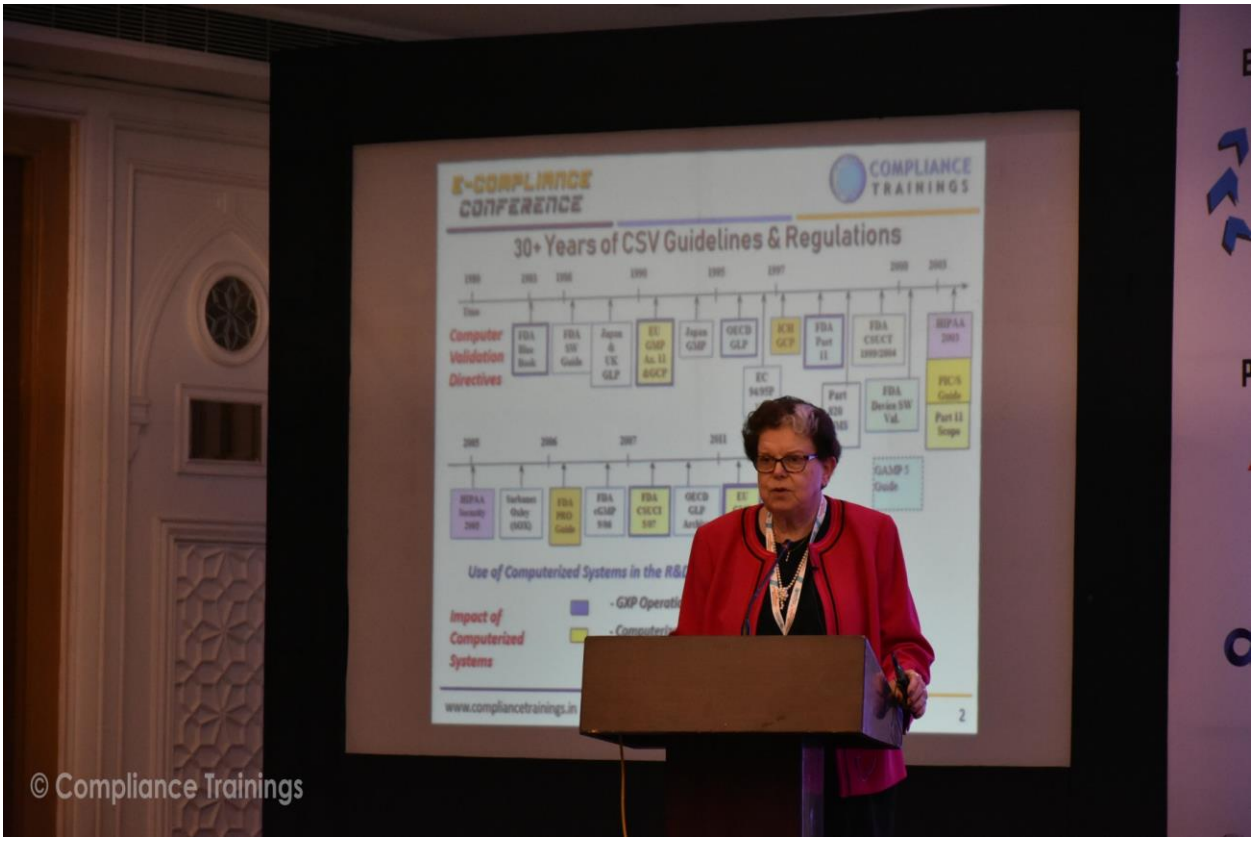
E-Compliance Conference – Sept. 26-27, 2019 – ITC Kakatiya, Hyderabad, India

The Compliance Trainings agenda for CSV & IT Systems Validation used CSV experts to review global regulations. Experienced industry professionals shared practical advice on compliance issues currently being reported in 483s and Warning Letters across the GXP spectrum. Medical Device Software Validation, Agile SDLC compliance, and assuring Cloud Computing compliance were among the many topics addressed.

On Day 1, Dr. Stokes defined the four major themes across all GXP regulations and described what audit evidence is needed across the working life cycle of a computer systems handling GXP data. In the IT breakout session on Day 2, Teri presented the GAMP approach to computer system validation (CSV).

On Day 2 afternoon Teri conducted a plenary Masterclass session on Data Integrity to address a current FDA audit hot topic – Data Integrity. The MHRA GXP Data Integrity Guidance and Definitions; Revision 1: March 2018 was used to define key concepts for data integrity and quality. Then delegates worked a Case Study exercise to analyze and map MHRA concepts on to the FDA Warning Letter sent to a company in India in 2016.

This Masterclass session is available for onsite or remote training in your own company. Contact Dr. Stokes for more information. (+1.781.354.3537)



Dr. Stokes at the podium on Day 1

Teri with Cytel delegates from Pune: Shailesh Kultha, Manjusha Gode, Vibhavari Deo, Devendra Mahajan