C-CAMP hosts US FDA workshop for start-ups & innovators addressing anti microbial resistance

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New Delhi: The Centre for Cellular and Molecular Platforms (C-CAMP) organized a one-day workshop on 'US FDA Regulatory Approval Process for Anti-microbials' on 6 Mar 2019 at C-CAMP, Bengaluru. Attended by start-ups, companies and innovators working in the Anti Microbial Resistance (AMR) space to develop antimicrobial therapeutics, diagnostics and preventives, the workshop was aimed at helping them to understand the regulatory approval process for anti-microbials, in the United States.

US FDA officials, Dr Edward Cox, Director of the Office of Antimicrobial Products, US-FDA and Dr Sumathi Nambiar, Director of the Division of Anti-Infective Products, Office of Antimicrobial Products, US-FDA, addressed the workshop.

Dr Edward Cox gave an overview of the stages in regulatory approval process for anti microbials. Talking about the generalisability of anti-microbial therapies, he said that regional differences in microbiology makeup can be countered with broad spectrum drugs that work beyond a niche, which is why US-FDA approval is sought after outside the United States. He urged start-ups to aim to satisfy as many regulatory approvals as possible at an early stage so as to avoid duplication of efforts when they are ready to seek approval. Dr Cox also gave a brief insight into the role of diagnostics in antibacterial drug development. Better stewardship of molecules can be achieved through diagnostics, he concluded.

Dr Sumathi Nambiar began with a brief introduction to the organisational structure of the US FDA. Talking about design of clinical trials, she elaborated on the difference between superiority trials and non-inferiority trials. She also focussed on FDA's new pilot program to modernize drug development and promote innovation in drugs targeted to unmet needs. She remarked that it is encouraging to see the rise in pre-Investigational New Drug (IND) stage consultations, which suggests that more and more startups are working in this area. Dr Nambiar concluded with some examples of failures in drug approvals and the corrective measures that eventually helped get an approval.

The workshop was highly interactive and the audience posed questions ranging from early drug development to drug failure trends which were succinctly answered by the speakers. Following the Workshop, some companies met with Dr Edward Cox and Dr Sumathi Nambiar, in one-on-one meetings, where they had an opportunity to address their specific queries.

In his opening remarks, Dr Taslimarif Saiyed, CEO and Director, C-CAMP, said "In India there's very little data on AMR & AMR sensitivity, although it is one of the most vulnerable regions of the world. AMR may just be the healthcare tsunami ready to overwhelm any moment. We are delighted that CARB-X has supported C-CAMP in connecting experts from US-FDA with Indian innovators who are working in the AMR space. This will go a long way in guiding innovations in antimicrobials from India when they approach the regulatory approval phase."

Dr Anand Anandkumar, Chief Executive Officer of Bugworks, while introducing the speakers said, "It is an unprecedented event, perhaps for the first time we have officials from FDA interacting with industry, academia and entrepreneurs in India."

Ramesh Jayaraman, Founder and Chief Scientific Officer of TheraIndx, who participated in the workshop said, "The workshop was very informative. It is a fantastic effort to bring officials from FDA to interact with startups in India"