

NDAs and INDs for Orally-Administered Drug Products

Date : Feb 28, 2018 - 10:00 AM

Event URL : <http://www.BostonEventsList.com/events/ndas-and-inds-for-orally-administered-drug-products-feb-2018>

Organizer : Netzealous LLC DBA - Compliance4All

Venue : Online Event

Location : 161 Mission Falls Lane, Suite 216,, Mission Falls Ln
Fremont, California, USA, ZIP: 94539
Phone: 8004479407

Ticket Price: One Dial-in One Attendee Price: \$150.00

Overview:

This webinar will be helpful to applicants conducting BA/BE studies during the IND period, also FDA guidance recommendations on how to meet the BA and BE requirements in 21 CFR 320 as they apply to oral dosage forms.

Why should you Attend:

Understanding when Bioavailability and Bioequivalence studies should be done can help attendees avoid having to re-do clinical trials, help to determine dosage regimen that achieves target drug exposure.

Areas Covered in the Session:

Review definitions necessary for understanding bioavailability and bioequivalence
Review of FDA guidance recommendations on how to meet the BA and BE requirements in 21 CFR 320 as they apply to oral dosage forms.
This webinar will be helpful to applicants conducting BA/BE studies during the IND period.

Who Will Benefit:

Regulatory Managers
Specialists
R&D

Production Personnel
Quality
Clinical Personnel
Laboratory Personnel

Speaker Profile:

Stephanie Cooke is the President/CEO of Cooke Consulting, Inc. Stephanie uses her roughly 20 years of experience to provide global consulting services in various areas of Regulatory Affairs, Quality Assurance and validation for pharmaceutical, biological/biotech products, medical device, combination drug/device and nutraceutical firms.

Event Fee: One Dial-in One Attendee Price: US\$150.00

Contact Detail:

Compliance4All DBA NetZealous,

Phone: +1-800-447-9407

Email: support@compliance4All.com

Event Categories :