



ACTREC Alumni Association

organizing

AAA Colloquia & Symposia Series

Venue: Khanolkar Auditorium, Khanolkar Shodhika,
Advanced Centre for Treatment, Research & Education in
Cancer (ACTREC), Tata Memorial Centre, Navi Mumbai
Tuesday, 12th March, 2013

Biotherapeutics: A Scientific and Industry Perspective

Dr Manoj Rajadhyaksha

Director, Bioanalytical Science Department,
Regeneron Pharmaceuticals Inc, Tarrytown, NY, USA



Event Coordinator:

Dr Surendra Chavan, CRI-ACTREC Alumnus
CTO & Co-founder
QuantImmune Solutions Pvt Ltd, Navi Mumbai

 *Program* 

10.00am –10.30am	Round-table with Director ACTREC & Dy Director ACTREC
10.30am – 11.00am	Round-table with Chairpersons, ACTREC
11.00am – 12.00	Seminar
12.00 – 1.00pm	Round-table with students
2.00pm – 4.00pm	Individual meeting with scientists/ clinicians

You may write to alumni@actrec.gov.in to have schedule fixed for colloquium with Dr Surendra Chavan and Dr Manoj Rajadhyaksha

Biography: Dr Manoj Rajadhyaksha



Dr. Manoj Rajadhyaksha has obtained his basic training in Molecular Immunology at Roswell Park Cancer Institute at SUNY Buffalo, NY. After his PhD graduation, he joined IMMCO Diagnostics Inc, where he held positions of increasing responsibility reaching upto Vice-President of R&D. In his diagnostic career, Dr. Rajadhyaksha identified the autoantigen for Celiac disease and established a 510K approved diagnostic test to diagnose celiac disease. He now holds a US patent for this discovery and the diagnostic test. Dr. Rajadhyaksha later moved to Centocor (now Janssen) where he led the effort of establishing cell based Neutralizing antibody assay unit and also directed bioanalysis for preclinical immunogenicity and biomarkers.

Dr. Rajadhyaksha then moved to Pfizer where as an Associate Research fellow he was leading the PDM efforts in Pfizer Neuroscience Therapeutic Area on multiple projects. He also led a group that was responsible for the development of preclinical & discovery phase bioanalytical assays for PK, biomarker and Immunogenicity for all biologic products in the Neuroscience, Oncology, and Cardiovascular Therapeutic areas product pipeline. At present, Dr. Manoj Rajadhyaksha directs the Bioanalytical Science Department at Regeneron Pharmaceuticals Inc, overseeing various aspects of preclinical, clinical, PK, biomarker, and immunogenicity assays. Overall Dr. Rajadhyaksha has total of three patents, two SBIR grants, more than thirty 510K approved commercial diagnostic tests for various autoimmune diagnostics disorders and several publications to his credit in various areas he has worked in.

He would cover following topics during his talk.

Brief history of Biotherapeutics will be followed by the different classes of biotherapeutics that have been successfully manufactured by the industry. This overview will include the different biotherapeutics, their key characteristics and the disease indications they cover. What are the key aspects of working in a GLP environment? Some key definitions and the regulatory pathways will be discussed. By providing some examples of major safety events that have occurred for some biotherapeutics the concept of immunogenicity and the underlying mechanisms will be discussed. The next phase of the talk will provide the overall AAPS structure leading to some of the key focus groups and what they do? The talk will then elaborate the Therapeutic Protein Immunogenicity Focus Group and its various subteams and what work is being conducted in these subteams? This will then lead to how students, post-docs and faculties can contribute and work together on these subteams with other colleagues from the industry and regulatory bodies. This participation can possibly assist students, post-docs and faculties build further collaboration at other universities worldwide and global industry teams.