

Products Used in Early Phase IND Studies

Date : Jan 19, 2018 - 10:00 AM

Event URL : <http://www.BostonEventsList.com/events/products-used-in-early-phase-ind-studies-jan-2018>

Organizer : Netzealous LLC DBA - Compliance4All

Venue : online

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

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

Overview:

How it may be integrated with the recommendations of the guidance documents on CMC requirements.

Areas Covered in the Session:

Discussion of the elements found in the guidance document for Phase 1 material

What to do at really early stages

What about special IND studies?

What about preclinical studies?

Who Will Benefit:

Regulatory Affairs personnel who coordinate activities for the CMC sections of submissions

QA/QC personnel who need to plan work on early stage material

R & D personnel who will contribute data to CMC sections

Project managers for product development studies

Quality systems auditors

Consultants

Speaker Profile:

Steven S. Kuwahara , Ph.D. is the founder and Principal of GXP BioTechnology LLC, a

consulting firm that works in the areas covered by the GLP and GMP of drugs, biologics, and nutraceuticals. Steve has over 30 years of experience in supervising quality control laboratories, including an animal testing facility, and in performing GLP and GMP audits of internal and external testing laboratories .

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Event Categories :