WEBINAR

Nanomedicine Development: Lessons Learned, Approval Earned

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10 AM – 11 AM EDT

This webinar will highlight the unique challenges of nanomedicine development, including the complex characterization requirements for these formulations and the hurdles of regulatory review. Having characterized more than 400 nanomedicines of all platform types, the NCL has amassed a knowledge base of nano-strategies that progress through the “critical path”... and those that don’t. This talk will share some of the lesson learned for nanomedicines, how to identify critical quality attributes, and will attempt to de-mystify the regulatory requirements for nanomedicines. In addition, the presentation will highlight special considerations for the development and translation of follow-on, or generic, nanomedicines.

Scott McNeil is Director of the Nanotechnology Characterization Laboratory (NCL) for Leidos Biomedical Research and Frederick National Laboratory for Cancer Research, where he coordinates preclinical characterization of nanotech cancer therapeutics and diagnostics. The NCL tests candidate nanotech drugs and diagnostics, evaluating safety and efficacy, and assisting with product development -- from discovery-level, through scale-up and into clinical trials. NCL has assisted in characterization and evaluation of more than 400 nanotechnology products, several of which are now in clinical trials.

Dr. McNeil's professional career includes tenure as an Army Officer and as a Senior Scientist in the Nanotech Initiatives Division at Leidos where he transitioned basic nanotech research to government and commercial markets. He received his BS degree in chemistry from Portland State University and his PhD in cell biology from Oregon Health Sciences University.