PROGRAM ANNOUNCEMENT

Wednesday, 15 April 2020

Monthly Program

Europe's New IVDR and Why US Clinical Laboratories, Not Just IVD Companies, Need to Be Paying Attention to It

Program Speaker:

Natalie J. Kennel, RAC, ASQ CQE & CQMgr, FRAPS,

Founder and President
NJK & Associates

Event Agenda:

DATE: **Wednesday**, **15 April 2020**

TIME: 6:00 – 6:05 PM ONLINE Welcome and Announcements
6:05 – 7:05 PM ONLINE Program Presentation
7:05 – 7:30 PM ONLINE Q & A

LOCATION: Not applicable - This is an ONLINE event

Click here to register for this event.

Program Topic:

Think that the Europe's new IVD Regulations won't affect you as a clinical laboratory? Think that this is an IVD company issue only? You need to come to this session. The In Vitro Diagnostic Medical Device Regulation (IVDR) EU 2017/746 was published on May 5, 2017 in European Union with a five year transition period to implementation. This new regulation is significantly more extensive and far ranging than the current EU In Vitro Diagnostic Directive (IVDD). Two years into this transition, the In Vitro Diagnostic industry is starting to feel the pressure as companies scramble to meet the product requirements of the new standard. At

the same time, the clinical laboratory community has barely noticed this impending regulation and few understand how they are likely to be impacted by this regulation. If specimens from European citizens are tested on Laboratory Developed Tests (LDT) in their commercial clinical laboratory, these LDT(s) are likely to be considered 'distance sales' and the test(s) will need to be CE IVD marked under the new regulation. This requirement will have a profound impact on many clinical laboratories that are currently providing diagnostic testing services to EU citizens. The purpose of this session is to explore the impact of the IVDR on the clinical laboratory from multiple perspectives including the Quality Manager of the Commercial Clinical laboratory, Notified Body and the Regulatory consultant.

The objectives of this session are to introduce the IVDR and specifically how the clinical laboratory may be impacted by it and also to discuss what planning and activities the laboratory should initiate right now including doing a gap analysis of existing validation data against the IVDR performance data needs and how to achieve CE Mark.

Speaker Biography:

Natalie has more than 30 years of experience with development and manufacturing as well as RA/QA and clinical roles most devoted to medical devices. She has experience working with both major and start up medical device companies including in vitro diagnostics devices, molecular diagnostic systems and assays for infectious diseases, human genetic testing and oncology, various clinical chemistry and immunoassays, and point of care lateral flow assays. Natalie founded NJK & Associates in 2005 and she has submitted more than thirty-eight 510(k)'s, three de novo's, and more than 40 Pre-submissions, including international submissions for Canada, Australia, Europe, Singapore, Taiwan, and WHO.
Natalie has previously been the President -Elect, President, and Vice President of Programs for San Diego Regulatory Affairs Network. She holds a BS degree in Chemical Engineering from the University of Rochester.

Registration Information:

Online registration (through Monday 13 April 2020 through start of the event):

$7 SDRAN Member $7 Non-Member

For Questions Email: membership@sdran.org