PROGRAM ANNOUNCEMENT

Wednesday, 16 January 2019

2019 Annual Meeting

Learn what SDRAN did in 2018, and listen and participate in the panel discussion entitled:

What are the Updates and Challenges in the Regulatory Landscape in 2019?

Panel Members: Jennifer Grodberg, Natalie Kennel, and Malcolm Lloyd Smith

Moderator: Frank Pokrop

SDRAN serves all levels of Regulatory, Clinical, and Quality professionals

Event Agenda:

Date: **Wednesday, 16 January 2019**

Time*:
5:00 – 5:30 pm: Registration, Networking, & Light Snacks
5:35 – 5:40 pm: Welcome - Iman Hana & Christine Federovitch, 2018 and 2019 Presidents of SDRAN, respectively
5:45 – 5:50 pm: Lifetime Membership Awards – Christine Federovitch
5:55 – 6:40 pm: Annual Meeting
6:45 – 7:30 pm: Panel Discussion

*Times are approximate.

Panel Discussion:
Regulations for drugs and medical devices change frequently, and it is critically important to keep up-to-date with the changes. We will hear from our panel experts on what the key changes and updates to look forward to in 2019. Come, join the discussion, and to share your experiences and ideas.

Biographies:

Jennifer Grodberg, PhD, RAC has over 24 years of experience in the pharmaceutical industry, spanning the pre-IND enabling phase through NDA submission, including FDA pre-approval inspections and Advisory Committee Meetings. Prior to joining Forge, Jenny was VP, Regulatory Affairs at VenatoRx Pharmaceuticals, leading the successful IND filing and acquisition of both Qualified Infectious Disease Product and Fast Track designations for their lead β-lactam/ β-lactamase antibiotic program, VNRX-5133. She previously served as Senior Director of Regulatory Affairs at Trius Therapeutics, Inc., participating in the development and ultimate FDA approval of the oxazolidinone antibiotic, Sivextro. Before entering the pharmaceutical industry, Jenny held a faculty appointment at Harvard Medical School in the Department of Medicine. Jenny has a PhD in Microbiology and completed postdoctoral work at both the Weizmann Institute of Science in Rehovot, Israel

and at Harvard Medical School. For fun, Jenny enjoys the theatre and dance performances, plus she is an avid binge reader.

Natalie J. Kennel, RAC, ASQ CQE & CQMgr founded NJK & Associates to bring her practical perspective to medical device, quality, and regulatory affairs. With more than 30 years in the industry, mostly devoted to medical devices, Natalie has hands-on experience with development and manufacturing, as well as RA/QA and clinical roles in both major and start-up medical device companies. Natalie applies her expertise to the regulatory, quality, and clinical needs of medical device companies.

Since forming her consulting business in 2005, she has submitted more than thirty-five 510(k)'s, three de novo's, and more than 35 pre-submissions (including pre-IDE's). The types of products cover both medical devices and in vitro diagnostic devices; including, but not limited to, multiple orthopedic implants, intraocular lenses, infusion pumps, gynecological devices, complex medical monitoring and neurology equipment, software only products, 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. She has set up quality systems for several different companies and has provided on-going RA/QA for several companies. Natalie has prepared several international medical device submissions, including Canada, Australia, Europe, Singapore, Taiwan, and WHO. In addition, Natalie has set up quality systems and provided regulatory affairs support for a novel tissue bank.

Natalie has been published in RAPS regarding clinical trials for medical devices, and has spoken on multiple regulatory, quality, and clinical topics for SDRAN, ASQ, and ACRP. Since 2002, Natalie has taught the medical device submission section of the SDRAN US RAC study group. She also teaches a seminar regularly for the USC regulatory affairs master's program on software validation. She has organized and chaired several SDRAN and SDRAN/OCRA events including on IVD's, Corporate Compliance and Supplier Interactions. Natalie has previously been the President, President-elect, and Vice President of Programs for SDRAN. Natalie holds a BS degree in Chemical Engineering from the University of Rochester.

Malcolm Lloyd Smith has an honors bachelor's degree in pharmacology from the University of Leeds and a masters in pharmacological biochemistry from the University of Hatfield, both in the UK. He started his career in regulatory affairs with Bayer in the UK before joining the European office of DuPont Pharmaceuticals in Frankfurt, Germany. He then transferred to DuPont's office in Geneva, Switzerland, where he led the European Regulatory and QA organization. After 7 years in Switzerland, he moved to Delaware with the formation of the DuPont Merck Pharmaceutical Company, where he established an international regulatory function. Three years later, he returned to the UK as the VP of European Regulatory Affairs where he secured EU approval for a highly effective HIV treatment at a critical time in the AIDS epidemic. He remained with DuPont through the sale of the pharmaceutical business to BMS in 2001.

Malcolm then joined Elan Pharmaceuticals in the UK as the VP of International Regulatory Affairs, moving with them to San Diego as the VP & Head of Global Regulatory Affairs in 2004. During this time, he lived the "high" of the FDA approval of Tysabri, a highly effective monoclonal antibody for the treatment of multiple sclerosis, but 5 months later, he lived the "low" when it had its market withdrawal due to a serious safety issue. Malcolm left Elan in 2008 to join Cadence Pharmaceuticals in San Diego as Senior VP of Regulatory Affairs and QA, later expanding his role to cover all the development functions in the company plus medical affairs. Following FDA approval of the intravenous acetaminophen product, Ofirmev, and the sale of Cadence to Mallinckrodt in 2014, Malcolm joined Neurocrine Biosciences as Chief Regulatory Officer with responsibility for regulatory affairs, project management, QA, and medical writing. Ingrezza, approved by the FDA in 2017, was the first product to be approved for the treatment of tardive dyskinesia, an involuntary movement disorder. It was also Neurocrine's first product approval.

During his career Malcolm has built top performing regulatory teams both in the US and Europe, and has successfully filed and obtained approval for 17 BLA's, NDA's, or MAA's for both small and large molecules in the psychiatry, pain, addiction, cardiovascular, radiopharmaceutical, CNS, and HIV therapeutic areas.

Frank Pokrop has worked in the medical device arena for more than 20 years, and is employed at Sotera

Wireless in San Diego as the Senior Director for Regulatory Affairs and Quality Assurance. His prior experience covers manufacturing quality assurance for large and small volume parenteral drugs.

Frank's responsibilities cover: management of staff and budget, global submissions, worldwide regulatory intelligence, project management, auditing and compliance, recall management, and training. In one role with a Fortune 100 company, he was the formal liaison to the FDA and worldwide health agencies representing drugs, devices, IVD's, and infant formula, w he reported to a corporate officer.

A long-standing supporter of training and personnel development, Frank has spent a considerable amount of time in volunteer positions including: (1) being a member of MD&DI's Editorial Advisory Board from 2006 - 2016, (2) An officer and volunteer with SDRAN since 2010, and was President in 2017, (3) a member of the "B" IRB at UCSD since 2015, and, (4) has taught an introductory course on medical devices at UCSD since 2017. Frank is frequent contributor and speaker with ASQ and RAPS, both locally and at national meetings. While volunteering for SDRAN, Frank has organized seminars on jobs and careers, and has routinely assisted members with resumes, cover letters, and finding employment.

Frank holds the following certifications: RAC, CSQE, CISA and CPGP

Location: BD - directions on the next page of this flyer
3770 Torrey View Court
San Diego, CA 92130

To register for the meeting, click on this link to access the SDRAN registration system (123Signup) for this event.

*** **Please make your reservation early. The pre-registration due date is *Monday, 14 January 2019*. Advanced registration is appreciated to assist in event planning.**

On-line Registration:
$10 for SDRAN Members and Non-Members

On-site Registration:
$10 for SDRAN Members and Non-Members

For Questions Email: membership@SDRAN.org

Directions to BD:

From the North I-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 I-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