

GMP for Phase I Investigational Drug Products 2018

Date : Mar 22, 2018 - 10:00 AM

Event URL : <http://www.BostonEventsList.com/events/gmp-for-phase-i-investigational-drug-products-2018-mar-2018>

Organizer : Netzealous LLC DBA - Compliance4All

Venue : online

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

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

Overview:

Phase I clinical trials are the first time that investigational new drugs are introduced into human subjects and, although it is very, very important for all drugs to be manufactured using GMPs, it is probably more important than at any other time during the lifecycle of the product, that a product be safe whenever humans are being exposed to it for the first time.

Why should you Attend:

FDA's guidance document "Good Manufacturing Practice for Phase I Investigational Drug Products" applies to correct GMP requirements to drug products made for the purpose of using an investigational drug product on human subjects for the first time, during conduct of Phase I clinical trials, which can begin if your IND is not put on clinical hold in 30 days after receipt by the FDA.

Areas Covered in the Session:

- Statutory and Regulatory Requirements
- Personnel requirements
- QC Functions
- Facility and Equipment Requirements
- Control of Components and Containers and Closures
- Manufacturing and Records

Who Will Benefit:

Senior Quality Managers, Quality VPs
Quality Associates or Specialists
Regulatory Management or Regulatory Specialists
Compliance Professionals

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

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Event Categories :