OUT OF SPECIFICATIONS: Don’t Shoot the Messenger!

Thursday, March 3, 2016
8:00a.m.–5:00p.m.
ECU Heart Institute
Conference Room A
$150

Participants will gain skills in:

• Applying OOS principles to assay, impurities, CU, dissolution and other tests
• Conducting lab and full OOS investigations
• Using guidance for re-analysis, retesting, and resampling
• Applying the FDA Guidance: Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production (CDER, October 2006)

This course will use a combination of pre-course study, lecture, and practical exercises.

James S. Bernstein, Ph.D., is a pharmaceutical consultant with expertise in the CMC development of small molecule pharmaceuticals. He is the president of Live Oak Pharmaceutical Consulting. Founded in 2007, Live Oak provides a full range of CMC consulting services (synthesis, formulation, analytical, regulatory, safety assessment, statistics, and project management) through its network of consultants.

Jessica A. L. Blomberg, Ph.D., is a pharmaceutical consultant with expertise in quality assurance, project management, and analytical development. Prior to founding her own consulting practice, she served in quality assurance, project management, and product development roles with Erimos, Inspire, and BioCryst Pharmaceuticals.

All visitors should park in lot SM-27, located in front of the Family Medicine Building, across from the East Carolina Heart Institute. Participants who choose to park behind the building may enter through the back entrance and go through the patio area. This series will be held in conference room A which is located on the other side of the hand and heart sculpture.

For more information on how to register, please visit https://www.enrole.com/ecu/jsp/course.jsp?categoryId=10010&courseId=PDMCE16