C-CAMP - A CARB-X Accelerator

presents

A Workshop on

'US FDA Regulatory Approval Process for Anti-microbials'
6th March, 2019
Chausa, C-CAMP, Bengaluru

Agenda

10.15 – 10.30 am:	**Networking over Coffee**
10.30 -10.40 am:	**Opening Remarks** Dr. Taslimarif Saiyed CEO & Director, C-CAMP
10.45 – 11.30 am:	**Regulatory Approval Process for Anti-microbial drugs** Dr. Edward M Cox Director, Office of Antimicrobial Products, US FDA
11.30 – 11.45 am:	**Q & A**
11. 45 – 12.30 pm:	**Clinical Trial Design & Challenges and Lessons learnt in Clinical development of Anti-microbial drugs** Dr. Sumathi Nambiar Director, Division of Anti-infective products, Office of Antimicrobial Products, US FDA
12.30– 12.45 pm:	**Q & A**
12.45 – 1.00 pm:	**Role/use of diagnostics in anti-infective trials** Dr. Edward M Cox Director, Office of Antimicrobial Products, US FDA
1.00 – 2.00 pm:	**Lunch**

2.00 – 3.30 pm:	**Meetings with a few Indian Companies working in the anti-microbial area**
3.30 – 4.00 pm:	**Coffee Break**
4.00 – 5.30 pm:	**Meeting with C-CAMP & Close**

Speakers

Dr. Edward Cox is Director of the Office of Antimicrobial Products, where he has served since 2007. As Director for the Office of Antimicrobial Products, Dr. Cox oversees the review, approval and safety of antimicrobial (antibacterial, antiviral, antifungal, and antiparasitic) drugs and immunosuppressive agents for patients who have received solid organ transplants. Dr. Cox has worked extensively on the science and design of clinical trials for evaluating antimicrobial drugs. He also serves on the Transatlantic Task Force on Antimicrobial Resistance.

Dr. Cox was a Morehead Scholar at the University of North Carolina at Chapel Hill where he received his undergraduate degree in chemistry. He received his M.D. from the University of North Carolina School of Medicine. He completed an internship and residency in Internal Medicine at the Hospital of the University of Pennsylvania and an Infectious Disease fellowship at the National Institute of Allergy and Infectious Diseases of the National Institutes of Health. He also holds a Master of Public Health Degree from the Johns Hopkins School of Hygiene and Public Health. He joined FDA in 1998.

Dr. Sumathi Nambiar is Director of the Division of Anti-Infective Products, Office of Antimicrobial Products, since July 2013. Dr. Nambiar joined the Division of Anti-Infective Products in 2002. In her current role, Dr. Nambiar provides regulatory oversight for anti-infective products, including antibacterial, antifungal, and antiparasitic drugs.

Dr. Nambiar is board-certified in pediatrics and pediatric infectious diseases. She completed her pediatric residency at the Inova Fairfax Hospital for Children, VA and her fellowship in pediatric infectious diseases at Children's National Medical Center, Washington DC. She received her MPH from The George Washington University School of Public Health.