PROGRAM ANNOUNCEMENT

Wednesday, 14 November 2018

Monthly Program

Laboratory Developed Tests (LDTs): Regulatory Requirements and Challenges

Program Speaker:
Claudia Ibarra, CCS, MB (ASCP)

Event Agenda:

Date: Wednesday, 14 November 2018

Time:
5:15 – 6:00 PM Registration & Snacks
5:30 – 5:55 PM Speed Networking
6:00 – 6:05 PM Welcome and Announcements
6:05 – 7:05 PM Program Presentation
7:05 – 7:30 PM Q & A

LOCATION: BD (former CareFusion) (directions on last page of this flyer)
3770 Torrey View Court
San Diego, CA 92130

Program Speaker: Claudia Ibarra, CCS, MB (ASCP)

Program Topic:

Laboratory developed tests (LDTs) refer to an *in vitro* diagnostic test that is designed, manufactured and used within a single laboratory. Although the uses of an LDT may be the same as an FDA-cleared or FDA-approved *in vitro* diagnostic test, LDTs are not regulated in the same way. In fact, LDTs generally do not have any oversight or review by FDA prior to use. In 2010, FDA reconsidered its approach to LDTs and started a conversation with LDT stakeholders. However, the LDT topic remains complex and the method of enforcing LDTs is still under development eight years later.

Program Summary:

The program will provide an overview of Laboratory Developed Tests (LDTs) including:

- FDA Perspectives from 2010 to now
- Regulations pertaining to LDTs under Clinical Laboratory Improvement Amendments (CLIA) vs. FDA

- Validation and implementation of LDTs in a CLIA laboratory
- College of American Pathologists (CAP) regulations and checklist
- Updates on state regulations (e.g. New York and California)
- Audits and inspections, license renewals, proficiency testing
- Personnel licensure and continuing education
- Reimbursement strategies

Speaker Biography:

Claudia Ibarra has over 25 years of experience in the clinical diagnostic field. She is currently the Senior Vice President of Laboratory Operations at Exagen Diagnostics. Mrs. Ibarra joined Exagen Diagnostics in 2012 as head of operations, where she grew the clinical laboratory to 25+ scientists who perform over 10,000 tests per day in the area of rheumatology. Mrs. Ibarra started her career at the Children's Hospital Ricardo Gutierrez where she was trained in Chemistry and Hematology. She worked in a variety of cutting-edge clinical laboratories in Argentina in the areas of Clinical Chemistry, Endocrinology and Immunology. Mrs. Ibarra was the Director of the Molecular Oncology Laboratory at Genoptix, a Novartis Company, where she expanded laboratory capacity ten-fold in five years and was in charge of the validation and transfer of new assays. Mrs. Ibarra also acted as the coordinator of the California State Clinical Genetics Molecular Scientist Training Program. Mrs. Ibarra holds a degree in Biochemistry with specialization in Clinical Laboratory Science from University of Buenos Aires, Argentina, a Clinical Chemistry license from the State of California, and a Molecular Biology license from ASCP.

Click the link to access the SDRAN registration system (123Signup) for this event.

Please make your reservation early. The online registration due date is November 12th, 2018. Credit Cards are accepted online only. Cash and Check are accepted at the door.

Online registration (through Monday 12 November 2018):

$15 SDRAN Member $25 Non-Member

Onsite Registration:

$25 SDRAN Member $35 Non-Member

For Questions Email: programs@sdran.org

Directions to BD (former CareFusion):

From the North 5:

I-5 South toward San Diego
Exit toward Carmel Mountain Rd Left onto Carmel Mountain Rd
Left onto Torrey View Court Facility is on the right

From the South 5:

I-5 North toward Del Mar Merge onto I-5 local Bypass
Take Carmel Mountain Rd exit (32) Turn right onto Carmel Mountain Rd Turn left onto Torrey View Court Facility is on the right