

SCCR GCP Workshop

Software as a Medical Device (SaMD)

21 CFR Part 11 and its applicability in Clinical Research for Drugs and Devices



Tuesday, June 8th, 2021, 9:00-10:30 AM

Zoom Webinar

Click [HERE](#) to Register!

The mission of the Stanford Center for Clinical Research (SCCR) includes offering educational resources, training, and support for investigators and research staff. We have invited highly experienced Clinical Quality and Compliance leader, **Bhanu Sharma, PhD**, to present on 21CFR Part 11 (aka Part 11) and its applicability in Clinical Research for Drugs and Devices when performing research electronically. The course will provide an overview of Part 11 and discuss in detail important areas that must be addressed to maintain compliance. At the end of the course, you will gain the knowledge to implement in your research to meet compliance.

At the conclusion of this class, you will be able to:

- Describe what Part 11 is - Electronic Records and Electronic Signature
- Determine how to know where it is applicable
- Identify the Electronic Systems such as Software as a Medical Device (SaMD), Electronic Data Capture, Database, Cloud Storage, Paperless Clinical Trials
- Explain how to make a software system Part 11- compliant
- Learn FDA current thinking on Part 11

Attendance is open to all research staff

About the Instructor:

Bhanu Sharma, PhD holds a PhD degree in Biochemistry from University of Mysore. He obtained his postdoc at The Ohio State University and Michigan State University, then went on to start his career in industry developing commercial diagnostic tests for toxins, bacteria, viruses, stem cells and large molecules. He has published 5 books in the areas of diagnostics, immunology and targeted therapeutic systems. He holds 1 patent and has published over 20 papers in peer-reviewed journals. He was a key opinion leader on 21CFR Part 11 when this regulation was in its infancy. He was invited to speak on this topic around the world. His love for academia and compliance brought him back to SCCR 3 years ago as a Quality & Compliance Leader.

BRN OPTIONAL

Spectrum is an approved provider by the California Board of Registered Nursing, Provider Number CEP15435 for 2 contact hour(s).

To receive your certificate with BRN credit, you are required to complete an evaluation at the conclusion of this class.

BRN Cancellation Policy: If you wish to cancel your registration, please contact Susan Saba at ssaba@stanford.edu.