

USFDA-CDSCO-DIA

Workshop on Global Anti-Infective Drug Development: Challenges and Opportunities

8th March, 2019 | Novotel Juhu Beach, Mumbai

PROGRAM CO-CHAIR(S)



Ed Cox
Director CDER/OAP
USFDA



Anand Eswaraiah
Head - Medical and
Regulatory affairs
Syngene International

PROGRAM COMMITTEE MEMBERS



Kristan Callahan
International Relations
Specialist
USFDA



Sudheendra Kulkarni
Medical Products Safety
Coordinator
USFDA



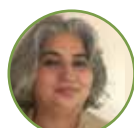
Sumathi Nambiar
Director, CDER/OAP/
DAIP USFDA



Zili Li
CDER/OAP, Representative
USFDA



Chandana Pal
Accreditation & Quality
Systems Incharge
Apollo Research &
Innovations (ARI)



Anupama Ramkumar
Managing Director
Arkus Research



Srikanth Tripathy
Director in Charge
National Institute for
Research in Tuberculosis
ICMR, Govt. of India
Chennai

Antimicrobial resistance (AMR) is one of the major threats to human health in the 21st century, with some bacterial pathogens acquiring resistance to all clinically available antibiotics. Worldwide, infections caused by multi-drug resistant (MDR) bacteria are now a major cause of morbidity & mortality and have markedly enhanced healthcare costs.

Learning Objective

- Hear and learn about the regulatory approach and the science behind the development of anti-infectives through actual case studies shared by the USFDA's experts from the Department of anti-infective products.
- Opportunities and challenges in this field in India and a peek into the current landscape including the regulator's perspective
- Explore the possibilities of synergies that can be leveraged in your own drug development programs through this Workshop

Workshop Highlights

- Advancing Regulatory Science and Innovation to Accelerate Global Anti-Infective Drug Development
- Panel Discussions
- Case Studies

Who should attend

- Clinical trial industry professionals
- Pharmaceutical Experts working in novel drug development, clinical design and strategy
- Academicians engaged in research

MEETING MANAGER

Pradeep Dass

Sr. Manager - Business Development & Event Operations
DIA (India) Private Limited
cell: +91 91.6053.5566
Pradeep.dass@diaglobal.org

DIA India Pvt. Ltd.

Office Number 250, Unit No 1, Level 2, B Wing| Times Square, Andheri Kurla Road|Andheri East, Mumbai 400059 INDIA
+91 22. 6608 9588 (tel) | +91 9029098844 (cell) | www.DIAglobal.org | India@DIAglobal.org

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AGENDA

9:00 – 9:30	Welcome and Opening Remark: (30 minutes) DIA CDSCO US FDA – OIP India Office
9:30 – 12:00	Advancing Regulatory Science and Innovation to Accelerate Global Anti-Infective Drug Development 9:30-10:00 USFDA perspective Ed Cox Director CDER/OAP USFDA Sumathi Nambiar Director, CDER/ OAP/DAIP USFDA 10:00-10:30 CDSCO perspective P. B. N. Prasad Deputy Drugs Controller CDSCO West Zone 10:30-10:45 Tea / Coffee break 10:45-11:30 ICMR perspective Nilima Kshirsagar National Chair, Clinical Pharmacology ICMR Kamini Walia Senior Scientist, Antimicrobial Surveillance Network ICMR 11:30-12:00 Industry Perspective V Balasubramania Co-Founder & Director, Bugworks Research India Pvt. Ltd.
12:00 – 13:00	Panel Discussion Session How can US and India Regulators and Industry Work Together to Combat the Global Challenge of AMR? Where the FDA's regulatory science effort and global collaboration effort, and India regulatory landscape and ecosystem for anti-infective drug development will be discussed under this session Moderator Nilima Kshirsagar National Chair, Clinical Pharmacology ICMR Panelists Ed Cox Sumathi Nambiar P. B. N. Prasad Kavita Singh Mahesh Patel Director Director CDER/ Deputy Drugs Mission Director Director CDER/OAP OAP/DAIP USFDA Controller National Biopharma Drug Discovery USFDA CDSCO West Zone Mission Research BIRAC Wockhardt
13:00 – 14:00	Lunch
14:00 – 15:15	Case Study #1- Regulatory and Clinical Considerations for Developing Drug Products for Treatment of Multidrug Resistant Tuberculosis Ed Cox Director CDER/OAP USFDA
15:15 – 15:30	Tea / Coffee Break
15:30 – 16:45	Case Study #2- Regulatory and Clinical Considerations for Developing Drug Products that Address an Unmet Medical Need for Treatment of Resistant Gram Negative Infections Sumathi Nambiar Director CDER/ OAP/DAIP USFDA
16:45 – 17:00	Closing Remarks

USFDA-CDSCO-DIA: Workshop on Global Anti-Infective Drug Development: Challenges and Opportunities
Event I.D. 19660 | 8th March 2019 | Novotel Juhu Beach Mumbai

VENUE:

NOVOTEL MUMBAI JUHU BEACH
BALRAJ SAHANI MARG, JUHU BEACH, MUMBAI - 400049
T 91 80 6660 4444 D 91 80 6660 4239

CONTACT PERSON: AMOL ADHAV

CATERING SALES EXECUTIVE
MOBILE: +91 98 19 65 41 22 TEL.: +91 (22) 66 93 44 44

MEETING MANAGER

Pradeep Dass
Sr. Manager - Business Development & Event Operations
DIA (India) Private Limited
cell: +91 91.6053.5566
Pradeep.dass@diaglobal.org

CANCELLATION POLICY: ON OR BEFORE FEBRUARY 22, 2019

- Cancellations must be in writing and received by FEBRUARY 22, 2019
- Registrants who do not cancel in writing by that date and do not attend the event will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations.
- DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.
- UPON CANCELLATION, the administrative fee that will be withheld from refund amount is 25 % of the delegate fee

FULL MEETING CANCELLATION

- All refunds will be issued in the currency of the original payment

Online registrations: visit our website www.diaglobal.org

REGISTRATION FEES FOR ONE DAY CONFERENCE (Registration fee includes refreshment breaks and luncheons.)

Standard

	Basic Rate (INR)	Service Tax 18 %(INR)	Total INR
INDUSTRY	8000	1440	9440 <input type="checkbox"/>
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STUDENT REGISTRATIONS

A student is an undergraduate/graduate who can document enrollment in a signature accredited, degree granting, academic program. Please send completed registration form, payment and copy of student identification.

CHEQUE / DRAFT

Completed form, along with draft/cheque made payable to DIA (India) Private Limited should be sent to:

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Senior Executive Accounts
Bhavesh.vora@diaglobal.org
DIA India Pvt. Ltd.
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