



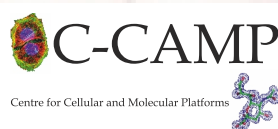
# BIOSIMILAR |

## WORKSHOP 2018

ICT, MUMBAI  
Nov. 29-Dec.1

Supported by TEQIP III and ICT innovation council

— In association with —



BOOKLET



# LEADERSHIP CONCLAVE

### About Institute of Chemical Technology (I.C.T.)

[UNIVERSITY UNDER SECTION-3 OF UGC ACT-1956 WITH MAHARASHTRA GOVT.'S ELITE STATUS AND CENTER OF EXCELLENCE]

The Institute of Chemical Technology (ICT) Mumbai was established as the Department of Chemical Technology on 1st October, 1933 by the University of Mumbai, through active support of industries and philanthropists. The Institute with research as its integral part was most popularly known as UDCT, Mumbai. The UDCT grew significantly in stature and was granted autonomy under UGC regulations by the University of Mumbai and further converted in to an Institute on 26th January, 2002. Under the World Bank TEQIP programme, the Maharashtra government granted it full autonomy in June 2004. Due to the recommendations of the Government of Maharashtra and University of Mumbai, the ICT was granted Deemed University Status by the MHRD on 12th September, 2008, with all provisions of the UGC for funding and support as the state owned deemed university. The MHRD had evaluated all deemed universities in the country in 2009 and granted “A” grade to 38 universities among 135 deemed universities. The ICT is rated as Number One Deemed University with “A” grade. It is the only one among 4 in Maharashtra State, the other 3 being centrally funded TIFR, TISS, and CIFE.

The Institute with a glorious history of 78 years has produced many industrialists, academics, bureaucrats, Padma awardees, and secretaries to Government Departments, directors of CSIR labs and over 500 first generation entrepreneurs. The institute has very strong linkages with industry and produced some of the topmost academics and industrialists. Some of the distinguished alumni include- Padmavibhushan Professor M.M. Sharma, Member, Scientific Advisory Committee to the Cabinet, Padmabhushan Dr. R. A. Mashelkar, former Director General, CSIR, Shri Mukesh Ambani, Chairman and Managing Director, Reliance Industries, Padmashri Dr. K. Anji Reddy, Chairman, Dr. Reddy's Lab, Shri Ashwin Dani, Vice-Chairman, Asian Paints Ltd., etc. The ICT has been receiving various grants and projects from the UGC, DAE, DBT, DST and other agencies, and Indian and foreign industries, with several centers of excellence: Centers of Advanced Studies in Chemical Engineering, Food Engineering and Technology, Pharmaceutical Science and Technology, Physico-Chemical Aspects of Textiles, Fibres, Dyes & Polymers; UGC Networking Resource Centre in Chemical Engineering; DBT-ICT Centre in Energy Biosciences; ICT-DAE Centre in Chemical Engineering Education and Research; Centre for Green Technology.

### **Status of Biopharmaceutical Research at I.C.T., Mumbai**

Biopharmaceutical development and characterization has gained significant pace across the globe. Realizing the prowess of biopharmaceutical research in today's context, Institute of Chemical Technology has commenced the research efforts on several grounds in this area.

Clone development by genetic engineering of mammalian cells for the production of high titers of monoclonal antibodies (mAbs) has been one of the major thrust areas of research. Design of feed and feeding strategy for improvement in the production of mAbs has been another area of interest. This also include efforts to carry out process optimization for scale up to bioreactor level for the generation of high titers of antibodies.

Glycosylation is one of the major post-translation modifications that an endogenous protein undergoes. Efforts are being undertaken to analyze these modifications at molecular level through healthy collaborations with industries. Moreover, analysis of charge variants, one of the primary impurities present in proteins of therapeutic interest constitute another area of focus. Biophysical characterization of biosimilars/proteins using analytical ultracentrifugation, dynamic light scattering and circular dichroism spectroscopy is being extensively carried out in the institute. These techniques are being applied for the determination of molecular weight, sedimentation coefficient and aggregation behavior of relevant proteins.

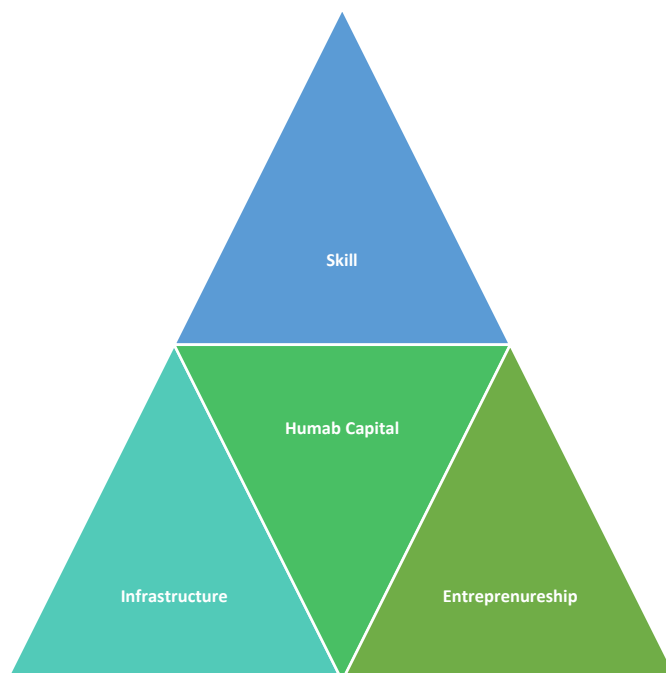
Downstream purification of monoclonal antibodies comprise yet another significant area of study. The research groups in the institute also foresee development of bioassay for mAb characterization. In addition to this, efforts to develop continuous and sustainable process for formulating recombinant therapeutic proteins has been very well received and is expected to prosper the realms of research undertakings by the institute.

## Biosimilar Workshop 2018: Leadership Conclave Dec 1 2018 An Initiative of Institute of Chemical Technology, Mumbai

**Conveners:** Dr. Ratnesh Jain and Dr. Prajakta Dandekar Jain

The biopharmaceutical sector in India, comprising therapies, vaccines, diagnostics and devices, is currently valued at nearly \$20 billion and accounts for the lion's share of the \$35 billion Indian BioEconomy. With the Indian BioEconomy projected to grow to \$100 billion by 2025, the biopharma industry could grow at a compounded annual growth rate (CAGR) of over 16% in the next eight years. The biopharmaceutical industry in India faces a gamut of challenges that include a time-consuming approval process, sub-optimal infrastructure, high regulatory barriers, lack of funding avenues, little or no incentives and a shortage of highly skilled talent, among others (Reference: Economic Times, August 7, 2017)

Biosimilar Workshop 2018: Leadership Conclave in trying to address some of these challenges. As a part of academic ecosystem our priority is to generate "Human Capital". Generating and sustaining "Human Capital" is one of the biggest challenge in our opinion. A proactive, rapid and strategic approach from all the stakeholders of the biopharmaceutical industry is desired to generate and sustain the "Human Capital" to accelerate the growth of biopharmaceutical and future industries which are based on deeper understanding of biology and manufacturing.

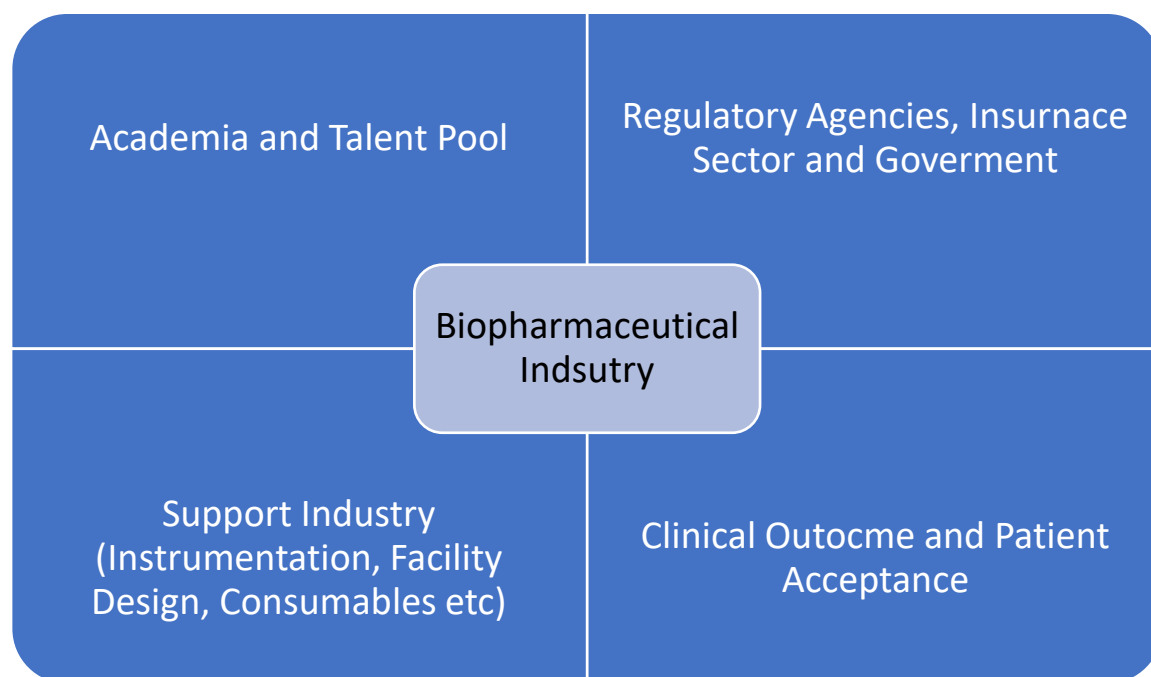


**Figure 1: Human Capital is a central requirement for Skill, Entrepreneurship and Infrastructure Development for Biopharmaceutical Industry.**

A significant investment has been done by biopharmaceutical industry for the in-house infrastructure development for the major requirements to achieve approvals of the certain biosimilars they have launched. Certain biopharmaceutical industries have also

initiated their training academies to mitigate skill requirements. Success of Biopharmaceutical Industry, however, is dependent on various stakeholders depicted in

**Figure 2**



**Figure 2: Stakeholders of Biopharmaceutical Ecosystem**

It has been concluded during our interaction with all the stakeholders over the period of last five years that a systemic and strategic approach is desired to achieve desirable growth in biopharmaceutical industry. One of the important strategy is to generate skilled "Human Capital" through a systemic approach. Biopharmaceutical industry is primarily dependent on the higher qualification for the critical requirement and success of biosimilar development. India is generating a significant number of qualified talent pool, however, the skillset desired by biopharmaceutical industry is not met by this talent pool. This is one of the biggest gap in our current ecosystem. Regulatory requirements, data integrity, documentation, understanding complex science and data interpretation are few of the biggest challenges in addition to series of soft and management skills needed. The talent pool is also spending very little time in understanding industrial objectives and practises while in education.

Unlike other industrial requirements, biopharmaceutical industry needed Science, Chemical Engineers, Technologist and Pharmacy professionals in different R&D and manufacturing operations. Since, all the education system indicated above are based on different principles a cross disciplinary approach and system is desired to make the talent pool inclined towards biopharmaceutical requirements. It is also equally important that without achieving this inclination, desired talent pool and entrepreneurship cannot be generated. Cross-disciplinary approach will not only provide desired skill set towards employment but will also provide necessary motivation to understand underlying challenges biopharmaceutical industry faces. A largest part of instrumental and consumable requirement for the industry is sourced through developed countries and we are in need of path breaking innovations to mitigate these requirements. The same is true for service model industry where critical services are outsourced to laboratories

situated in developed countries. All these challenges can be very well taken up by entrepreneurs in a focused approach. Generating successful entrepreneurship model can accelerate employment and promote innovation. However, India require affordable bioincubating facilities, clusters and research parks largely sponsored by Govt. or PPP models. These facilities will require intensive capital investment but at the same time it will also need experienced “Human Capital”. India has several centralized facilities and many of them possess difficulty to access, technical expertise to interpret the data, operational issues and skilled manpower. Even after a huge capital investment, the ROI of these facilities is not encouraging since there is no specific revenue model has been placed. In summary, we wish to achieve the a policy initiative from Govt., Industry and Industrial organizations to meet this critical demand so Biopharmaceutical Companies can be a significant stakeholder in Indian GDP and societal changes.

A proposed panel is expected to provide solution to some of the questions addressed in this document.

### Panel 1: Skill Development for Biopharmaceutical Industry

Q1. India is generating a large pool of science graduates/postgraduate (Biotechnology, Biochemistry, Molecular Biology etc.), chemical engineers and pharmacy professionals. Most of the above are absorbed in Biopharmaceutical Industry. The skillset desired by Biopharmaceutical Ecosystem (Refer Figure 2) is an amalgamation of these principles.

- 1.1 How to achieve the desired skill set at recruitment stage?
- 1.2 How to augment the skill set of already hired professionals?
- 1.3 If Skill Modules has to be started, what are the priorities?
- 1.4 Is industry willing to give defined problems to academia for better research outcome and better skillset? If yes, what would be the terms and conditions?

Q2. Primary focus of the policy is to generate larger number of skilled work force for the country. Biopharmaceutical industry typically needs quality more than the quantity. What kind of policy initiative should be addressed to mitigate these questions?

Q3. Skill development is not necessarily a one time requirement towards career development. Rapidly changing technology environment require skill development at every stage of the career. How much time each organization is providing to their members? What is biggest roadblock in case these programs are not very popular in the organizations?

Q4. Skill Development of Regulatory professionals and Govt. Organization is a key requirement. How a specific policy initiative is needed to augment skills at various govt. and regulatory organizations?

Q5. How society should consider Biopharmaceuticals as an attractive career options? How to achieve the awareness of the ecosystem to the masses?

Q6. How to achieve and measure handling of biopharmaceuticals at hospitals and in clinical settings to make sure that product is appropriately handled and administered? What skill set should be developed ?

### Panel 2: Entrepreneurship development for Biopharmaceutical Industry

Q1. What are the major requirements which are typically outsourced to third party by biopharmaceutical industry? Whether these requirements can be considered as entrepreneurial activity?

Q2. How to mitigate the investment risk in Biopharmaceutical investments?

Q3. How to diversify investment portfolio to support early stage researchers? Whether investments firms can fund through institutes and academia?

Q4. What are the biggest challenges of a biopharmaceutical startup? Whether large biopharmaceutical industry contribution is desired?

Q5. India has proven track record in the service industry. However, life science service industry is not flourished due to multiple reasons. In terms of investment scenario, how this industry can achieve leadership position? What are the risk involved?

Q6. How support industry can play a catalytic role in generating high end service based industry at India? What are the challenges? How to overcome these challenges?

### Panel 3: PPP infrastructure for Biopharmaceutical Industry

Q1. Infrastructure is a key requirement for generating skill and entrepreneurship. How to generate world class infrastructure for biopharmaceutical development.

Q2. What are the priorities for the infrastructure requirements? What kind of infrastructure is critically needed and what should be the vision to supplement future industries?

Q3. Why there is a need for a skill development institute? How these institute should be established? Whether they should work in collaboration with academic institutes? How to achieve the best case scenario?

Q4. How Investment towards generating high end infrastructure should be achieved. Whether industry would be ready to invest in such a model? What would industry expect against the investment?

Q5. Human capital is biggest requirement for the industry, support industry and entire ecosystem. Major policy initiatives are typically focused on generating capital infrastructure at institutes and industry.

Q6. What kind of policy is needed to create and sustain quality people in the ecosystem? How salary packages should be re-defined so that competitive packages are offered to sustain and growth of the infrastructure.



## **Panel #1: Need and Challenges of Skilled Workforce for Biopharmaceutical Industry**

### **Dr. Cyrus Karkaria**

President, Biotechnology Division, Lupin Ltd.



Cyrus Karkaria is currently President of the Biotechnology division of Lupin Pharma (Pune). Prior to that, he was Vice President at Celldex Therapeutics and CuraGen Corporation in New Haven, Connecticut, USA heading Operations and Biopharmaceutical Process Sciences. He has also held positions at Biogen Idec and Scios. He has been part of teams that have developed multibillion \$ blockbusters in the field of neurology, immunology and oncology such as Avonex, Amevive and Tysabri (Biogen Idec) from the bench to manufacturing scale (2000L to 15,000L). As a part of the commercialization process, he has also faced Regulatory bodies from the US FDA, EMEA, Australian TGA etc., through pre-IND to BLA filings. He holds a PhD in Biochemistry from the University of Maryland and was a post-

doctoral researcher at Harvard Medical School.

### **Dr. Mahesh Bhalgat**

Executive Director and COO, Shantha Biotechnics Pvt. Ltd.



Dr. Mahesh Bhalgat has over 20 years of experience in the field of biotechnology and biologics. Following the completion of his B.Pharm from the University of Mumbai, Mahesh went to USA for advanced studies and completed his Ph.D. from the University of Utah. During his 20 year stay in the USA, his breadth of experience grew through working in many different areas of the biotechnology industry. He has hands on experience working in the areas of R&D, Analytical Development, Technology Transfer, Regulatory Sciences and Quality. Dr. Bhalgat has first hand experience with the diversity seen in industry working with both small and large companies such as Celera Genomics, Molecular Probes, Monsanto and Amgen. After spending several years

working on agricultural biotechnology products, Dr. Bhalgat has focused on the development of therapeutic proteins from biotechnology where he has contributed to the submission of multiple clinical product regulatory dossiers while also having worked on existing commercial biotech products.



### **Dr. Prasad Krishnamurthy**

Associate Vice President- R&D, Intas Pharmaceuticals Ltd. (Biopharma Division)



Dr. Krishnamurthy is a strong scientific leader with good scientific background in cell culture and molecular biology. He has more than 8 years of experience in research and development in well renowned biopharmaceutical industries with a strong understanding of drug discovery process and biosimilar development. He has a good understanding of the cGMP system for the manufacturing of bio-pharmaceuticals. He has experience in handling and managing projects that involve business collaboration with partners outside India.

### **Dr. Satyanarayana Subrahmanyam**

Senior Director and Head (QC), Dr. Reddy's Laboratories



He joined Dr.Reddy's in 2001 as Head of Molecular Biology and continued at DRL till 2015, leaving as the Head of Analytical Development. Further, he worked in Biocon as Head Quality Control for Biologicals and Insulin. Then, he returned to DRL in 2017 as Head of Quality Control, Biologics. He conducted his post-doctoral research from Brookhaven National Labs- New York where he worked on the structure- function studies of plant fatty acid desaturases. He is MS and PhD in Microbiology from the University of Illinois at Urbana Champaign, where he worked on the Lipid Metabolism of *E.coli*.

### **Dr. Dhananjay Patankar**

Vice President- Biologics and Pharmaceutical Department, Syngene International Ltd.,



Dr. Dhananjay Patankar, Ph.D. serves as Head of Pharmaceutical and Biopharmaceutical Development at Syngene International Ltd. Dr. Patankar joined Syngene in October 2010 and heads formulation, biologics development and cGMP manufacturing for all biologics as well as drug products. He was associated with Intas Biopharmaceuticals Ltd. Ahmedabad, as Chief Operating Officer and with the Biotechnology Division of Wockhardt Research Center, Aurangabad as a Senior Scientist and Group Head for product development and manufacturing. Prior to joining Syngene, he led the CMC development of a biosimilar which has received Marketing Authorization in Europe. Dr. Patankar served as an industry representative on a National Task Force for establishing regulatory pathway for biosimilars in India. He serves as the Chairman of the Institutional Animal Ethics Committee. He serves

as Chair of a US Pharmacopeia Expert Committee for Biologics and Member of US Pharmacopeia Council of Experts.

### **Mr. Manish Kumar**

Managing Director & Chief Executive Officer, National Skill Development Corporation



His area of expertise lies in Public Service, Water and Sanitation. Presently, he is Managing Director & Chief Executive Officer of National Skill Development Corporation (NSDC). He is an IAS officer of 1991's batch. He has rich experience of over 24 years spread across various roles with national and international institutions including secretary to Government of Tripura - power & home departments. Mr. Kumar is senior water and sanitation specialist. He also worked with UNICEF and known as senior institutional development specialist and country coordinator. He worked with water & sanitation program at the World Bank.

### **Mr. Ranjit Madan**

CEO, Life Sciences Sector Development Council, New Delhi.



An alumni of Henley College, London, UK (EDP), IIM Ahmedabad (MBA), and St Stephen's College (BA Hons, Economics), Ranjit Madan has over 25 years' experience in leading MNC's (ICI, Ciba and Mobil), growing running businesses and establishing start-ups in India and overseas— handling Asia Pacific (AP) region, based in Singapore. He has been associated with diverse businesses—from petrochemicals to pharmaceuticals, and dyestuffs to defence. Previously, he has held several top management positions in reputed Indian and MNC companies in India/ overseas. They have keen a interest in issues of socio-economic relevance, he has written several papers in this space, which have received accolades from reputed institutions—in India and overseas.

### **Dr. Surinder Kher**

Advisor, BioQuest Solutions Pvt. Ltd.



Dr. Kher is a physician by training and a clinical development expert with broad expanse of business experience in biological and clinical sciences providing strategic visionary direction and leadership. His experience within the pharmaceutical industry includes early drug development, pharmacovigilance, regulatory affairs and post commercialization medical product management to overall strategic business planning covering various therapeutic areas. As a business leader, he got an opportunity with some of the well-known pharma and pharma services companies where he defined business objectives and finance strategies that lead to stable, sustainable and profitable income growth for the businesses. He has lead from the front in expanding the business operations and development across the globe

including Asia and the USA. Currently, he is advising healthcare companies in the area of clinical and medical research, product development, medical communications and portfolio management.

### **Prof. R.D.Kulkarni,**

Pro-Vice Chancellor, University of Mumbai



Dr. Kulkarni is a Professor and Head, Department of Oils, Oleochemicals and Sufactant Technology (DOOST) at the Institute of Chemical Technology, Mumbai. He has been appointed as a pro Vice Chancellor at Mumbai University. He has majorly contributed in Oleochemicals & Surfactants; Biolubricants and Tribology; High Performance Paints; Surfactant Mediated Synthesis of Nanopigments; UV Cure Coatings; Paints; Perfumes, Waxes & Cosmetics and has been credited with 39 international research publications and 7 patents. His research has awarded him as best researcher in academics as well as in industrial field for successful completion of 29 projects. Dr. Kulkarni is a life member of Oil Technologists' Association of India, Indian Society for Technical Education (LM) and Asian Polymer Association.

### **Mr. Aseem Gupta**

Secretary, Skill Development and Entrepreneurship Department, Govt. of Maharashtra



Mr. Gupta is a Secretary of the Skill Development Program conducted by Government of Maharashtra. Previously, he was secretary of the Rural Development & Panchayati Raj Dept. Mr. Gupta was also chief Officer of Slum Rehabilitation of Mumbai. He was Commissioner of various cities in Maharashtra such as Sangli-Miraj-Kupwad, Pimpri-Chinchwad, Aurangabad, Nagpur, Mumbai, Thane, etc. In line with the Hon'ble Prime Minister's vision, Mr. Gupta, aims to equip 45 million Indians with employable skills by 2022. This is expected to improve livelihoods and contributes to the economic growth of the society.

### **Dr. Ranjan Chakrabarti**

Vice President and Head - Global Biologics Lab & Standards, USP- India



Dr. Ranjan Chakrabarti is currently Vice President – Biologics and Biotechnology at United States Pharmacopeial Convention at their India office. He has over 18 years of experience in Pharmaceutical and Biopharma industries. Before joining to Industry, he worked in Academics at SUNY, Buffalo and University of Massachusetts Medical Centre at USA and successfully coordinated research projects in Cancer Cell Biology and Diabetes. He has guided several Ph. D. students. Dr. Ranjan was leading the Biology Group at Dr. Reddy's Drug Discovery unit and was involved in discovering several clinical candidates, out licensing deals and leading collaborative projects with MNCs. He has also served at key management position in GVK Biosciences for both Drug Discovery services and collaborative Drug Discovery research. In this role, he has worked with several National and International Pharma and Biopharma companies for discovery and development of both chemical and biological molecules. Dr. Ranjan is the Co-Inventor of 32 US Patents, published 52 papers in peer reviewed International Journals and presented 57 lectures in International and National Conferences.



### **Dr. Sireesha Yadlapalli**

Senior Director and Strategic Marketing & External Affairs, USP-India



Dr. Sireesha heads the Strategic Marketing and External Affairs, for US Pharmacopeia, in India. In this role, she oversees Marketing, Customer Development, Market Research and Analytics, and the Government and Stakeholder Relations functions for USP India. Her team works with the Pharmaceutical, Biotech, Food and Dietary Supplement industries as well as Indian regulators, policy makers and trade organizations, to promote the use quality standards in drugs and food. Sireesha has over fifteen years of experience in the Healthcare, Education and Real Estate sectors. This experience spans areas of Marketing, Business Development, General Management, Strategy, Finance and Market Research in the US and Indian markets. In the US, she worked with Johnson &

Johnson since 2000, for several years in various positions of increasing responsibility, across the Pharmaceutical and Medical devices sectors. In her last role with J&J, she was the Finance Manager, Strategic Business Group, Ortho McNeil-Janssen Pharmaceutical. Sireesha worked with Dr.Reddy's as a Strategy consultant in 2013, as the Director, Strategic Initiatives in 2014, leading centrally driven initiatives within Biologics, and as the Program Manager for two Biosimilar Programs, in 2015, all within the Biologics Division of Dr.Reddy's Laboratories Ltd. Sireesha has a Bachelor's in Business Management from Bangalore University, a B.A in Economics from Rutgers University, USA and a Post Graduate Program in Management from the Indian School of Business. Sireesha also serves on the Board of Sirveen Properties Private Ltd.

### **Dr. Deepesh Vendoti**

Consultant, Observer Research Foundation



Dr. Vendoti is a consultant with Observer Research Foundation, Mumbai, working on the Foundation's Health Initiative. His current research focus is on pharmaceutical policies, health systems and the emerging problem of anti-microbial resistance. Deepesh brings diverse healthcare insights from his work across various settings — from rural public health work, through SHARE India and WHO — humanitarian work in Africa and Central India, through Medecins Sans Frontieres Belgium — to the recent urban health work in Mumbai and Maharashtra, closely with state and city governments through WHO — Government of India's tuberculosis control project and ORF Mumbai. Deepesh is a medical doctor by training and a public health management

graduate from Yale University. Well-travelled across India and abroad — Deepesh is interested in the intersection of rational healthcare delivery, development, technology and entrepreneurship.

### **Mrs. Rubina Bose**

Deputy Drugs Controller (India), CDSCO (WZ), Ministry of Health & Family Welfare



She is currently working as Deputy Drugs Controller (India), CDSCO (Western Zone). She has worked as Deputy Drugs Controller (India) in CDSCO (HQ), Govt. of India in the divisions of new drug, import registration and quality assurance of vaccines. Mrs. Bose, with regulatory experience of over 20 years, has also been working as WHO facilitator in various national and international Advanced Good Manufacturing (GMP) Training of Inspectors in countries like China, Thailand, Indonesia, Vietnam, Iran, etc. She has also been working as WHO expert for developing GMP guidelines of biological, Good Regulatory Practices, National Regulatory Authorities (NRA) assessment tools.

Mrs. Bose has also been working as WHO focal point for NRA assessment of vaccines, GMP inspection of vaccine manufacturing facilities, capacity building and training of inspectors. SOPs, guidelines of pharmacovigilance activities, Good distribution practices, etc. She has worked as Assistant Drugs Controller (I) and have had looked after zonal offices. Moreover, she was nominated by Government of India to be a part of WHO (HQ) Geneva as Technical Officer in vaccine Prequalification team. After working in Quality Management System (QMS) in Biologicals since 2011, she has been part of various meetings held for finalization of the Biosimilar guidelines.



## **Panel #2: Entrepreneurship Model Needed for the Growth of Biopharmaceutical Industry**

### **Dr. Himanshu Gadgil**

Director and CSO, Enzene Biosciences Ltd



Dr. Himanshu Gadgil is the Chief Scientific Officer and is responsible for all operations at Enzene. He has a proven track record of managing multi-layered organizations toward successful global product launches of Biosimilars and development of Block-buster novel Biologics. He is a passionate innovator with over 50 publications/patents in field of Biologics drug development. Dr. Gadgil has a PhD in Protein Purification, Biochemistry from The University of Tennessee Health Science Center, Memphis, USA and post doc from UT Medical Centre. Prior to joining Enzene, Dr. Himanshu Gadgil was associated with Intas Biopharmaceuticals, Amgen and Waters Corporation.

### **Mr. Siddharth Daftary**

Director, Bharat Serums and Vaccines Ltd.



Mr. Siddharth B. Daftary, Syd serves as Director of Bharat Serums and Vaccines Limited. Mr. Daftary looks the business development activities in Bharat Serums & Vaccines Ltd. He actively involved in the business development, sales and operational activities of Advy Chemical, a diagnostic sister concern of Bharat Serums & Vaccines Ltd. He serves as Director of Bharat Serums and Vaccines Limited. He graduated with a Bachelor of Science degree in Life Sciences from the University of Mumbai and holds Master of Science degree in Molecular & Genetic Medicine from the University of Sheffield, England.

**Ms. Kavita Iyer Rodrigues**  
CEO, Zumutor Biologics, Inc.



Ms. Kavitha has been in the space of Biotech for 17 years. She has an MS in Clinical Microbiology from KMC Manipal and an MBA from IIM, Bangalore. She has worked across larger biopharma's like Biocon, Millipore before her first start-up Inbiopro. Inbiopro was in the space of Biosimilar development and she was VC funded in 2007 and sold the company in 2012 to stride with a compelling pipeline of MAbs and Microbial products. In 2013, she co-founded Zumutor which has 4 major VC's participating in value creation in the niche space of immuno-oncology. Zumutor has successfully established proprietary platforms in the space of phage and yeast display technologies. This has been an enabler in global co-development and partnership deals. Her pipeline of Immuno Oncology targets focused in the NK cell therapy space has

gained enough momentum and the company is poised to raise another round of monies for Phase 1 studies.

**Mr. Krishna Kalyan**  
Executive Director and COO, Richcore Lifesciences



He is a dynamic and results driven Senior Business Leader with extensive experience developing operational and financial excellence as well as managing cross-functional high-performance teams in early stage and large organizations across multiple geographies and industries. He has a distinct experience optimizing business processes, managing supply chains, scaling operations, enabling strategic commercial growth and driving cost optimization with strong financial planning, program management, IP strategy and systems consulting expertise. He has been successful in implementing cloud based ERP systems and setting up and managing offshore IT teams which has resulted in improved process efficiencies. He is a business leader with over 15 years of progressive global experience in

technology, business analytics and business process optimization and proven ability to achieve operational excellence while working with new technologies, business models, processes and customer base. With his multi-disciplined experience across various industries, he has helped Richcore grow from strength to strength.

### **Mr. Narasimha Rao Nedunuri**

Managing Director and CEO, Clonz Biotech Ltd.



Dr. Nedunuri co-promoted Clonz Biotech Ltd. along with 3 other promoter partners who were instrumental in the development of World's 1st Biosimilar mAb. He leads an innovative group of Scientists towards development of Biosimilar mAbs, making the treatment affordable to the diseased population in India and rest of the World. Prior to joining Clonz Biotech Ltd., he worked as a product manager at BioRad Laboratories where he looked into the business and application support of their fully owned Indian Subsidiary and at Vimta Labs as Manager of Molecular Biology where he established an advanced Molecular Biology laboratory comprising Proteomics and Genomics Platforms which include Key equipment viz. Mass spectrometry (MALDI TOF/TOF), Robotics and softwares for differential expression analysis of proteins, Gene Chip Array Platform and Mass based SNP analysis systems. He also worked as a research assistant at CCMB, Hyderabad where he worked with first group of researchers who worked on fully integrated Proteomics Platform in India. He holds a post graduate degree in Life Sciences from Pondicherry University.

### **Mr. Nitin Deshmukh**

Managing Partner, Kotak Investment Advisors Ltd.



Mr. Deshmukh is a career Venture Capital / Private Equity professional with over 29 years of investment experience. He has lead and managed investments in over 70 companies, a number of which have grown at a scorching pace attaining leadership position in their respective sectors. Over 40 of these companies have been in Life Sciences (Pharmaceuticals, Biotech & Health Care) many of them are today's global players. Nitin has a strong association with the India's Biotech and Pharmaceutical Industry, having served as the first honorary Director General of Association of Biotechnology Led Enterprises (ABLE), the apex industry association of biotech companies in India. Nitin is actively associated with BIRAC (Biotech Industry Research Assistance Council), DBT's agency funding innovation excellence in India in Life Sciences, Venture Center, Pune, and C-CAMP, Bangalore.

### **Mr. Vineet Chadha**

Managing Partner, TATA capital-Innovations Fund



Mr. Vineet joined Tata Capital in December 2009 and is a part of the leadership team which successfully raised and managed investments relating to the Tata Capital Innovations Fund.

Vineet's experience is across private equity, investment banking and shop floor manufacturing. Prior to joining Tata Capital he was with Old Lane PE responsible for investments in Indian Infrastructure sector and earlier with Ernst & Young and SBI Capital Markets in their Investment Banking businesses. Vineet received a Bachelor's Degree in Engineering from National Institute of Technology, Rourkela and Master's Degree in Finance from Delhi University. He is also a CFA Charter holder.

### **Dr. P.K.S. Sarma**

General Manager & Head Technical (Discovery & Product Development), Biotechnology Industry Research Assistance Council (BIRAC)



Dr. Sarma has seventeen years of industry research and five years of science management experience. His expertise includes Identifying discovery compounds/technologies that are of commercial and social benefit, due diligence for early stage technologies, anticipating future needs in priority areas and plan for research, translational activities, strategizing translational activities from research to product development and providing networking support to industry, funding agencies and academia. Prior to joining BIRAC, Dr. Sarma worked as Director-Medicinal Chemistry/Synthesis at Jubilant. He obtained his Ph.D from University of Hyderabad & Post-doc from Queen's University, Belfast. His domain Expertise includes Medicinal chemistry, organic synthesis, methodology development, parallel synthesis, total synthesis of natural products & process development and has functional expertise in leading

and collaborating on multi-disciplinary discovery teams. His accomplishments include ~80 patent applications, 10 publications, three reviews and three poster presentations in ACS meeting. Dr. Sarma's name was mentioned in the inaugural edition of Marquis's Who's Who in Asia.



### **Mr. Suresh Narayanan**

Chief Operating Officer, Association of Biotechnology Led Enterprises – ABLE



Mr. Suresh is an accomplished journalist and was the Group Editor of Bio Spectrum, Asia's first biotechnology published simultaneously from India and Singapore. A masters in Physics from Central University of Hyderabad, Suresh has covered India's strides in science & technology, first for Times of India from Delhi and for CyberMedia and MM ActivSci-Tech Communications publications from Bangalore over the last three decades. Suresh was also the Group Editor of MIT Technology Review India Editor published for five years from India and anchored its EmTech Conference and selection Young Innovators under 35 for four years in India and Singapore. For more than a decade, Suresh has championed the cause of India's biotechnology sector and pioneered the annual ABLE-BioSpectrum Biotech Industry Survey

since 2003, showcased the industry's highlights around the world, built a highly successful media platform to engage the biotech industry across Asia-Pacific and a communicator of the industry's work to the student community and the public. In the current role, Suresh will be striving to expand the footprint of ABLE to reach out to the entire biotech community and push it towards the goal of achieving a \$ 100 billion BioEconomy in the country by 2025.

### **Dr. Vishal G Warke,**

Director- R & D (Cell culture and immunology department), HiMedia Laboratories Pvt. Ltd.



Dr. Vishal G Warke, Ph.D (Cell Biology & Molecular Genetics from University of Maryland at College Park, MD, USA) and M.B.B.S (Mumbai University), is currently the R & D director of The Department of Cell culture and Immunology at HiMedia Laboratories Pvt. Ltd., Mumbai, India. Additionally, he has also been awarded the Medical Research Fellowship of The Walter Reed Army Institute of Research (June 2002), Silver Spring, MD, 20910 USA and was granted a scholarship for registration and participation in the Sixth National Symposium: Basic aspects of Vaccine, sponsored by Walter Reed Army Institute of Research, May 2000. With his extensive knowledge in biology and biotechnology, he has further consistently educated himself on process flow technologies and has successfully implemented various reforms since he has joined the company in 2003. He has developed Serum Free Media and Chemically Defined Media for Animal Cell Culture

applications; vegetable (Plant) based peptones for use in animal free cell culture applications; DNA and RNA extraction and purification kits for indigenous manufacture in India and is working on developing many more innovative, economical and high quality media products. He received the prestigious Rajeev Gandhi National Quality Award for HiMedia from Mr. K.V Thomas (Minister of State for Consumer Affairs, Food and Public Distribution) in 2011. The Animal Tissue Culture (ATC) department that he heads prides itself on being the first manufacturer of Lymphocyte Separation Media, Granulocyte Separation Media and Viral Transport Medium (VTM) in India, all of which are supplied at economical prices with a quality that is at par with international standards. Millions of swine flu kits were sold during the Swine Flu outbreak in 2008-09 at very affordable prices in the Indian market under Dr. Vishal's guidance, thus fulfilling his objective of extending support to the country.

### **Mr. Ashwin Raghuraman**

Founding Partner at Bharat Innovation Fund



Mr. Raghuraman is an early stage tech investor, venture capital fund manager, institution builder, startup advisor, public policy contributor and shipee., currently serving as the founding partner of Bharat Innovations Ltd. He served as the Chief Operating Officer at IKP Investment Management Company. Previously, he was a Vice President at the firm. Mr. Raghuraman also served as the director of iKen Solutions Pvt. Ltd. He is a mechanical engineer with an MBA degree from Symbiosis Institute of Business Management.

### **Dr. H. Purushotham**

Chairman and Managing Director, National Research Development Corporation (NRDC)



Dr. H. Purushotham is the Chairman & Managing Director of National Research Development Corporation (NRDC), an enterprise of DSIR. He is currently a member of various Investment Committees of many VC firms (UTI, ASSCENT INDIA FUND, GVFL, APIDC VENTUREAST, SCICOM) and Government bodies (DST, DSIR, MoMSME, MHRD, TIFAC, TDB, CSIR, IITs etc.) promoting Innovations. He was a founding head of the Department for Chemical Process Design and Development at CSIR-CLRI, Chennai, Technology Transfer Division and Centre for Knowledge Management of Nano-Science & Technology at ARCI, Hyderabad. He has led many multi-disciplinary teams in R&D, IP Management, Technology Transfer & Commercialisation, Consultancy projects and executed successfully more than 100 projects as a team leader in Agro-Chemicals, Coal, Oil, Leather, Biotechnology, Agriculture, ITES, Pharma, Energy, etc. majority of the projects were funded by government, industry and multilateral agencies like World Bank, UNIDO, UNDP, ADB etc. as a CMD of NRDC, he is spearheading Commercialisation of Innovative Technologies Developed by various public funded R&D Labs and Universities in the country and contributing significantly to Start-up India and Make in India Missions of Govt. of India.



### **Panel #3: Development of Shared Infrastructure/Biopharmaceutical Institute under PPP model for Biopharmaceutical Industry**

**Dr. Taslimarif Saiyed**

Director and CEO, Centre for Cellular and Molecular Platforms, Bangalore



Dr. Taslimarif Saiyed is the Director and COO at the Centre for Cellular and Molecular Platforms (C-CAMP), in the Department of Biotechnology, based in Bangalore, India. Dr. Saiyed's initial training has been in neuroscience where he received his PhD from Max-Planck Institute for Brain Research, Germany, and followed by postdoctoral training at University of California San Francisco.

**Dr. Maharaj Sahib**

Director, Wockhardt- Genomics & Biotechnology



Dr. Maharaj Sahib is currently Director of Genomics and Biotechnology, Wockhardt. Prior to working with Wockhardt, Dr. Sahib was Sr. Asst. Director CDRI Lucknow. He worked as a visiting Scientist in various renowned institutes like NIH, Bethesda; National Institute of Medical Research Mill Hill, London; Institute Pasteur, Paris. He was an Assistant Professor in University of Colorado, Banaras Hindu University as well as a research associate at Harvard Medical School. He has received awards from various sources like Governor of Maharashtra State's (India) nominee to membership of Management Council & Senate, Dr. Babasaheb Ambedkar Marathwada University, Aurnagabad, Maharashtra Dr. C.R. Krishnamurty memorial oration award, several awards from Wockhardt. He is also an active member on

several national boards. He has more than 100 peer reviewed international Journals and several international patents to his credit. He started and established Biotechnology Research Center at WOCKHARDT and has successfully developed biosimilar recombinant human/humanized therapeutic proteins, vaccines, fermentation products with an international recognition.

### **Mr. Shreehas Tambe**

President and COO – Biologics, Biocon



Shreehas Tambe currently employed as President and Chief Operating Officer in the field of Biologics at Biocon. He has been working in Biocon since 21 years, during which he served as Senior Vice President & Head in Global Insulins Business and Group Projects. During which he successfully lead and managed development, manufacturing operations and commercialization of the portfolio across geographies as well as established strategic opportunities for in-licensing, co-development of products, devices, technology platforms. He played a leading role in Biocon's multi-million dollar investment in Malaysia for recombinant therapeutics.

### **Mr. Sandeep Majumdar**

Vice President, Intas Pharmaceuticals Ltd. (Biopharma Division)



Sandeep Majumdar currently affiliated with Intas Pharmaceutical as a Vice President in Operations (Biologics) is skilled in Protein Chemistry, Plant Operations, GMP, Biotechnology, and Cell Culture. Prior to Intas, he worked as Senior Director in Biocon as fermentation technology specialist. He was employed as General Manager in Manufacturing of Therapeutic Proteins and Biochemicals. He is also known as a strong operations professional with credentials focused on Pharmaceuticals and Fine chemicals where he was awarded with a degree from UDCT Mumbai.

### **Dr. Venkata Ramana**

Chief Scientific Officer, Reliance Life Sciences Pvt. Ltd.



Dr. Venkata Ramana currently holds the position of Chief Scientific Officer in Reliance Life Sciences, Mumbai, India. He obtained Ph.D. (Biochemistry) degree from CFTRI, Mysore. He worked in University College London, UK for his postdoctoral research. He worked in Shantha Biotech, Hyderabad, developing recombinant Hepatitis B vaccine and other recombinant proteins. For the past eighteen years in Reliance, Dr. Ramana is engaged in developing recombinant proteins, monoclonal antibodies and novel therapeutics.

### **Dr. Umesh Shaligram**

Director (R&D), Serum Institute of India Pvt. Ltd.



Mr. Umesh Shaligram, leads the development and manufacturing of several recombinant products like Hepatitis-B vaccine, HPV vaccine, CRM197, Acellular pertussis component based vaccine, Erythropoietin, Polysialylated Erythropoietin, Polysialic acid, r-BCG vaccine, GCSF and Pegylation of recombinant products as well as development of liposomal delivery at Serum Institute of India. His professional and educational background is in the process development of recombinant products and has experience in genetic engineering and bio-physics DNA structure and oligoneucleotides manufacturing during his studies from the Indian Institute of Science and also University of Pune.

### **Dr. Samir Kulkarni**

Founder, InBioCognate Life Sciences Pvt. Ltd.



Dr. Samir Kulkarni is a recognized leader in biosimilars product development with about 17 years of overall experience in the subject, ranging from Process development to business strategy. He has recently founded InBioCognate Life Sciences Pvt. Ltd., which plans to focus on developing preclinical packages for Biosimilars and provide consulting services on different aspects of product development for biosimilars. Previously, he was associated with Intas Biopharmaceuticals (R&D and Program Strategy) as an Associate Vice President. He has also headed Global Biologics Business Development and Project Management at Accutest Laboratories. He has been Associate Director of Dr. Reddy's Biologics (Process Development and Strategic Program Management). He was also a group leader at USV Biotech and research scientist at OakRidge National Laboratory (TN, USA). He pursued degree in executive management at IIM, Bangalore after completing PhD (Chemical Engineering) and M.Tech. (Bioprocess Technology) from Institute of Chemical Technology, Mumbai.

### **Dr. Samir Vyas**

Country Application Manager, Agilent Technologies



Dr. Vyas has a vast exposure in analytical research from lead identification through IND filing for various biological targets. He specializes in structure elucidation of small organic molecules and drug metabolites by LCMS, MS/MS, 1D and 2D NMR techniques, achiral and chiral method development and validation as per ICH & US FDA guidelines. He has purified 4000 plus small organic compounds by preparative HPLC with regulating quality, speed, and cost. He has worked on evolution of physiochemical properties of drug molecules and preparation and review of SOP, Standard test procedures, Specification, Protocols and Reports. He has previously worked in extensive analytical research with Alembic Pharmaceuticals Ltd., Ranbaxy and Advinus Therapeutics. He holds

a Ph.D degree in Analytical Chemistry.

### **Mr. V Sankaranarayanan**

Managing Director & CEO, Eppendorf India Pvt. Ltd.



Mr. V. Sankaranarayanan is an experienced and young, CEO with a demonstrated history of working in the analytical and life science instrumentation industry. He is a strong business development professional with science and management education. He has been associated with Eppendorf since 15 years as the MD and CEO. Previously, he worked with Metrohm India Ltd. as the product manager and sales executive at Niulab Equipment Company Pvt. Ltd. He has a post graduate degree in Marketing and Finance.

### **Mr. Sachin Indane**

Vice President and Country Leader, Pall Corporation



Mr. Indane is responsible for India operations for Pall Corporation. He is a leader in Filtration & Separation technologies with 300 employees in India engaged in sales, marketing, manufacturing, support functions, scientific services, global IT and global engineering. He has been previously associated with GE as the vice president and the general manager. His basic training is in mechanical engineering and holds a post graduate degree from IISc.



### **Dr. Madhvi Rao**

Senior Program Manager-National Biopharma Mission, BIRAC



Dr. Rao is an experienced drug discovery professional with global pharma work experience. She is currently working towards empowering the Biotechnology ecosystem in the country through National Biopharma Mission, a unique project of BIRAC, in collaboration with DBT and World Bank. She has previously worked with Daiichi Sankyo India Limited and Ranbaxy Research laboratories. She has contributed majorly as project lead and in vivo lead, to bridge the gaps of PK-PD by establishing novel models, identifying clinically relevant disease biomarkers while evaluating compounds from various classes. She has successfully contributed to company's mandate of one clinical candidate nomination per year. She holds a Ph.D in Microbiology for her research on *Mycobacterium* spp.

### **Mr. N.N. Rao,**

CEO, Skill Development Institute, Bhubaneswar, Orissa



N.N. Rao is working as the CEO of Skill Development Institute which is providing short term professional skill training for unemployed and under privileged youth, where he is responsible for managing the Institute, development of Courses, assessment and certification and placement of students through the short term vocational programs with over 200 participants per batch. In this role he is also responsible for overseeing and growing the learning and certification programs and led the development of new Skilling programs in a new upcoming main campus focused on skill development, research, thought leadership, and best practices, further helping the SDI become a best multiskilling centre for the unemployed youth.

He has 31 years of experience in the Oil industry and two years initial experience with last posting as the Engineering head of IndianOil in West Bengal where he oversaw IOCL interests during the implementation of the engineering projects. In this role at SDI, he is working closely with SDI's eight promoting member Oil Public sector companies to grow their participation in a way that helps them meet their CSR objectives.

He has received bachelor's degree in Mechanical Engineering from Andhra University in 1985 and an MBA from Lubljana university, Slovenia and Post graduate certificate in Research and analytics from MICA, Ahmedabad.

## NOTES





## NOTES



## NOTES



## NOTES



## NOTES



## NOTES



## NOTES





## NOTES



## NOTES



## NOTES



## NOTES



## NOTES



## NOTES





## NOTES





# LEADERSHIP CONCLAVE