FDA Keynote Speakers at SMi's 4th Annual Pharmaceutical Microbiology East Coast Virtual Conference in 3 weeks

SMi Group Reports: Keynote FDA speakers, Qiao Bobo and John Arigo, to present at the 4th Annual Pharmaceutical Microbiology East Coast, taking place virtually.

BOSTON, MA, UNITED STATES, April 7, 2021 /EINPresswire.com/ -- With just three weeks remaining until the highly-anticipated conference, SMi Group are delighted to announce two key FDA Speakers joining the 4th Annual Pharmaceutical Microbiology East Coast Conference. This event will take place virtually on April 28th and 29th 2021.

Looking into manufacturing facility assessment during the pandemic and sterility assurance assessment respectively, speakers Qiao Bobo, Division Director, Office of Pharmaceutical Quality, FDA/CDER and John Arigo, Division of Microbiology Assessment Director, Office of Pharmaceutical Manufacturing Assessment, FDA/CDER, are to bring unique insight and a wealth of experience to this years' conference.

Interested parties can register online at US$499 for pharmaceutical and biotechnology companies and $999 for commercial organisations on http://www.microbiologyeastcoast.com/PR5.

FDA speaker and keynote presentations details include:

Dr. Qiao Bobo joined FDA in 2010, and currently serves as a Commander (CDR) in the United States Public Health Service (USPHS) and as a Division Director in the Office of Pharmaceutical Quality, Center for Drug Evaluation and Research (CDER), at the Food and Drug Administration (FDA). Qiao oversees the scientific review and quality evaluation of pharmaceutical manufacturing of sterile drugs.
Qiao is also co-chairing the two-day conference with Lynne Ensor at Parexel.

Qiao's presentation details include:
Keynote Presentation on 'Manufacturing Facility Assessments during COVID Pandemic'
- Introducing the changes to the manufacturing facility assessment to support application required in light of the COVID Pandemic
- Insight into how the FDA CDER Office of Pharmaceutical Quality has evolved its approaches to continue manufacturing facility assessments
- Recommendations to manufacturers for a successful remote manufacturing facility assessment

Presented by Qiao Bobo, Division Director, Office of Pharmaceutical Quality, FDA/CDER

Dr. Arigo is the Director of the Division of Microbiology 1 in the Office of Pharmaceutical Manufacturing Assessment at the FDA. John's division assesses the sterility assurance and manufacturing submissions to support ANDA, NDA, and INDs. Dr. Arigo began his career with the Office of Generic Drugs Microbiology team in 2008 and has been involved in multiple reorganizations to the current state. Dr. Arigo obtained his Ph.D. from The Johns Hopkins University School of Medicine.
Dr Arigo's presentation details include:
'Common Issues in the Sterility Assurance Assessment'
- Introduction to FDA small molecule microbiology/manufacturing
- Common deficiencies seen in applications
- Recommendations for applications to expedite approval

Presented by John Arigo, Division of Microbiology Assessment Director, Office of Pharmaceutical Manufacturing Assessment, FDA/CDER

This is a must-attend event for those wanting to gain essential insights and expert understanding of key topics in the field.

The full speaker line-up, updated brochure and program are available on http://www.microbiologyeastcoast.com/PR5

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For sponsorship enquiries contact Alia Malick on +44 (0)20 7827 6164 or amalick@smi-online.co.uk

For media enquiries, contact Simi Sapal on +44 (0) 20 7827 6162 or ssapal@smi-online.co.uk

SMi's 4th Annual Pharmaceutical Microbiology East Coast
Virtual Conference: Online Access Only
Conference: April 28 – 29, 2021
Workshops: April 27, 2021
http://www.microbiologyeastcoast.com/PR5
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Simi Sapal
SMi Group
+442078276000
email us here