SOCRA designates this educational activity for a maximum of 16.65 Continuing Education Credits for SOCRA CE and Nurse CNE.

SOCRA designates this live activity for a maximum of 16.65 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

**Device Basics - Preconference Workshop - maximum 4 5 CE Device Regulations - 2 day Conference - maximum 12 15 CE*

CNE for Nurses: The Society of Clinical Research Associates is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation

CME for Physicians: The Society of Clinical Research Associates is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians

SOCRA Course Series: 900

April 23 and 24, 2020

Boston, MA USA

Courtyard Boston Downtown
275 Tremont Street
Boston, MA 02116

Hotel Phone: (617) 426-1400
Reservations: (800) 321-2211

SOCRA's hotel room rate of $229 (plus applicable taxes) is available until March 31, 2020 or until the SOCRA room block is filled. You must mention SOCRA to receive the room rate.

SOCRA
FOR CLINICAL RESEARCH EXCELLENCE

14th Annual Device Research & Regulatory Conference

The Premier Conference for Device Professionals

April 23 and 24, 2020

Device Basics Preconference Workshop
April 22, 2020 (11:30 a.m. - 5:00 p.m.)

Boston, MA USA

Goal:
This annual medical device conference, now in its 14th year, provides attendees with a main program preceded by a half-day device basics workshop. The entire program features over 13 experts presenting topics to assist those in roles specific to medical device design, development testing, analysis, and post market management. The preconference half-day workshop is designed to provide a comprehensive medical device regulatory overview and is a fundamental precursor to the main program.

Objectives:
Learning Objectives - Preconference Workshop
The participant will be able to:

- Discuss FDA regulations including risk categorization and device classifications
- Discuss the IDE application process for sponsor-Investigator research
- Discuss sponsor-investigator requirements and responsibilities in IDE trial
- Discuss the coordination or multisite IDEs
- Explain the investigator-initiated clinical study process.

Learning Objectives – Main Conference
The participant will be able to:

- Discuss the meaning and use of Broad Consent. Discuss
- the 510(k) determination and submission process
- Describe the FDA De Novo process including classification and submissionee
- Discuss the HUD and HDE application and approval processee
- Discuss types of device trials including Category A and B IDEs.ee
- Discuss the research reimbursement process.ee
- Describe how to help patients in research trials avoid financiale liabilitiesee
- Discuss Expanded Access Program, the Early Feasibility Studyee Program and the Breakthrough Devices Programee
- Discuss the use of clinical evidence in the IDE process.ee
- Discuss how new technologies and capabilities are impacting the medical device industryee
- Discuss the Medical Device Single Audit Program (MDSAP)ee
- Discuss cultural aspects to consider when implementing and conducting clinical research studies internationally.ee
- Discuss the challenges of integrating generationally-diversity populationsee
- Discuss the unique differences of conducting research in the United Kingdomee

Member Fee: $675 **Non-Member Fee: $750***

Optional ½ day Device Basics Workshop: $175

*** Non-Member Fees include a non- refundable one year SOCRA membership**

**** All fees are USD**

Register Online or Download a Registration Form at
www.socra.org/conferences-and-education/live-courses

Society of Clinical Research Associates | 530 West Butler Ave, Suite 109, Chalfont PA 18914 | U.S.A.
Phone (215) 822-8644 | Fax (215) 822-8633 | office@socra.org | www.socra.org