Sharing sticky medical microtech ideas

General Lectures Uniting Everyone

EMORY UNIVERSITY · Georgia Tech · Children's Healthcare of Atlanta · ACME POCT Atlanta Center for Microsystems Engineered Point-of-Care Technologies

50 SHADES of FDA

A case study to highlight the regulatory perspectives of a new diagnostic

What: A Zoom Role Playing Event!
When: Friday, April 28, 2023 @ 12 PM
Registration: https://bit.ly/3K1yqQn

EVENT REGISTRATION LINK

Navigating a medical device through the FDA's regulatory maze can be a daunting affair…
To shed light on the process Cathy Cambria and Erika Tyburski will demonstrate the steps through a mock innovative COVID-19 assay, from both the point of view of the innovator and a regulatory agency. They will touch on the many regulatory considerations necessary for getting truly innovative and novel technologies to market.

About the Speakers

Cathy Cambria has over thirty years of experience in regulatory compliance, quality systems management, and has successfully run her own consulting company for over two decades. Through her ongoing contact with different branches of the FDA, Cathy has completed multiple filings for Class I, II, and III 510(k) submissions as well as premarket approval (PMA) supplements, and real-time reviews to the FDA. **Erika Tyburski** is a biomedical engineer and CEO of Sanguina, a company that develops wellness tools and point of care and home use technologies. She has over a decade of experience in the biomedical industry and has executed more than a dozen studies required to support 510(k) clearances.

About the GLUE Lecture Series

General Lectures Uniting Everyone (GLUE) is the Atlanta Center for Microsystems Engineered Point-of-care Technologies (ACME POCT) flagship event series and serves as our primary venue to educate on the entrepreneurial pathway and product lifecycle. It provides a forum to pitch clinical problems and teach about the technologies most promising for meeting these clinical needs.