The PDA India Chapter presents the …

Workshop for Vaccines & Biologics
Right First Time – Quality in Manufacturing
March 23-24, 2017 | Novotel, Pune

PDA Parenteral Drug Association India Chapter

CONFIRMED SPEAKERS FOR THE WORKSHOP

Dr. Akshay Goel,

Sr VP- Technical Development; Biological E. Ltd, India

Dr. Goel's career encompasses R&D, technology transfer, process development, process scaleup, process validation, clinical manufacturing, commercial manufacturing and regulatory approval of several vaccine candidates in both US and India. Prior to joining the Biological E, Dr. Goel was the Chief Scientific Officer (CSO) at MSD Wellcome Trust Hilleman Labs in Delhi . Dr Goel was instrumental in building the company's scientific portfolio, with a focus on developing affordable vaccines for the developing world. Dr. Goel served as Director, new vaccines, Serum Institute of India. He had a leadership role in the development and launch of the Meningococcal A conjugate vaccine (MenAfriVac).His portfolio at SIIL also included technology transfer, process development, process validation, clinical and commercial manufacturing, NRA registration and WHO prequalification of a Hib conjugate vaccine. Dr. Goel was interviewed for a feature article in GAVI Alliance progress report titled "India,Expanding the world's vaccine production". Before returning to India in 2005, Dr. Goel worked at Baxter and Pfizer in US. As a part of Pfizer Global Manufacturing in Kalamazoo MI, he successfully led the legacy process revalidation effort of approximately fifty products, which was the root cause of a US-FDA warning letter. As a part of the Baxter BioScience Vaccines Strategic Business Unit at Beltsville, MD, Dr. Goel was involved with the rapid development and launch of a Meningococcal C conjugate Vaccine. He received Baxter's distinguished corporate technical award in 2001 for the project titled "A novel conjugate vaccine against meningococcal C meningitis". Dr. Goel graduated with a B.Tech in Chemical Engineering from Indian Institute of Technology Kanpur. He completed his PhD in Biochemical Engineering from University of Pittsburgh and did a post-doctoral assignment at University of Maryland, Baltimore. He has over 30 publications.

Dr. Gopi Vudathala,

Executive Director & Head - Quality Advocacy, GSK Vaccines

Dr. Vudathala is Executive Director and Head of Quality Advocacy at GSK Vaccines. He was previously Head of Global Regulatory Affairs CMC, Compliance at GSK Vaccines (former Novartis Vaccines), where he provided regulatory CMC, Compliance strategy and support for the global approval and commercialization of Vaccines to prevent various diseases. Dr. Vudathala has had extensive experience in regulatory and quality policy. He was Vice-Chair of the Technical Development and Operations Committee, Pharmaceutical Research and Manufacturers of America, influencing the industry and Agency thinking on key Quality challenges and current issues pertaining to pharmaceutical drugs, e.g., drug shortages, track and trace, anti-counterfeiting measures, quality-by- design and quality risk management. He has contributed to the development of several ICH guidelines. He has led many symposia and workshops on key current topics of interest. He is the founder of X Cell Pharma Consulting, was Associate Vice President at Sanofi and Senior Manager at P&G Pharmaceuticals as well as Health Canada and has considerable experience in the regulatory and quality aspects for small molecules, biologics, drug-device combinations and vaccines. He gained his Bachelor's degree in Pharmacy from Bangalore University and his Ph.D. in Pharmaceutics and Drug Design from the University of Alberta.

Dr.Dhananjay B. Patankar ,

Vice President - Pharmaceutical & Biopharmaceutical Development, Syngene International Ltd, India

Dr. Patankar is Vice President–Pharmaceutical and Biopharmaceutical Development at Syngene International Ltd. Dr. Patankar heads the Biologics business unit, in addition to other business units dealing with formulations and analytical and stability services. He has over 20 experience in the biopharmaceutical industry and in this tenure, he led the development and manufacturing of seven biosimilar products which are currently sold in the Indian and other markets, as well as the first Indian biosimilar product approved and currently sold in Europe. At Syngene, he has led a contract R&D and manufacturing group that developed and supplied 8 novel biologics which have entered human clinical trials. He has established and led manufacturing facilities to obtain European Union GMP certification in his current and previous organizations. Prior to Syngene, he was Chief Operating Officer at Intas Biopharmaceuticals and Senior Scientist at Wockhardt. Dr. Patankar has also served on a national task force for the establishment of regulatory pathways for recombinant products in India in 2004. He served with USP (US Pharmacopeia) as Chair of the Medicines Compendium–Biologics Expert Committee and currently is a member of the BIO2 Expert Committee on Proteins. Dr. Patankar is a Chemical Engineer and did his Ph.D. at the University of Utah, followed by post-doctoral research at Rutgers University.

Workshop for Vaccines & Biologics Right First Time – Quality in Manufacturing

March 23-24, 2017 Novotel, Pune

Dr. Himanshu Gadgil,

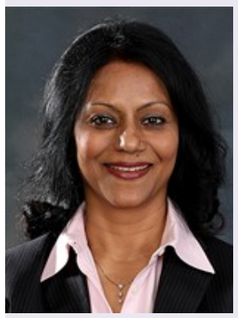
Chief Scientific Officer & Operational Head- Enzene Biosciences, India

Dr. Gadgil is the Chief Scientific Officer and Operational head at Enzene biosciences, a subsidiary of Alkem Laboratories. Prior to this Dr. Gadgil was with Intas Pharmaceutical Biosciences division, Under his leadership the company launched 6 biosimilar products in India and 1 Biosimilar product in EU. He has worked for over 10 years in leadership positions in esteemed companies in the US such as Amgen Inc. and Waters /Micromass Corporation. Dr. Gadgil is accomplished leader in biopharmaceutical process and analytical development with several years of experience from pre-IND to post commercialization of therapeutic proteins with In-depth knowledge of the up-stream and down-stream unit operations and process parameters for the production of the mAb platform. Dr. Gadgil has broad expertise in Discovery Research, Process development, Formulation Development, Manufacturing and Quality with over 40 publications and patents. Dr. Gadgil has pursued PhD in Biochemistry from University of Tennessee, Memphis, USA.

Dr. Rajesh Kumar,

Deputy General Manager– Regulatory Affairs, Gennova Biopharmaceuticals Ltd, India

Dr. Rajesh Kumar Singh is Deputy General Manager at the Gennova Biopharmaceuticals Ltd., Pune, India, a leading biotechnology company. He started his career as a fermentation technologist at the International Centre for Genetic Engineering and Biotechnology (ICGEB), New Delhi, India and then went to complete his PhD at the European Molecular Biology Laboratory (EMBL), DESY Hamburg, Germany. At EMBL, as a part of TB Structural Genomics Consortium, he worked towards solving structure of targeted proteins by using X-ray crystallography methods. After two years of Post Doc at the Institute of Biochemistry, University of Greifswald, Germany, he joined the National Chemical Laboratory (CSIR), Pune, India. All his works were published in the peered reviewed journals of international repute. He has been with Gennova since 2011 and is responsible for Regulatory Affairs and the upstream process development of biotherapeutics and vaccine development program in close collaboration with both national and international academic and industrial partners, especially for malaria, HPV, leishmaniasis and tuberculosis.



Dr. Ranjana Pathak

Global Head- Quality , Cipla Ltd, India

Dr. Pathak leads Cipla's Worldwide Quality enterprise throughout the product's lifecycle from development to commercialization, through institutionalization of robust quality processes, systems and policies across own as well as LL/P2P manufacturing sites in order to ensure compliance with applicable regulatory agencies while consistently ensuring the highest quality and reliability in all of Cipla's products. She has over three decades of experience in the pharmaceutical industry in the USA, held senior leadership positions with increasing responsibilities in various organizations. She worked for Branded and generic companies such as Watson/Actavis, Endo/Dupont Pharmaceuticals, Zenith Goldline, Thames Pharmacal, with extensive experience in dealing with regulatory bodies such as FDA, MHRA, ANVISA, MCC, WHO, to name a few. Dr. Pathak served in the role of Sr. Vice President of Global Quality for Watson/Actavis Pharmaceuticals, was responsible for world-wide quality. Prior to Watson/Actavis, Ranjana worked as Vice President of Quality and Compliance at Endo Pharmaceuticals.She has a Doctorate in Health Administration from the University of Phoenix, USA,MBA from Dowling College, New York; Post Graduate Diploma in Pharmaceutical & Chemical Analysis from Sophia College, Bachelors of Science (Honors) in Chemistry from Mithibai College, Mumbai, Leadership course in Pharmaceutical and Biologics from Harvard University. She has been published a few times and lectured in many pharmaceutical seminar on various topics. Dr. Pathak was also awarded "Rising Star" Award in 2006 by Healthcare Business Association.

Workshop for Vaccines & Biologics Right First Time – Quality in Manufacturing

March 23-24, 2017 Novotel, Pune

Ravi B Menon,

Additional Director - Production, Serum Institute Of India Pvt Ltd, India

Ravi B Menon is the additional director of Production at Serum Institute Of India Pvt Ltd, he is heading the production system capable of delivering 120 million vials of Vaccine per annum (MMR, Influenza, OPV, IPV, Polysaccharide Conjugate group vaccines, Vero Rabies, Rotavirus Vaccines and Rabies Monoclonal antibodies), he is also part of the team developing, Polyvalent Meningitis, Dengue and Pneumococcal vaccines at SIIL. He was also responsible for setting up three fill and finish lines for Esvee Pharmaceuticals as a works manager. As part of Hindustan Antibiotics Ltd, he was responsible for LVP manufacturing facility of capacity 12 million bottles per annum operating at greater than 95% capacity utilization. The product mix included Plasma Volume Expander in addition to conventional IV Fluids. Over the span of more than two decades he has faced multiple successful audits . He also worked with Ranbaxy and during his tenure in the company he was In-charge of the Aseptic subdivision operations of an Ampoule line. Ravi Menon has masters in Pharmacy from Birla Institute of Technology and science, Pillani and Masters in Management Studies (Systems) from Symbiosis Institute of Business Management.

Dr. Reinhard Glueck,

Chief Scientific Officer, Zydus Cadila, India

Dr. Reinhard Glueck is the Chief Scientific Officer at Zydus Cadila Healthcare, Amedabad. He is chairing the Zydus research center, Etna Biotech, Catania, Italy, too. Previously he held the same position at former Berna Biotech, today Crucell. He is an expert in innovative vaccine development. He has first in history developed the so called Immunostimulatoary reconstituted influenza virosome or virosome technology which is today applied in millions of influenza and hepatitis A vaccines worldwide. He also introduced new adjuvants such as non-toxic HLT for influenza vaccines which has obtained marketing authorization in Switzerland in 2001. In his role of CSO at Zydus Cadila Healthcare Ltd, he has entered into collaboration with world class institutions (IDRI, Thelormedix, Statens Serum Institute Denmark, ICGEB, New Delhi and others) to evaluate new and better adjuvants. Dr. Glueck was until recently the President of Swiss Biotech Association and has been awarded with the Honorary Presidentialship of this organization. He is member of many scientific boards, worldwide. In his career he published more than 100 peer reviewed papers and holds more than 10 patents.

Capt. Ricky Bithar

CEO - Absolute Cold, India

Capt. Ricky Bithar is the CEO of Absolute Cold, and has over 15 years experience in providing a variety of cold chain solutions for physical movement of thermo-sensitive products requiring short-long term specific temperature windows for storage . Ricky started Absolute Cold In 2002 as a distribution arm of Absolute Cold GmbH, marketing and distributing cold chain shippers to the Indian pharmaceutical market . The organisation provides products and services to UAE, Bangladesh , and Malaysia . The concept of reusable shippers was brought to the space of anti cancer vaccines by Ricky and his team, for the first time in the country.

Workshop for Vaccines & Biologics Right First Time – Quality in Manufacturing

March 23-24, 2017 Novotel, Pune

Dr. Rustom Mody

Sr. Vice President, Head R & D (Biotech), Lupin, India

Currently the Head of R&D at the Biotech division of Lupin Ltd. Biotechnologist by profession, he has over 20 years of Biopharmaceutical industry experience. He has handled wide-ranging operations as Head of R&D / Manufacturing / Quality. His current role is to provide techno-commercial support for Lupin Biotechnology by way of selection and development of marketable biological products and technologies, management of business partners and evaluation of technologies. He has hands-on experience in developing 6 Biosimilar products from concept to commercialization. He is overseeing the development often biosimilar products, four of which are for global markets. He has over 33 publications and 30 filed patents. He has directly contributed in the development and commercialization of recombinant Hepatitis B vaccine which currently has global sales of INR 3 Bn. He was on the Council of Experts for Biotherapeutics for United States Pharmacopoeia (Medicines Compendium) and Indian Pharmacopoeia.

Swapnil Ballal

Senior Director Quality Assurance Product Operations - Dr Reddy's Laboratory, India

Swapnil Ballal leads the Quality Assurance of Biologics Development and Operations at Dr. Reddy's Laboratories as Senior Director QA, Product Operations. Swapnil has over 21 years of experience in the biotechnology industry covering Development, Manufacturing and Quality Assurance of biopharmaceuticals. He majored in Marine Biotechnology, with Masters of Sciences from Goa University. With a vast experience in bio manufacturing operations he has played key role commercializing several key biosimilar products. His current roles and responsibilities include development of quality compliance systems and strategies for regulated biotechnology products. Prior to Dr. Reddy's, he has worked with Biocon, GE Healthcare, Intas Biopharmaceuticals and Wockhardt. He is an active member of ISPE, ASQ and PDA.