INNOVATION. QUALITY. GLOBAL REACH.

9TH GLOBAL PHARMACEUTICAL QUALITY SUMMIT 2024

Advances in Manufacturing and Quality – Patient Centricity

27-28 June, 2024

Venue: Taj Lands End, Mumbai

AGENDA & SPEAKERS PROFILES

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Agenda

Day 1: Thursday, 27 June 2024

0800 hrs onwards	**Registration and Breakfast**
Session 1 0900 – 1030 hrs	**Welcome and Setting the Context** Sudarshan Jain - Secretary General, Indian Pharmaceutical Alliance (IPA) **Opening Remarks** Nilesh Gupta - Chair, Quality Committee, IPA and Managing Director, Lupin Patrizia Cavazzoni - Director, Center for Drug Evaluation & Research (CDER), USFDA **Special Remarks** Rajeev Raghuvanshi - Drug Controller General of India, Government of India **Keynote Address** Arunish Chawla - Secretary, Department of Pharmaceuticals, Government of India **Release of IPA Best Practices Reports**
1030 - 1100 hrs	**Tea / Coffee Break**
Session 2 1100 – 1140 hrs	**Glimpse into the Future of Pharma Operations: Strategic Priorities for the Next Decade** Sathya Prathipati - Sr Partner & Lead, Lifesciences Practice in Asia, McKinsey & Co
Session 3 1140 – 1230 hrs	**Introduction to Quality Management Maturity (QMM): Key Expectations from the Industry** Jacquin Jones - International Relations Specialist, India Office, USFDA Samantha Atkinson - Executive VP & Principal Consultant, Lifesciences, NSF
Session 4 1230 – 1330 hrs	**Panel Discussion – Enhancing Current Cybersecurity: Securing the Digital Future** **Moderator:** Kaushik Pandya - Advisor, Federation of All India IT Association & Co-founder, Kalp Systems **Panelist:** Phani Mitra B - Global CIO & CDO, Dr Reddy's Laboratories Sreeji Gopinathan - Director, SKG Advisory and Ex-CIO, Lupin Dheeraj Sinha - EVP and Global CIO, Sun Pharmaceutical Industries Sanjay Moralwar - Senior General Manager, IT, Zydus Lifesciences

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1330 – 1430 hrs	**Networking Lunch**
Session 5 1430 – 1515 hrs	**Use of AI in Pharmaceutical Quality and Operations** Mark Birse - Vice President Technical, Strategic Compliance Consulting, Parexel International
Session 6 1515 – 1620 hrs	**Panel Discussion: Modern Control Strategies to Minimize Cross Contamination** **Moderator:** Shirish Belapure - Senior Technical Advisor, IPA **Panelist:** Kellia Hicks - Consumer Safety Officer, India Office, USFDA Krishna Venkatesh - Head, Global Quality & Pharmacovigilance, Dr Reddy's Laboratories Karan Khairnar - Global Technical Consultant, Ecolab Life Sciences Ranjana Pathak - Chief Quality Officer, Lupin Gopi Reddy - VP & Head - Corporate Compliance, Sun Pharmaceutical Industries
1620 – 1635 hrs	**Tea / Coffee Break**
Session 7 1635 – 1705 hrs	**Sponser Showcase**
Session 8 1705 – 1805 hrs	**Data & Documentation Imperatives of the Future** Miral Patel - Sr Consumer Safety Officer, Office of Pharmaceutical Quality (OPQ), USFDA Ian Jackson - Unit Manager Inspectorate, Risk, Control & Governance, IE&S, MHRA
1805 – 1815 hrs	**Day 01 Concluding Remarks** Rajiv Desai - Senior Technical Advisor, IPA
1915 – 2230 hrs	**Cocktail Reception & Networking Dinner - All Participants**

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Day 2: Friday, 28 June 2024

0800 hrs onwards	**Breakfast**
Session 9 0900 – 0905 hrs	**Opening Remarks** Sarah McMullen - Country Director, India Office, USFDA
Session 10 0905 – 0955 hrs	**Regulatory Reforms in India** Chandrasekhar Ranga - Joint Drugs Controller (India), CDSCO, Government of India **Single Global Development** Susana Almeida - Secretary General, International Generic and Biosimilar Medicines Association (IGBA)
Session 11 0955 – 1040 hrs	**Winning the "War for Talent": Advanced Competency-Building and Talent Acquisition** Archana Bhaskar - CHRO & Head, Corporate Communications, Dr Reddy's Laboratories Prashant Sharma - Chief Technical Officer, Zydus Lifesciences
1040 – 1055 hrs	**Tea / Coffee Break**
Session 12 1055 – 1110 hrs	**Skilling Institute for Quality and Manufacturing Excellence** Davinder Singh Marwah - Director, Foundation for PAGE and Fmr VP & Head, Global Manufacturing, Sun Pharmaceutical Industries
Session 13 1110 – 1210 hrs	**Panel Discussion: The Biopharma Opportunity, Shaping Future Patient Need** **Moderator:** Rustom Mody - Senior Vice President, Sun Pharmaceutical Industries **Panellists:** Ratnesh Jain - MD, Mumbai Biocluster & Associate Professor, Institute of Chemical Technology (ICT) Sanjeev Gupta - Sr Vice President & Head, Biosimilars, Ipca Laboratories Ravi Shankara - Senior GM, Biopharma, Sun Pharmaceutical Industries Dhananjay Patankar - Fmr Vice President, Pharmaceutical and Biologics Syngene International
1210 – 1310 hrs	**Networking Lunch**
Session 14 1310 – 1355 hrs	**Enhancing Pharmacovigilance: Navigating Compliance and Value for Future** Avinash Kakade - Global Head of Pharmacovigilance, Dr Reddy's Laboratories
Session 15 1355 – 1440 hrs	**Smart Operations: Vision of End-to-End Technology Enablement** Sasikanth Dola - Partner & Co-lead, Operations Practice in India, McKinsey & Co

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1440 – 1500 hrs	Tea / Coffee Break
Session 16 1500 – 1630 hrs	**Panel Discussion - Blueprinting for the Future: Charting out the Next Decade of Pharma Quality & Operations** **Moderator:** Sathya Prathipati - Sr Partner & Lead, Lifesciences Practice in Asia, McKinsey & Co **Panellists:** Umang Vohra - Managing Director and Global CEO, Cipla G V Prasad - Co-Chairman and Managing Director, Dr Reddy's Laboratories Nilesh Gupta - Managing Director, Lupin Dilip Shanghvi - Chairman and Managing Director, Sun Pharmaceutical Industries Pankaj Patel - Chairman, Zydus Lifesciences
1630 – 1645 hrs	**Concluding Remarks** Nilesh Gupta - Chair, Quality Committee, IPA and Managing Director, Lupin
1645 – 1655 hrs	**Vote of Thanks** Shirish Belapure - Senior Technical Advisor, IPA

Archana Bhaskar
Chief Human Resources Officer &
Head Corporate Communication
Dr Reddy's Laboratories Limited

Archana Bhaskar is the Chief Human Resource Officer at Dr. Reddy's and a member of the Management Council. Archana oversees HR and orporate Communication for Dr. Reddy's. Archana joined Dr. Reddy's in June 2017 and has more than 31 years of people management experience across diverse industries, geographies and companies. Prior to joining Dr. Reddy's, Archana was with Royal Dutch Shell Singapore, where she was the global head of human Resources for the Commercial businesses. Earlier, she worked with Unilever, where she held positions of European and global responsibility, as well as large Indian corporations with whom she consulted in professionalising HR policies and practices. Archana is an alumna of Lady Shri Ram College, Delhi University, where she majored in Psychology & Mathematics, and the Indian Institute of Management, Bangalore, from where she completed her Master's Degree in Business Administration.

Arunish Chawla
Secretary
Department of Pharmaceuticals -
Government of India

Arunish Chawla is an IAS Officer of the 1992 batch, presently posted as Secretary to Government of India in the Department of Pharmaceuticals.

He holds a Ph.D. in Economics from the London School of Economics with specialization in Macroeconomics and his areas of interest include macro-economic modelling, monetary and fiscal policy, financial inclusion, and green growth.

Arunish Chawla has previously worked as Joint Secretary in the Ministry of Finance from 2014 to 2016, as India's Minister Economic to the United States from 2016 to 2019, and as Senior Economist at the International Monetary Fund in Washington DC from 2020 to 2022.

Avinash Kakade
Global Head – Pharmacovigilance
Dr. Reddy's Laboratories

Dr Avinash Kakade is currently the Global Head of Pharmacovigilance at Dr Reddy's Laboratories. He is a medical doctor who is trained on Biostatistics as well. He has been in the pharmaceutical industry for close to two decades now of which for 8 years he has been leading global pharmacovigilance departments for Cipla and Lupin, prior to Dr Reddy's Laboratories.

Davinder Singh Marwah
Director
Foundation for Pharma Academy for
Global Excellence (PAGE) & Fmr VP & Head
Global Manufacturing

Davinder Singh is working on building Skilling Institute. Previously Davinder Singh was working as Executive Vice President of Sun Pharmaceutical Industries Ltd, heading the Global Manufacturing. Plants in India, Russia, USA, Romania, Hungary, South Africa, Nigeria, Egypt, Malaysia & Bangladesh.

Davinder joined Sun Pharma in June 2017. He has significant experience in Global Pharma Operations and has an established track record of success. He joined Sun Pharma from Cipla where he was the Global Technical Director in his last assignment. He successfully set up more than 40 Greenfield manufacturing facilities covering various dosage forms and APIs in India and abroad complying with USFDA, MHRA and WHO standards. Cipla was the 1st company in India to get the US FDA approval in 1985 & he was part of the team.

Davinder is exceptionally experienced in formulations and API manufacturing, technical services including Corporate Quality Assurance, Factory Management, GMP and EHS. He has handled various roles in Cipla with increasing levels of responsibility over his 37 years of association with the company

Dhananjay Patankar
Former Vice President, Pharmaceutical and Biologics
Syngene International

Dr. Dhananjay Patankar is an independent biopharmaceutical professional and freelance consultant, and previously worked with Wockhardt, Intas Pharmaceuticals and Syngene.

He has been intimately involved in the growth of the Indian biopharmaceutical industry since its early days.
Over his career, he led teams that developed India's first biosimilar therapeutic product (EPO), India's first biosimilar approved for marketing in Europe (Filgrastim), India's first EU-GMP certified biologics manufacturing facility (Intas), and India's first commercial contract manufacturing of a novel biologic for the US market (Syngene).

He has served in various national committees and biotechnology industry bodies in India, and was Biologics Expert Committee member at the US Pharmacopeia from 2011 till 2020.

By education he is a Chemical Engineer with bachelor's degree from IIT Mumbai and Ph.D. from University of Utah in the US.

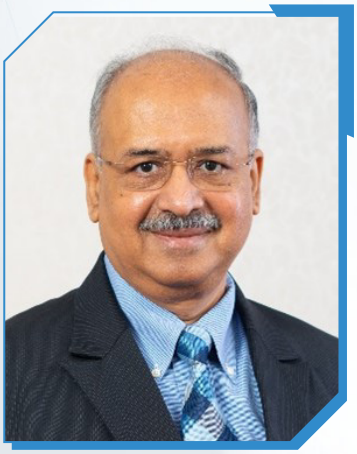
Dheeraj Sinha
Executive Vice President & Global CIO
Sun Pharmaceuticals Industries

Heads the Global IT and Digitalization , its strategy and execution for SUN PHARMA Group, the largest Corporate in Pharma Industry in India. Sun Pharma operates across the globe through its Sales and well spread Manufacturing plants.

In the immediate past, was heading the Global IT for JSW group, a $24 billion conglomerate with presence and manufacturing setups in India, USA and Europe. It has strong footprints across core economic sectors, namely, Steel, Cement, Energy, Ports, Infrastructure, Paints, Ventures and Sports with a diverse workforce.

Operating a bimodal IT Organization focused on technology and applications forming the core, with functional innovations with speed and agility as been the forte. Answerable to the Audit committee and the Risk Committee of the board of Directors for all digital transformations, Cyber Security, ICFR and all other regulatory Compliances and their effectiveness. Managing outcome-focused technology initiatives, creating full scale Innovative Supply Chain practices and generating large scale impacts has been a constant endeavor. Strongly believe that success lies in creating empowered teams having strong belief is their capabilities, an Outside-in approach and long term strategic thinking.

Provided Digital Business/Supply Chain/IT leadership in my career across companies and domains, from Office Automation, Automotive industry, Core Manufacturing, Healthcare and Metals and Mining. I always push the agenda for Business Process Improvement & Organizational Effectiveness. While being part of the IT and Digital Networks and Advisory councils, have been member of the Jury panel for Industry awards across sectors.



Dilip Shanghvi
Managing Director
Sun Pharmaceutical Industries

Dilip Shanghvi, 68, is the Chairman and Managing Director of Sun Pharmaceutical Industries Limited (Sun Pharma), world's 4th largest and India's No. 1 specialty generic pharmaceutical company. He is also the Chairman of Sun Pharma Advanced Research Company Ltd., which is engaged in R&D of new innovative drugs and delivery technologies. He was honored with the Padma Shri, in recognition of his distinguished contribution to the Indian Trade & Industry, in 2016. Mr Shanghvi has played a vital role in the globalisation of the Indian pharmaceutical industry and continues to inspire generations of entrepreneurs in their journey to success.

G V Prasad
Co-Chairman and Managing Director
Dr Reddy's Laboratories

G V Prasad is the Co-Chairman and Managing Director at Dr. Reddy's. Having joined in 1990, Prasad led the company's growth from a mid-sized domestic operation to a diversified and trusted global pharma player. His emphasis on research, innovation, transparency, business ethics and leaner corporate structures has helped shape Dr. Reddy's into an organization of global repute with sharp focus on the planet, purpose, and patients. He has brought in many initiatives in the company to make it more sustainable. Along with his responsibilities as Co-Chairman and MD, Prasad is also involved in other causes. he serves as a Board Member of various educational institutions, industry institution and organisations. Prasad also has many accolades to his name. He is a photography enthusiast and supports nature and wildlife. In academia, he holds a graduate degree in Industrial Administration from Purdue University and a Bachelors in Chemical Engineering from Illinois Institute of Technology, Chicago.

Himanshu Gadgil
Chief Executive Officer
Enzene Biosciences

Dr Himanshu Gadgil, CEO of Enzene Biosciences Ltd. Under his leadership, Enzene transformed from a startup biotech into a multi-vertical, multi-site biopharmaceutical enterprise. Previously, he served as Sr. Vice President at Intas Pharmaceutical Ltd., where he revitalized the commercial product pipeline by successfully launching numerous biosimilar products across various global markets. During his stint in the US, he led different facets of process and product development at Amgen spearheading IND, BLA and Market authorizations of various blockbuster biotech products. Early in his career, he joined Waters Corporation, pioneering QBD methodologies that enabled multi-attribute characterization in biopharmaceuticals. Himanshu holds a PhD in Biochemistry from the University of Tennessee and has authored over 50 publications and patents, showcasing his leadership and innovation in science.

Jacquin Jones
International Relations Specialist
India Office, USFDA

Dr Jacquin (Jackie) Jones is an International Relations Specialist. She has previously worked as a program lead and consumer safety officer in the Office of Compounding Quality and Compliance, policy lead and project manager in the Office of Policy for Pharmaceutical Quality, and project manager for drug applications in CDER. Previously she worked as a nurse at NIH managing various aspects of research protocols and clinical care. She worked in public health, regulatory compliance, policy development and implementation, clinical research, stakeholder engagement, training, and leadership.

Dr. Jones holds a Doctor of Health Sciences with a Global Health concentration, a Master of Science in Nursing Informatics (Sigma Thea Tau), and a Bachelor of Science in Nursing.

Karan Khairnar
Global Technical Consultant
Ecolab Life Sciences

Karan Khairnar MSc (Hons), is a Post graduate Microbiologist, a Qualified CQI/IRCA PQS Lead auditor and a Six Sigma Black Belt Certified from EG-ASQ & TUV-Rhineland and with more than fifteen years' experience within the pharmaceutical industry working in Quality functions.

Karan is currently working as Sr. Global Technical Manager APAC, Ecolab Life Science.

Karan has experience working with a wide range of pharmaceutical formats, including sterile parenteral, non-sterile & medical device products. He has also worked in a variety of vertical organization functions including Corporate & Compliance Quality, Quality Operations, Microbiology, Remediation, Capital Projects and Operational Excellence.

Karan's core areas of knowledge include the design and development of Quality Management Systems, Sterility Assurance, Aseptic Techniques, Microbiology, Cleaning and disinfection, contamination control, VHP development for isolators, Operational Excellence and Statistics.

Kaushik Pandya
Advisor
Federation of All India IT Association & Co-founder
Kalp Systemsr

Mr. Kaushik Pandya is an IT Entrepreneur with 34 years of experience managing Kalp Systems, a Network Solution and System Integration company in Ahmedabad. He holds certifications as a Certified National Cyber Security Scholar and NSD Certified Cyber Security Governance Professional, specializing in Information Security and Cybersecurity. Additionally, he serves as a leading project consultant in the ICT industry, contributing expertise to sectors including e-commerce, human resources, communications, fintech services, education, HealthCare and other specialised areas. He was formerly President & Advisor of FAIITA – Federation of All India IT Associations and has extensive experience in the technology and security domains.

Kellia Hicks
Consumer Safety Officer
India Office, USFDA

Kellia Hicks, Level II, Drug Specialist is Senior global regulator with the U.S. Food and Drug Administration (FDA) where she has played a pivotal role in ensuring the safety, efficacy, and quality of medical products available to consumers both in the US and abroad. Her contributions have positively impacted patient safety on a global scale. With 15 years of domestic and international regulatory operations and regulatory compliance experience with the FDA, she has established herself as a Subject Matter Expert (SME) in the complex landscape of sterile and non-sterile pharmaceutical manufacturing operations, pharmaceutical quality, and regulatory compliance.

In addition to her regulatory work, she engages in, and is passionate about capacity building, fostering collaboration, and knowledge-sharing within the pharmaceutical industry. She frequently serves as a SME speaker and panelist at conferences and workshops with both the private industry and international government stakeholders, where she shares her insights on emerging regulatory trends, best practices in regulatory compliance, and the evolving global regulatory landscape.

Kellia holds of Master of Public Health and a Bachelor of Science in Biology, minoring in Psychology. She is honored to join this conference as a Panelist, where she looks forward to sharing her knowledge, insights, and experiences with industry experts and stakeholders to foster collaboration and innovation in the area of global regulatory drug compliance.

Krishna Venkatesh
Head, Global Quality and Pharmacovigilance
Dr Reddy's Laboratories

Mr. Krishna Venkatesh is the Global Head of Quality & Pharmacovigilance. Mr. Venkatesh has over 28 years of experience in the pharmaceutical industry and has been with our company for 14 years. His experiences span across areas of product development, process engineering, technology transfer and manufacturing operations. Prior to joining our company, he worked with Barr Pharmaceuticals and Teva in the United States. Mr. Venkatesh holds an MS degree in Pharmaceutics from University of Mississippi and a B. Pharm degree from BITS Pilani.

Mark Birse
Vice President Technical,
Strategic Compliance Consulting
Parexel

Mark is a strategically orientated regulatory compliance professional, with a 30+ year career spanning the regulation of pharmaceuticals and medical devices. In his current role Mark provides a full range of consulting services including strategic compliance, inspection readiness, regulatory strategy, GMP audits and remediation activities. Often acting as a trusted advisor to clients on issues that lack precedent or are not clearly defined.

Prior to joining Parexel, Mark previously worked at the MHRA where held a number of leadership roles, including Head of MHRA Inspectorate. In this roles, Mark worked extensively with international regulators including FDA, EMA and TGA developing compliance and risk-based inspection methodologies with a focus on inspection collaboration and reliance. He was also an Executive Bureau member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and also assessed the capability and performance of regulators and provided international training for both regulators and industry.

Miral Patel
Senior Consumer Safety Officer
Office of Pharmaceutical Quality (OPQ)
USFDA

Dr. Miral Patel serves as Senior Consumer safety Officer within the Office of Pharmaceutical Manufacturing Assessment (OPMA) under OPQ. In this role, Miral is responsible for primary review of Pharmaceutical Manufacturing Process and Facilities for new and generic drug application submissions which are pending FDA approval and also participate as SME in Pre-approval Inspections (PAIs). Miral is also a part of Data-Integrity working group within the office, where she has been involved in assessing impact of various data integrity cases. Prior to joining the FDA, she worked in large and small pharmaceutical firms such as Barr Pharmaceuticals, Teva Pharmaceutical and Edenbridge Pharmaceuticals in Product development/ formulation, Pre-formulation, Tech transfer and scale up on various dosage forms. She received her Ph.D. in Pharmaceutics from Long Island University, Brooklyn, NY.

Nilesh Deshbandhu Gupta
Managing Director
Lupin

Nilesh Gupta is the Managing Director and member of the board of Lupin. He is a Chemical Engineer from the Institute of Chemical Technology, Mumbai and an MBA from the Wharton School, Philadelphia.

As Managing Director of Lupin, Mr. Gupta co-leads the Company and has helped establish Lupin's research platforms, expanded its manufacturing operations and strengthened its quality standards. Mr. Gupta is also responsible for the Company's R&D and technical operations in India, and leads the Company's Quality and Supply Chain functions, in addition to the commercial function for the India, API and Asia Pacific regions which are close to half of the company's global revenues of USD 2.5 billion.

Pankaj R. Patel
Chairman
Zydus Lifesciences

Mr. Pankaj Patel is the Chairman of Zydus Lifesciences Ltd., a discovery-driven, global Lifesciences company with operations in 55 countries worldwide. A stalwart and a visionary, Mr. Pankaj Patel combines both research and techno-commercial expertise. He has published over 100 research papers in peer reviewed journals and is a co-inventor in more than 64 patents. He has been conferred with Dsc. (Honoris Causa) by Dr. A.P.J. Abdul Kalam Technical University, Lucknow.

Mr. Patel has been appointed as the Non-official Director in Central Board of the Reserve Bank of India. He is on the board of several institutions, including Chairperson of the Board of Governors of IIM Ahmedabad and Chairman of IIM Udaipur and Invest India. He is also a Member of the Governing Board of India Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare, Government of India. He is also a Member of the CEO Advisory Committee of International Generics and Biosimilars Association (IGBA). Mr. Patel is a Past President of the Federation of Indian Chamber of Commerce & Industry (FICCI). He also officiates on the board of several Not-for-Profit & charitable institutions. Mr. Patel is the Executive Chairman of the Gujarat Cancer Society and Chairman of the Gujarat Cancer and Research Institute, a Regional Cancer Centre and one of the largest cancer centres of India, reaching out to the needy and underprivileged cancer patients. He also officiates as the Chairman of the Deaf and Mute School, Ahmedabad. He is also a Director and Chairman on the Board of Zydus Foundation which set up Zydus Hospital and Medical College, Dahod.

In recognition of his contributions to the healthcare industry in India, Mr. Pankaj Patel is a recipient of several awards including the Acharya PC Ray Memorial Gold Medal Award and the Eminent Pharmacist Award, the India Innovator Award at the India Business Leaders Awards instituted by CNBC. For his entrepreneurial vision, Mr. Patel was awarded the Ernst & Young Entrepreneur of the Year Award in the Life Sciences category

Patrizia Cavazzoni
Director
CDER, USFDA

Patrizia Cavazzoni, M.D., is Director of the Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration. Dr. Cavazzoni received her medical degree from McGill University and completed a residency in psychiatry and a fellowship in mood disorders at University of Ottawa. She subsequently joined the Faculty of Medicine at the University of Ottawa as Assistant Professor in Psychiatry.

After her tenure in academic medicine, Dr. Cavazzoni worked in the pharmaceutical industry for several years and held senior executive positions in clinical development, regulatory affairs, and safety risk management across multiple therapeutic areas. She joined the FDA in 2018.

Phani Mitra B
Global CIO & CDO
Dr Reddy's Laboratories

Phani is currently working as the Chief Digital and Information Officer for Dr. Reddy's Laboratories Ltd. In this role, he has global responsibility for Digital Transformation, Process Excellence and Information Technology Management for the organization.

Phani joined Dr Reddy's in 2014 and played various roles – setting up the Analytics Center of Excellence, leading corporate strategy and digital transformation for Dr Reddy's India and Emerging markets businesses. Before joining Dr Reddy's, he worked with Hewlett Packard for over 11 years with roles in strategy, analytics & transformation consulting for customers across industries in US, India & Asia Pacific. In 2021, Phani was listed in the Analytics India Magazine's 50 Most Influential AI Leaders in India.

Phani holds a Bachelors in Engineering From BITS Pilani and an MBA from IIM Bangalore.

Prashant Sharma
Chief Technical Officer
Zydus Lifesciences

Prashant Sharma is a part of Zydus Senior Leadership Team and manages Group Manufacturing & Operations for Formulations & API at Zydus Cadila. He has been in business roles for over 3 decades and managed Global Supply Chain, Human Resources, Corporate Communications & Operations portfolios in MNCs and Global Indian organizations.

He believes that Learning Agility & Formative Experiences shape a leader. The foundation for both is a keen desire to keep learning & challenging oneself, taking risks and building teams that perform better than oneself.

Rajeev Singh Raghuvanshi
Drug Controller General of India
Government of India

Dr Rajeev Singh Raghuvanshi has completed his Bachelors and Masters from IIT-BHU (Formerly IT-BHU), Varanasi and PhD from National Institute of Immunology, New Delhi. His PhD work is in the area of Extended Release Formulation of Vaccines, a project conceptualized to help reduce the number of injections required to be given for complete immunization. He has also done ISB-Kellogg Global Advanced Management Program.

After working for 7 yrs at National Institute of Immunology, New Delhi, Dr Rajeev moved to join the leading Indian multinational, Ranbaxy Laboratories Ltd., where he worked for development, registration and launch of NDDS, Generics and Branded Generics for various global markets. After having spent 12 years with Ranbaxy, he moved to another Indian Multinational, Dr Reddy's Laboratories Ltd, Hyderabad. In his 11 years of stay with Dr Reddy's Labs, 1rst eight years was in development of 505b(2) NDA products for US market. In this role, he successfully led the CMC team to get 6 products approved in 1st review cycle by USFDA. During this tenure, he had the opportunity of multiple face to face interactions with USFDA, MHRA and agencies from South Korea, Sweden, Romania etc. Last three years at Dr Reddy's has been in a different role of establishing an R & D Team for markets like India, China, Russia and other Emerging Markets in the space of Pharmaceutical Product Innovation / Differentiation, registration and launches. He is widely travelled throughout the world and has worked with team members and partners in countries like USA, UK, China, Russia, South Africa, Romania, Sweden, Canada, France, Australia and Japan.
Dr Raghuvanshi's expertise lies in dosage form design and development,

mainly in the domain of pharmaceutical innovation. He has been involved in development of different kind of products like Oral Solids, Oral liquids, Topicals, Injections, Nasal Sprays, Auto-injectors, Sublingual, Mouth Dissolve, Extended Release and Delayed Release for global markets. More than 200 products developed by him and his teams are currently being sold in India, US Europe and Emerging Markets. Dr Raghuvanshi has 14 granted US patents along with more than 250 published PCTs and Indian Patents. He has more than 25 publications in peer reviewed journals and has co-authored 6 chapters in books. He has been visiting faculty at NIPER – Hyderabad and IIT-BHU and has taught students of NIPER-Mohali. He is a regular speaker at different International and National conferences on Pharmaceutical Innovation. For his contribution, Dr Reddy's Labs has twice awarded him with "Dr Reddy's Excellence Award".

Leadership development has been his passion and many of his team members mentored by him are holding leadership roles in Indian and global pharmaceutical companies.

After a very successful career with corporate pharma, he decided to do something completely different which is socially more impactful. Of many possibilities, he chose to work with Govt. of India and joined Govt's Ministry of Health and Family Welfare, as Secretary-cum-Scientific Director of Indian Pharmacopoeia Commission on 16 Feb'21. In a short stint of 2 yrs, he changed the face of IPC and bought multiple long lasting changes impacting quality standards for medicines being sold in India. Cultural shift to more open and receptive organization scaling up the Impurity Standards inventory, harmonization of quality specification with ICH and other global standards, increasing user base for IP and IPRS, PDG membership for IP, international recognitions and scaling up of Pharmacovigilane and Materiovigilance program of India are some of them.

Govt of India has now been given him the responsibility of Drugs Controller General of India. He joined the new position of 23rd Feb 2023 and working towards changing the way Indian pharmaceutical regulation is looked in this country and beyond.

Rajiv Desai
Senior Technical Advisor
Indian Pharmaceutical Alliance

Dr Rajiv Desai is the Senior Technical Advisor at the Indian Pharmaceutical Alliance. He formerly headed the Corporate Quality Management at Lupin Ltd in India

Dr Rajiv Desai has around 30 years of experience in Pharmaceutical Industry. In his previous assignments, he has worked as heads of Corporate Quality Management at Dr Reddys, Mylan, Piramal and Alembic Pharmaceuticals. He started his career with Ciba Geigy (now Novartis) in R&D and Technology transfer in India and Switzerland.

His experience in the Pharmaceutical Industry spreads across basic research, Technology transfers, Quality Management and Regulatory affairs.

Selected as an US Pharmacopeia Expert committee between 2010 and 2015. He has been invited to deliver lectures at various international and national scientific forums. He has actively worked on several board of studies of reputed universities in India for short term teaching assignments and syllabus revision programs for post graduate courses. At UDCT, he was appointed as visiting faculty, under the Daiichi Karkaria memorial endowment faculty program for the year 2013 - 2014

Dr Rajiv Desai, has a Ph.D from UDCT (now ICT) in Pharmaceutical Chemistry and a post graduate degree in Management from NMIMS.

Chandrashekar Ranga
Joint Drugs Controller (India), Zonal Office
CDSCO

Chandrashekar Ranga has more than 33 years' experience in Drugs Control Departments of the State and Central Governments in various capacities He is currently heading Global Clinical Trials and Drug Safety, International Cell, Amendments to the sub-ordinate legislation, E-Governance, Ayush vertical, Legal Cell, etc. Further, he is the Chairman of the Technical Committee of the Strengthening of Pharmaceutical Industry Scheme of the DoP and Member, NPPA.

Earlier he was Head of New Drugs and Biologics. He played a key role in establishing relations with International Regulatory Agencies He has initiated the e-Governance program and Intelligence Cell at CDSCO. He was convener of various sub-Committees of the DCC leading to notification of the Rules.

Ranjana Pathak
Chief Quality Officer
Lupin

Ranjana is a seasoned pharmaceutical professional with over three decades of global experience. Her expertise lies in quality and related functions, and she currently oversees Lupin's global quality operations.
Before joining Lupin, Ranjana held the position of Global Head for Quality and Pharmacovigilance at Dr. Reddy's. During her tenure, she was a key member of the Dr. Reddy's Management Council, contributing to several positive outcomes for the company. Her leadership journey extends across various branded and generic pharmaceutical companies, including Cipla, Actavis, Endo, Zenith Goldline, and Thames Pharmacal. Ranjana's academic achievements include a Doctorate in Health Administration from the University of Phoenix, USA, an MBA from Dowling College, New York, a Post-Graduate Diploma in Pharmaceutical & Chemical Analysis from Sophia College, Mumbai, and a B.Sc. (Hons) in Chemistry from Mithibai College, Mumbai. Additionally, she has received specialized training in pharmaceutical and biologics leadership at Harvard University.

Ratnesh Jain
Managing Director, Mumbai Biocluster and Associate Professor, Institute of Chemical Technology (ICT)

Dr. Ratnesh Jain is the Managing Director of Mumbai Biocluster (an upcoming cGMP infrastructure) and an Associate Professor at the Institute of Chemical Technology (ICT), Mumbai. His research group (NRG) focuses on analytical methods for protein and peptide characterization, mammalian cell culture, media, and upstream process development. With over 100 publications and 350+ conference abstracts, he is also the convener of the "Biologics Workshop," a major learning and skill development platform. Dr. Jain is a leading biopharmaceutical consultant for product development and regulatory approval, and he mentors startups and promotes entrepreneurship through the Government's Innovation Ambassador program.

Ravishankara MN
Senior General Manager, Biopharma
Sun Pharmaceutical Industries

Ravishankara MN currently hold the position of Senior General Manager at Sun Pharmaceutical Industries Limited and leading Team involved in Analytical activities related to development of Biologics and Peptides. He is having about 22 years of experience and his research interest includes Critical Analytical Method Establishment for Biosimilars, Generic Peptide Products and Novel Peptide Products. He is also extensively worked on Extended Characterization of Peptide products and branded biologics. Prior to current role, he was also additionally leading team involved in Analytical activities related to New Chemical Entities and Bioanalytical activates pertaining to Drug Metabolism and Pharmacokinetics (DMPK) at SPARCL. He was responsible for Analytical and Bioanalytical method development & validation, PK, TK analysis & its evaluation, In-vitro & In-vivo metabolism studies for New Chemical Entities and Dose Formulation analysis. He is post graduated from Gujarat University with Master of Pharmacy (Quality Assurance) and University of North Gujarat with Ph.D in Pharmacy. He is recipient of “Young Pharmaceutical Analyst-2008” Award from Indian Drug Manufacturing Association.

Reem Malki
Executive Vice President - Chief Quality Officer
Sun Pharmaceuticals

Reem Malki joined Sun Pharma as the EVP and Chief Quality Officer in October 2023, overseeing all aspects of quality management. She is known for her strategic vision, focusing on continuous improvement and leveraging data-driven insights to enhance quality across the organization. Her passion is to ensure patient accessibility to high quality, affordable medicines and does this through fostering a strong culture of Quality. She believes that excellence is achieved not just through processes and systems, but through the empowerment and cross-functional engagement of employees at all levels, to ensure Quality is a collaborative practice by all. With a career marked by dedication, innovation, and a commitment to Quality and excellence, Reem continues to lead the way in Quality management and set new standards for the industry.

Reem joined Sun with over 30 years of Quality, Regulatory Compliance and Executive Leadership experience. Most recently, she was SVP and Chief Quality Officer at Amneal Pharmaceuticals and prior to that she was associated with Alvotech hf as CQO and a number of senior roles within the Mylan organization. Before Mylan, she held various diverse, technical roles at Andrx Pharmaceuticals, Inc., Zymark Corporation and Wyeth-Ayerst Pharmaceuticals. Reem holds a Bachelor of Science degree in Chemistry from the University of Maine.

Rustom Mody
Senior Vice President
Sun Pharmaceutical Industries

A biotechnologist having experience of directing Biopharmaceutical programs for 4 multinational biopharmaceutical companies spanning over 28 years. He has handled wide-ranging operations - as Head of Research and Development / Manufacturing / Quality and currently serving as Sr. Vice President and head R&D Biologics division of Sun Pharmaceutical Industries.

He was directly involved in the development and commercialization of recombinant Hepatitis B vaccine in India.

He has developed various biotherapeutics, which includes vaccines, biosimilars and novel biologics for Indian and other markets, with marketing approvals for 14 biosimilars and 2 vaccines.

He is a President of Parenteral Development Association (India Chapter). He has contributed to 2 review articles, 2 book chapters, 41 publications in peer-reviewed journals and filed 24 patents with 18 patents granted.

Samantha Atkinson
Executive Vice President & Principal Consultant, Lifesciences
NSF

Executive Vice President, Pharmaceutical Services Pharma & Biotech
BSc (Hons), MSc, PhD, MBA, MRSC

Sam has joined NSF from a long career history with the UK Medicines and Healthcare products Regulatory Agency (MHRA) and the UK Department of Health & Social Care (DHSC). The majority of Sam's career has been spent in a variety of roles at the MHRA. Before joining the DHSC, Sam was Chief Quality and Access Officer at the MHRA with accountability for regulatory activities across the UK supply chain, including Inspectorate (all GxPs), Enforcement, Licensing, Clinical Trials, Pharmacopoeia & pre-market Medical Device activities. Sam also brings extensive experience of crisis management, having led national and international scale incidents, and was the Executive lead for the MHRA's response to the recent pandemic.

Sam has a doctorate in chemistry from the University of Reading and has also completed an MBA at Warwick University.

Sarah McMullen
Country Director
India Office, USFDA

Dr. Sarah McMullen is the Country Director for the FDA India Office. Her professional experience has included analytical method development and testing for multiple FDA-regulated commodities, establishment inspections, import operations and policy, and foreign office service. Her FDA career has spanned over 20 years working as a chemist, tissue residue specialist, consumer safety officer, and leader. The last nine years of her experience has focused on international arenas including import operations and foreign office service.

Dr. McMullen has a Doctor of Philosophy in inorganic chemistry and a Bachelor of Science in chemistry from Emory University.

Sanjay Moralwar
Senior General Manager, IT
Zydus Lifesciences

Strategic and results-driven Chief Information Officer with 34 years of experience in driving technology innovation, digitalization, managing large-scale IT projects, and leading cross-functional teams. Proven track record in transforming IT infrastructure, optimizing business processes, and aligning technology with business goals to enhance organizational performance, in conjunction with defining the roadmap/blueprint for the implementation and utilization of IT systems and components, managing IT governance, compliance and risk. And that support the company's business objectives. while having In depth understanding standards, procedures, directives, policies and regulations that are connected to the information Technology.

Sasikanth Dola
Partner & Co-lead, Operations Practice In India,
McKinsey & Company

Sasikanth Dola is a Partner in McKinsey & Company's India office and the Coleader of McKinsey's Operations Practice in India across service lines including manufacturing, supply chain, and quality & across all industry sectors including Pharmaceuticals.

He has led multiple programs across this value chain, including the World Economic Forum Advanced Lighthouse transformation and AI led transformations. Sasikanth also has experience in strategy and scaling operations for new digital business. He has convened the CEOs and Operations leaders in several industry roundtables.

Sasikanth also leads McKinsey Center for Social impact in India, which leads the social impact work of our office across pro-bono engagements with non-profits.

Sasikanth received an MBA from Indian Institute of Management - Ahmedabad (IIMA) and is a computer science engineer by qualification.

Sathya Prathipati
Senior Partner & Lead, Lifesciences Practice in Asia,
McKinsey & Company's India office

Sathya is a Senior Partner in McKinsey & Company's India office and the leader of McKinsey's Lifesciences practice in Asia overseeing the performance and health of the cell comprising 50 partner colleagues across Japan, China, India, Australia and SE Asia He led McKinsey's Pharmaceutical generics practice globally for 10 years (2013-23) and used to lead the India healthcare practice prior to his role currently in Asia. He advises clients in pharma, consumer goods, and healthcare on performance improvement, corporate strategy, and technology enablement.

Sathya has been a speaker and co-convenor at multiple international industry conferences such as the global generic bi-annual CEO conference. He is the co-author of the CII-McKinsey publication on 'Healthcare 3.0'. Sathya received a Post Graduate Diploma in Management from the Indian Institute of Management-Bangalore (IIMB) and is a mechanical engineer by qualification.

Shirish Belapure
Senior Technical Advisor
Indian Pharmaceutical Alliance

Education :- Post graduate degree in Pharmacy alongwith Diploma in Business Management &. Certification in general management from IIM Ahmedabad Experience :- Total experience of 42 years in managing pharmaceutical manufacturing Curently he is supporting the activities of Quality Forum of Indian Pharmaceutical Alliance as Senior Technical Advisor

Earlier he was Managing Director – Zydus Hospira Oncology P.Ltd., (ZHOPL) - A joint venture company of Zydus & Pfizer for Manufacturing and distributing sterile oncological injectables. This company exports Oncology injectables to 61 countries including USA, Japan & Europe with highest regulatory compliance and quality standards.(August 2016 till December2019

Prior to this job he was responsible for all the global manufacturing functions of Zydus Cadila from February'2001 till July'2016 as President Global Manufacturing. He was also a member of Executive Committee of Zydus.

His previous experience includes working in reputed companies FDC, Cipla, Cynamid and Sun Pharma in various capacities and departments .

Sreeji Gopinathan
Director
SKG Advisory and Ex-CIO, Lupin

Sreeji Gopinathan is a tech and management professional with three decades of experience across Pharma, Healthcare, FMCG and other sectors. He is the founder CEO of SKG Advisory firm, which focuses on advising tech companies to shape their products and solutions. By leveraging these portfolio companies, the advisory firm works with various organizations to create and shape their tech strategy and solutions with quality of delivery being at the center of it.

Up until a couple of months ago, Sreeji Gopinathan was the CIO of Lupin Ltd where he lead the end to end IT and Digital portfolio of Lupin.

Sreeji brings over 30 years of significant domain expertise and global experience. Priorto joining Lupin, he was with Reckitt Benckiser, Philips, Procter & Gamble, ISRO and Asea Brown Boveri. He was based in UK and the Netherlands for over a decade before moving back to India. Focused on BizTech by partnering across various functions and business units, he can drive value creation in tangible and intangible ways to drive business forward. Balances speed vs perfection based on the need, through the collaborative leadership approach and problem-solving attitude. He has won various awards like SKOCH CIO of the year 2023 for Digital transformation, Top global CIO100, 2023, CIO of the Year & CIO100 awards etc

Sudarshan Jain
Secretary General
Indian Pharmaceutical Alliance (IPA)

Sudarshan has a strong passion for healthcare and the education sector. He is currently the Secretary General of Indian Pharmaceutical Alliance (IPA), Senior Advisor with APAX Partners and is also a Board member of multiple organizations. He is also the Chair of International Generic and Biosimilar Medicines Association (IGBA) for 2021. He has served in several leadership positions over the years and was earlier the Managing Director at Abbott Healthcare Solutions.

Sudarshan has a rich healthcare business experience of over 40 years which includes stints in Abbott, Johnson & Johnson and leading Indian companies. He has got extensive experience in field force management, brand building and overall business operations in healthcare companies. He has been associated with over 30 brands which are among the top 300 in the Indian Pharmaceutical industry. His experience covers Pharmaceutical, OTC, Hospital, Diagnostic & Nutrition business. He has received number of recognitions for his contributions within the company, with academic institutions and with industry associations. He is the first Indian recipient of the Global Chairman's Award at Abbott.

Sudarshan has also served as Vice President of Organization of Pharmaceuticals Producers of India (OPPI) representing research based

pharmaceutical companies. He is currently the member of the Board of Abbott India, Healthium Limited (APAX portfolio company), member of the Advisory Board of Narsee Monjee University, Mumbai (NMIMS), Board Member of Indian Education Society (IES) and Charter Member of The Indus Entrepreneurs, Mumbai (TiE). He is a Certified Executive Coach from Coaching Foundation of India. He has also contributed in shaping the healthcare policy and improving access to healthcare in India.

Sudarshan is an alumni of St. Stephens College, Delhi and Indian Institute of Management, Ahmedabad.

Susana Almeida, PhD
Secretary General
International Generic and Biosimilar Medicines Association (IGBA)

Dr. Susana Almeida was nominated Secretary General of the International Generic and Biosimilar medicines Association (IGBA) in January 2024.
With over 20 years of substantial contribution to the role of the European and international generic and biosimilar medicines industry's trade bodies and companies, Susana brings significant experience in the process of international harmonisation of standards through the International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), as former topic leader of ICH M9 (BCS Based Biowaivers), member of the ICH Generic Discussion Group and deputy topic leader in the ICH M13 Expert Working Grup.
Before joining the IGBA, Susana was Clinical Development and Safety Director at Medicines for Europe. She has also worked in clinical trials and pharmacovigilance in Europe and in North America, and her experience includes the pharmaceutical industry and clinical research organizations.
Susana is a firm believer that the generic and biosimilar medicines industries play a vital role in fostering worldwide patient access to quality-assured medicines and that a strong off patent sector is essential to a healthy medicines ecosystem She holds a PhD in Clinical Pharmacology from the Faculty of Medicine, Universidad Autònoma de Barcelona (UAB), Spain (2011) and has authored several scientific papers and patents.

Suresh Rai
Global Chief Human Resources Officer
Sun Pharmaceutical Industries

In a career spanning over three decades; Suresh has worked with Unilever and Procter & Gamble and is now associated with Sun Pharma as Global CHRO.

In his 25+ years of association with Unilever, he held number of Senior Leadership roles which included CHRO – Global Nutrition, Global Vice President- Foods & Refreshment, Vice President Human Resources - South-East Asia & Australasia, Vice President Human Resources – Unilever Philippines, Leadership & Organization Development Director - Global Markets. Prior to Unilever, he was associated with Procter and Gamble in supply chain.

A C-suite Human Resources leader with global experience in consumer business with proven impact across HR strategy, M&A and disposals, creating high performing organizations, leadership pipelines, establishing agile workplaces, building digital, data and global capability centers. He has lived-in multi-country experience.

Suresh is a contributor on diverse topics in different forums & business bodies including INSEAD, HCLI- Singapore. He was also a guest speaker at Vietnam National HRD Conference, University of Amsterdam, and was instrumental in establishing Industry Digital HR Forum in Philippines. He was recognised amongst 12 Stellar HR leaders in Asia Hot List of HRD Asia magazine.

Suresh holds an MBA in HR from XLRI Jamshedpur and B Tech in Electrical Engineering from IIT Delhi.

He loves traveling, astronomy and reading about military history.

Umang Vohra
MD and Global CEO
Cipla

Umang Vohra is the Managing Director and Global Chief Executive Officer (MD & GCEO) of Cipla since September 2016. Umang joined Cipla in October 2015 as its Global Chief Financial Officer, and from January 2016 to August 2016 he was Cipla's Global Chief Operating Officer. Under Umang's leadership, Cipla has built strong momentum in its home markets, augmented its capabilities, strengthened its core, and shown significant improvement in its operating margin and profitability. At the helm of the Management Council, Umang is currently steering Cipla's ambition of becoming a leading global healthcare organization, underpinned by innovation and digital transformation. Known for his proactive approach and recognised as an action-oriented industry leader, Umang is a firm believer in the power of agile business models, disruptive technologies, data-driven analytics, and a future-ready workforce. His approach to shaping the healthcare ecosystem goes beyond the pursuit the profit, focusing on compassion and humanitarian values. Umang's big-picture agenda is to define and execute Cipla's strategic growth roadmap and geographical footprint, identify the next levers of growth, invest in innovation for the future, and build a future-fit organisation, while also ensuring that Cipla consistently upholds its commitment to providing patients and consumers with the highest quality of care. Umang's distinguished career spanning close to three decades includes roles in both India and the USA. He has been associated with renowned companies such as Eicher Motors and PepsiCo and Dr. Reddy's Laboratories. Umang's impressive academic background includes degrees in engineering, marketing, and finance.