POST APPROVAL CHANGE (PAC) MANAGEMENT WORKSHOP

DCVMN Regulatory Affairs Working Group

November 25th, 2022

12:00 PM - 02:00 PM
(CET)

AGENDA

12:00 PM	**Opening - Moderator** • Ms Laura Viviani, DCVMN
12:02 PM	**Welcome** • Ms Bernadette Hendrickx, DCVMN
12:07 PM	**Focus on the current PAC situation** • Mr Sebastian Comellas, Sinergium Biotech
12:37 PM	**DCVMN Members' experience** • Mr Cleber Augusto Gomes, Instituto Butantan • Mr Hiren Dave, Serum Institute of India • Dr Nagarjuna Akula & Dr Chaiti, Bharat Biotech International • Ms Ida Nurnaeni, BioFarma
01:17 PM	***Interactive session*** • *Other experiences to be shared.*
01:27 PM	**What can be done in the future to improve PACs Management?** • Mr Sebastian Comellas, Sinergium Biotech
01:47 PM	***Interactive session*** • *What are the possible solutions or approaches that can be considered?*
01:57 PM	**Closing remarks** • Ms Bernadette Hendrickx, DCVMN

Dr Bernadette Hendrickx

Consultant, DCVMN

Belgian citizen. Graduated in medecine at the Catholic University of Louvain , Belgium. Worked at Solvay pharmaceuticals, GSK (vaccines in Rixensart Belgium)and Sanofi Pasteur in Lyon, France where I was head of Regulatory Affairs WW and CMO (Chief Medical Officer WW).

Mr Sebastian Comellas

Head Pharmacist and Regulatory Affairs Manager, Sinergium Biotech

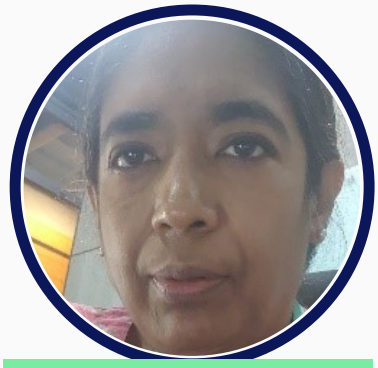
I Sebastian Comellas is the Head Pharmacist and Regulatory Affairs Manager of Sinergium Biotech in Argentina. He has been working in the pharmaceutical industry for 24 years and for 14 years in the vaccines industry, mainly in Production, Quality, Tech Transfer, Regulatory Affairs and Pharmacovigilance. He graduated from Universidad de Buenos Aires in 2005 with a bachelor's degree in Pharmacy and from UADE (Universidad Argentina de la Empresa) in 2012 with a bachelor's degree in Biotechnology. He got a MBA from Universidad Torcuato Di Tella in 2021. He is co-chair of DCVMN Regulatory Affairs Working Group (RAWG).

Moderator

Ms Laura Viviani

Senior Project Manager, DCVMN

Laura has been working in the field of implementation of new non animal based assays in vaccines and biologicals since 2011, first in Novartis International, then in Novartis Vaccines and Diagnostics, later GSK Biologicals. Since 2017, she works as consultant for many international organizations on the promotion of global regulatory alignment on implementation of non-animal approaches for human and veterinary biological products. In particular, she is supporting the Developing Countries Vaccine Manufacturing Network, and Humane Society International in non-animal methods implementation and acceptance. In addition, she's engaged in analyzing dynamics in how biomedical research is opening on new models and methods (organoids, in silico, etc.).



Dr Chaiti Roy

Associate Vice President & Leader of Quality Assurance, Operations and Regulatory Affairs, Bharat Biotech International

I'm currently an Associate Vice President & leading the team of 'Quality Assurance Operation and Regulatory Affairs', at Bharat Biotech International Limited, a leading Vaccine manufacturer and working with Bharat for 4 years. Prior to this, I worked in Dr. Reddy's Biologics for >21 years and engaged for Process design & development of bio-similar product (from clone development to commercialization & beyond), like Cytokines and Monoclonal antibody - process development, scale up / technology transfer and regulatory filing. Have broad cross-functional experience of 25+ years in Development, Intellectual Property development, Scale up manufacturing, Technology transfer Project planning, management, Regulatory & Quality.

Mr Cleber Augusto Gomes

Regulatory Affairs Coordinator - Post-licensing, Instituto Butantan

Mr. Cleber Augusto Gomes is the Regulatory Affairs coordinator - post-licensing of Instituto Butantan. Cleber Gomes has been working at Butantan for over 9 years. He is responsible for the regulatory activities regarding Instituto Butantan's portfolio products, post-licensing (vaccines and sera). Cleber Gomes has a bachelor's degree in Pharmacy.

Mr Hiren Dave

Deputy Manager of Regulatory Affairs, Serum Institute of India

I am a regulatory professional currently employed at Serum Institute of India Pvt. Ltd, and having total 13 years of experience in pharmaceutical and biotech industry . I am well versed with designing/preparing regulatory strategies, CMC authoring, review and Life Cycle Management for small molecules and biologics. During Pandemic, I have worked on several COVID-19 vaccines projects for India, WHO, MHRA & EMA. I am registered pharmacist (RPh) and holding a dual degree [Master of Pharmacy (M.Pharm) & Master of Business Administration (MBA) in Project Management].

Ms Ida Nurnaeni

Head of Regulatory Affairs, BioFarma

Ida Nurnaeni is the Head of Regulatory Affairs Department of PT Bio Farma (Persero), Indonesia. With 18 years of working experiences, she has spent the last 5 years of her career in Regulatory Affairs. She also spent 7 years in Influenza Vaccine Production and 6 years in Quality Assurance. She graduated from Institut Teknologi Bandung (ITB) in 2000 with a bachelor's degree in Pharmacy; and completed master's degree in 2003 and holds a Master of Science in Food Biotechnology from Strathclyde University in Glasgow, Scotland. Motivated and inspired daily by her husband and their two daughters, Ida likes to cook and bake in her free time with family.

Dr Nagarjuna Akula

President & Head, Quality Operations & Regulatory Affairs, Bharat Biotech International

Dr. Nagarjuna possesses three decades of progressive experience in overall Quality Operations, Regulatory Affairs, Project Management & Technology Transfers in leading companies like Bharat Biotech, Sanofi Pasteur, Dr. Reddy`s laboratories, and Excel Industries. His main exposure is in the Sterile Injectables manufacturing of human vaccines, pharmaceuticals, and Active Pharmaceutical ingredients. Handled several successful regulatory inspections including but not limited to US FDA, MHRA, and WHO.

THANK YOU!

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