

NCTM

NATIONAL CENTER FOR
THERAPEUTICS MANUFACTURING

CAPA CORRECTIVE AND PREVENTATIVE ACTIONS

March 24–25, 2015

**100 Discovery Drive
College Station, TX 77845**



Quality systems expert and pharmaceutical industry professional, **KRISTEN KNEZEVICH, ASQ-CQA**, instructs our 2-day “Corrective and Preventative Actions” workshop. Join us for an in-depth examination of effective root cause analysis and failure investigation, deviation management and documentation, corrective actions, and other elements of risk mitigation. The course explains the regulatory environment surrounding CAPA, how the CAPA system works, the basics of an investigation, and how an investigation is performed. Case studies, exercises and group activities allow participants to gain knowledge from the instructor, as well as peers.

SPECIAL Discount Price*: \$249

Student Discount Price: \$49*

**Workshop costs subsidized by federal funds.*

Participants will receive 1.6 CEUs from Texas A&M University upon completion.



REGISTER ONLINE: <http://engrevent.tamu.edu/event/101189>

If you need assistance, please call: 979-458-8506

ABOUT THE INSTRUCTOR

Kristen M. Knezevich, ASQ-CQA, is a twenty-five (25) year quality systems expert for the biotechnology and biomedical industries. Kristen’s predominate clientele include medical device, combination product and biopharma companies, to whom she provides services such as auditing (internal, gap analysis, external, vendor qualification, hosting) SOP and policy generation/review/revision, ISO & FDA compliant quality plans and systems, change control systems, Out of Specification (OOS) investigations, Corrective Action/Preventative Action (CAPA) and CAR (Corrective Action Report) systems, deviation/discrepancy systems, medical device reporting systems, quarantine and release systems, training, equipment qualification, facility validation, method validation, pre/post inspection plans, audit assistance, on-site inspection/audit support, and start-up business quality consulting.

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