
42 CFR Part 11, “Final Rule for Clinical Trials Registration and Results Information,” is a head-scratcher. In a 90-minute webinar Scott Cunningham Esq., will deconstruct the new final regulation into every day language.

Falls Church, VA (PRWEB) July 18, 2017 -- ClinicalTrials.gov and the New Final Rule (42 CFR Part 11) What Strategic Decisions Do You Need to Consider?
**An FDAnews Webinar**
Aug. 2, 2017 — 1:30 p.m. – 3:00 p.m. ET
http://www.fdanews.com/newfinalrule

42 CFR Part 11, “Final Rule for Clinical Trials Registration and Results Information,” is a head-scratcher. After reading and re-reading its 177 pages, can manufacturers honestly say:

- They are certain they’re submitting everything it calls for?
- They are in compliance with all required timelines?
- They understand what changes under the final reg, and what remains the same?

What to do?

Announcing an all-new FDAnews webinar featuring a star of the FDA regulatory bar, Scott Cunningham Esq., deconstructing the new final regulation into everyday language.

In a mere 90 minutes, Mr. Cunningham will zero in on the trickiest aspects of the final rule:

- The four elements of an “applicable drug clinical trial,” and how the FDA will interpret what these words really mean
- Who must submit clinical trial results to ClinicalTrials.gov
- Clinical trial data submissions deadlines
- The enforcement landscape: What the FDA can do to police non-compliance, and when enforcement might start
- Deciphering the ClinicalTrials.gov “voluntary submissions” provisions
- Navigating provisions on “delayed submission” of results to ClinicalTrials.gov
- FDA proposals for release of de-identified data — current status
- And much more!

Attendees will learn best practices in managing clinical trial disclosure requirements in the U.S. and hear some of the successes and failures that have occurred during the brief history of ClinicalTrials.gov submissions.

It’s barely several months since compliance became mandatory. There is still time enough to clean house. Discover what manufacturers need to know before the next visit from the inspectors.
Meet Your Presenter:
Scott Cunningham Esq. is a partner in Covington & Burling’s San Francisco-based Food and Drug Practice Group, representing pharma, biotech, regenerative medicine, and medical device firms. His expertise covers the gamut of FDA regulatory issues, including new product development/approval, clinical trials, IRBs, Hatch-Waxman exclusivities, advertising/promotion, false claims compliance, orphan drugs, pediatric exclusivity, cGMP/manufacturing, import/export, controlled substances and SEC disclosure.

Who Will Benefit:
• Medical Affairs
• Clinical Operations
• Regulatory Affairs
• Publications Directors
• Clinical Trial Regulatory Directors
• Clinical Trial Information Disclosure Directors
• Global Clinical Safety and Pharmacovigilance Officers

Webinar Details:
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