Partners in Quality Excellence

A PCPC GMP Workshop

Pre-Workshop Program

April 22, 2020
The Westin Galleria Dallas
13340 Dallas Pkwy
Dallas, TX

AFTERNOON SESSION:

1:00 – 2:30 **Trend Evaluation and CAPA Verification**
Jennifer D. Ahearn, Director of Regulatory and Compliance, ESi

2:30 – 3:00 Break

3:00 - 4:30 **Change Control**
Jennifer D. Ahearn, Director of Regulatory and Compliance, ESi

4:30 – 5:30 Networking Mixer

Presenter Bio:

Ms. Ahearn specializes in pharmaceutical and medical device regulatory compliance. She has served numerous roles within the FDA including bench chemist, domestic and international investigator, technical liaison for FDA's Office of Criminal Investigations, and member of FDA's National Training Cadre making her an expert in the interpretation and application of cGMP regulations in 21 CFR 210/211 relating to pharmaceutical manufacturing. Ms. Ahearn has assisted pharmaceutical and medical device companies preparing for FDA inspections, as well as responding to FDA 483 observations after an inspection. She has worked to resolve technical and FDA compliance issues for virtually all pharmaceutical dosage forms.