

Dr. Bobby George

**Assistant Vice President, Regulatory
Affairs, Reliance Life Sciences Pvt. Ltd.
Navi Mumbai, India**

Dr. Bobby George has specialized in Pharmacology from Panjab University, Chandigarh. He also holds Post Graduate Diploma in Hospital & Health Management (PGDHHM) apart from an Executive Certification in Project Management. At Reliance, he is currently responsible for providing regulatory guidance and strategic inputs for their biopharmaceutical & Pharmaceutical development programs to assure appropriate and timely regulatory filing and approval of new drugs, product variations and renewals, in accordance with business objectives across different regions. Prior to joining Reliance, he was with Dabur Research Foundation (DRF), Sahibabad (now known as Fransenius Kabi). He was instrumental in starting their clinical research unit and has worked there in different capacities. He had been part of their core team for oncology molecules.

In recognition to his contributions, he has been invited to a number of national meetings, workshops and conferences for delivering lectures. Dr Bobby has more than 22 research papers to his credit, mostly published in peer reviewed international journals. He is the recipient of the prestigious C.L Malhotra award in the year 1998 for the best paper published in Pharmacology/Allied Sciences and also the IDMA award for best research paper published in pharmacology – twice, in the year 1995 & 1997, respectively. He is also on the University panel of experts for review of M. Pharm and Ph. D thesis.

Registration of Blood products & the associated establishments: Regulatory challenges

Section 510 of the US Federal Food, Drug, and Cosmetic Act (the Act) requires drug and device manufacturers, including manufacturers of biological products, to register with FDA. Title 21, Code of Federal Regulations, Part 607 spells out the registration requirements for manufacturers of human blood and blood products. The Center for Biologics Evaluation and Research (CBER), Office of Blood Research and Review (OBRR), Division of Blood Applications, administratively processes the registration and listing information for human blood and blood products, including licensed products such as albumin, clotting factors, and immune globulin. The US FDA Modernization Act of 1997 (FDAMA) amended the registration provision of Section 510, at 510(i), to require that all foreign manufacturers of drugs and devices, including biological products, imported or offered for import into the US register with FDA. Unless exempt, as described below, any establishment that manufactures human blood or blood products by chemical, physical, biological, or other means must register with US FDA. Even establishments that collect or prepare blood cells, serums, or plasma for further manufacture into a drug or device need to be registered. This includes establishments that collect blood or blood components, plasmapheresis centers or those that supply pooled plasma to manufacturers of fractionation products.

India too has its set of regulations in place as far as registration & licensing of establishments those who manufacture blood products, process plasma and even import plasma or plasma intermediates. There are several challenges which are faced both by the establishments as well as the regulators. This presentation is designed to unravel and highlight some of these challenges and how possible we could overcome these.