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Engineering & Scientific Consulting

Nicholas Benetatos, Ph.D.

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Professional Profile

Dr. Nicholas Benetatos joined Exponent in 2019 bringing a wealth of knowledge and experience in regulatory affairs related to medical devices, combination products, pharmaceuticals and their associated underlying science. He advises clients on the strategic planning and the execution of important regulatory activities throughout the total product lifecycle including those impacting design and development, regulatory submissions, and post-market compliance.

Prior to joining Exponent, Nicholas held tactical and strategic regulatory affairs roles of key responsibility for large (Fortune 100) global business segments in the medical device and pharmaceutical sectors. In addition, Nicholas spent 7 years with the US-FDA Center for Devices and Radiological Health focused on regulatory science, regulatory review, and science-based decision making for total product lifecycle and public health issues. His experience has crossed a diverse range of disease states and technologies including: cardiovascular and interventional cardiology, orthopedics, ophthalmics, diabetes, drug-delivery systems, biodegradable implants, digital health solutions, wearables, pediatric devices, and active implantable electronic devices.

Nicholas is well versed in preparing regulatory submissions and providing stakeholders/customers with strategic direction and understanding of global regulatory landscapes, requirements, and risks. He has provided expert testimony and represented large organizations to health authorities - leading interactions, negotiations, and alignment regarding pathways for new product development, clinical, lifecycle management, and responses to review inquiries/deficiencies/audit findings etc. Device experience has included IDE, PMA, PMA supplements, 510k, CE marking, as well as early phase (IND, IMPD), registration (NDA, MAA), and post market support (sNDA) for drug-device combination products.

Nicholas received a PhD in Materials Science and Engineering from the University of Pennsylvania and has led multidisciplinary laboratory research in polymer science and regulatory science to further the understanding of the fundamental scientific issues that underlie regulatory decisions for new/emerging biomedical technologies. Laboratory work has investigated, for example, the complex inter-relationships between materials structure, manufacturing/processing methods, real-world performance, product safety/efficacy, and failure modes in materials, biomedical devices, and complex combination products.

Academic Credentials & Professional Honors

Ph.D., Materials Science and Engineering, University of Pennsylvania, 2006

M.S., Materials Science and Engineering, University of Pennsylvania, 2004

B.S., Physics, Saint Joseph's University, 2001

B.S., Chemistry, Saint Joseph's University, 2000

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Member of Sigma Xi - Scientific Research Honor Society

Member of Sigma Pi Sigma – University Physics Honor Society

Publications

Book Chapter

How FDA Really Works: Insights from the Experts: Chapter 7: Considerations for Combination Products, Edited by W.L. Pines and J.L. Zeller, 2022.

Benetatos N., Frohbergh M., Abraham S., Ong K. Development and Regulation of Innovations: In the Current State of Facts vs. Public Opinions, the Truth Does Not Always Prevail. Food and Drug Law Institute Updates Magazine, 2020.

Davis E.M., Benetatos N.M.*, Regnault W.F., Winey K.I., Elabd, Y.A.* The Influence of Thermal History on Structure and Water Transport in Parylene C Coatings Polymer 2011, 52, 5378-5386

Benetatos, N.M., Winey K.I., Nanoscale Morphology of Poly(styrene-ran-methacrylic acid) Ionomers: The Role of Preparation Methods, Thermal Treatments, and Acid Copolymer Structure Macromolecules, 2007, 40, 3223-3228.

Benetatos, N.M., Chan C.D., Winey K.I., Quantitative Morphology Study of Cu-neutralized Poly(styrene-ran-methacrylic acid) Ionomers: STEM Imaging, X-ray Scattering and Real-Space Structural Modeling. Macromolecules, 2007, 40, 1081-1088.

Benetatos, N.M., Heiney, P.A., Winey K.I., Reconciling STEM and X-ray Scattering data from a Poly(styrene-ran-methacrylic acid) Ionomer: Ionic Aggregate Size. Macromolecules, 2006, 39, 5174-5176.

Benetatos, N.M., Smith, B.W., Heiney, P.A., Winey K.I., Toward Reconciliation of STEM and SAXS Data from Ionomers by Investigating Gold Nanoparticles. Macromolecules, 2005, 38, 9251-9257.

Benetatos, N.M., Winey K.I., Ionic Aggregates in Zn- and Na-neutralized Poly(ethylene-ran-methacrylic acid) Blown Films. Journal of Polymer Science B: Polymer Physics 2005, 43, 3549-3554.

Selected Presentations

Benetatos N.M.., Van Trump J.I., “FDA and EPA Regulation of Antimicrobial Devices: Lessons Learned from the COVID-19 Pandemic.” Food and Drug Law Symposium - The Interconnected Regulatory Landscape: Exploring FDA’s Relationship with other Domestic Regulators, Webinar, 2022.

Benetatos N, Ong K. “Development and Regulation of Innovations: In the Current State of Facts vs. Public Opinions, the Truth Does Not Always Prevail.” Food and Drug Law Journal Symposium, Going Viral, Washington D.C., 2020.

Benetatos N.M. “Structure and Water Transport in Polymeric Coatings” McGroddy Frontiers in Science Invited Lecture, St. Joseph’s University, Philadelphia, PA, 2012Benetatos N.M., Winey K.I., et. al. “Quantitative Reconciliation of STEM and SAXS data from Ionomers.” American Physics Society, Baltimore, MD, 2006

Benetatos N.M., Winey K.I., et. al. “Toward Reconciliation of STEM and SAXS data from Ionomers by Investigating Gold Nanoparticles” American Physics Society, Los Angeles, CA, 2005

Benetatos N.M., Winey K.I., et. al. “Application of Analytical Electron Microscopy Methods in Ionomer

Systems: Using Nanoparticles to mimic Ionomer Morphology” Materials Research Society, Boston, MA, 2004

Benetatos N.M., Winey K.I., et. al. “Analytical Electron Microscopy Methods in Ionomer Systems” American Physics Society, Montreal QC, 2004