>	Lecture Theatre	Tushar Gore
1030-1100	Tea break	Foyer area	
1100-1230 (90 min)	Session 6: <ul style="list-style-type: none"> <li>A typical PharmaCo organization</li> <li>Spillover Topics/ Discussions/ Questions</li> </ul>	Lecture Theatre	Tushar Gore
1230-1300	Closure, feedback, certificate distribution	Lecture Theatre	V. Premnath
1300-1400	Lunch Break	Cafeteria	



**About the organizers**

	<p><b>About NIDHI-CoE, Venture Center</b>          The National Science and Technology Entrepreneurship Development Board (NSTEDB), Department of Science and Technology, Government of India has awarded Venture Center with the status of a NIDHI-CoE (National Initiative for Developing and Harnessing Innovations — Center of Excellence an umbrella programme conceived by DST). This award is accompanied by a grant of Rs. 50 Cr for 5 year duration to help Venture Center scale-up its activities and demonstrate greater success to accommodate more than 100 startups at any time and to upgrade and add new facilities for supporting science and technology based startups.          For more information, visit: <a href="http://nidhicoe.venturecenter.co.in/">http://nidhicoe.venturecenter.co.in/</a></p>
	<p><b>About NCL Technology and Entrepreneurship Club, NCL, Pune</b>          NCL Technology and Entrepreneurship club (NCL-TEC) is a club driven by research scholars and associates at NCL that aims to provide a common platform/forum for people with a shared interest in technology and translating it into products and services useful to people. The Club focuses on various aspects of technology, innovation and entrepreneurship. The club plans and organizes lectures, workshops and other events for the mutual benefit of the club members.          More on: <a href="http://www.venturecenter.co.in/ncltec/index.php">http://www.venturecenter.co.in/ncltec/index.php</a></p>

**Supported by**

	<p><b>About NCL Innovations</b>          The National Chemical Laboratory, India is a research, development and consulting organization with focus on chemistry and chemical engineering. It has a successful record of research partnership with industry. NCL Innovations is resource center of NCL that supports, promotes and champions the cause of technology innovations within NCL. More on: <a href="http://www.nclinnovations.org/">http://www.nclinnovations.org/</a></p>
	<p><b>About Venture Center</b>          Entrepreneurship Development Center (Venture Center) – a CSIR initiative – is a Section 25 company hosted by the National Chemical Laboratory, Pune. Venture Center strives to nucleate and nurture technology and knowledge-based enterprises by leveraging the scientific and engineering competencies of the institutions in the Pune region in India. The Venture Center is a technology business incubator supported by the Department of Science &amp; Technology’s National Science &amp; Technology Entrepreneurship Development Board (DST-NSTEDB). Venture Center focuses on technology enterprises offering products and services exploiting scientific expertise in the areas of materials, chemicals and biological sciences &amp; engineering.          For more information, visit: <a href="http://www.venturecenter.co.in/">http://www.venturecenter.co.in/</a></p>

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