PROGRAM ANNOUNCEMENT

Wednesday, 19 August 2020

Monthly Program

The Rapidly Evolving Regulatory Landscape for the Biocompatibility Assessment of Medical Devices: What Regulatory Affairs Professionals Need to Know?

Program Speaker:

Ron Brown

Risk Science Consortium, LLC

Event Agenda:

DATE: **Wednesday**, **19 August 2020**

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

LOCATION: Not applicable - This is an ONLINE event

Click here to register for this event.

Program Topic:

The process by which medical devices are evaluated for biocompatibility is undergoing an exciting change; one in which methods like toxicological risk assessment, computational modeling, and *in vitro* test methods are being developed as alternatives to traditionally used methods that largely rely on the results of animal testing to predict the safety of devices in patients. Notable among these new approaches is the preferred use of chemical characterization and toxicological risk assessment of compounds extracted from the device as means to assess some biocompatibility endpoints. Although this new approach promises to be less burdensome and ideally more predictive of real-world device safety issues, use of a chemical characterization/risk assessment approach for the safety assessment of devices and combination products is associated with significant challenges.

This talk will outline what regulatory affairs professionals need to know about this new biocompatibility approach and will identify the new guidance documents and consensus standards that describe these methods. The talk will also identify the most common problems encountered when implementing the chemical characterization/risk assessment approach and will explore strategies for addressing these problems when responding to deficiency letters from the FDA.

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Speaker Biography:

Ron Brown is a toxicologist with 35 years of experience in regulatory toxicology and risk assessment. He recently retired from the US FDA after 25 years of service. Currently he directs a small company, Risk Science Consortium, LLC, that provides consultation and training in toxicological risk assessment and computational toxicology.

At the FDA, Ron was the senior toxicologist responsible for developing and reviewing toxicological risk assessments of extractable and leachable (E&L) compounds from medical devices. While at the FDA, he served in a number of leadership roles in standards development organizations. At the international level, he served for many years as convener of ISO TC194 WG11 which is responsible for the development and revision of the ISO 10993-17 standard, Biological evaluation of medical devices-Part 17: Establishment of allowable limits for leachable substances. At the national level, he represented the United States as an expert on ISO TC194 WG11 and served as co-chair of the AAMI Biological Evaluation Committee.

Prior to his position at the US FDA, Ron served as a Senior Associate at the ILSI Risk Science Institute. He is founding member and former President of the Medical Device and Combination Products Specialty Section of the Society of Toxicology and former President of the Dose-Response Specialty Section of the Society for Risk Analysis.

Registration Information:

Online registration ends Tuesday, 18 August 2020.

$10.00 SDRAN Member $10.00 Non-Member

For Questions Email: Programs.committee@sdran.org