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Engineering & Scientific Consulting

Nicholas Benetatos, Ph.D.,

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Professional Profile

Dr. Nicholas Benetatos brings a wealth of knowledge and experience in medical devices, combination products, and global regulatory affairs. Prior to joining the practice, Nicholas led tactical and strategic regulatory affairs 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 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. Device experience has included class II and class III devices (IDE, PMA, PMA supplements, 510k, CE marking), while combination product experience included early phase (IND, IMPD), registration (NDA, MAA), and post market support (sNDA).

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 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

Member of Sigma Xi - Scientific Research Honor Society

Member of Sigma Pi Sigma – University Physics Honor Society

Publications

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 Poly(ethylene-co-vinylidene fluoride) 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.

Presentations

2012 McGroddy Frontiers in Science Invited Lecture, St. Joseph's University—Philadelphia, PA

“Structure and Water Transport in Polymeric Coatings”

2006 American Physics Society, Baltimore Md – “Quantitative Reconciliation of STEM and SAXS data from Ionomers.”

2005 American Physics Society, Los Angeles CA – “Toward Reconciliation of STEM and SAXS data from Ionomers by Investigating Gold Nanoparticles”

2004 Materials Research Society, Boston MA – “Application of Analytical Electron Microscopy Methods in Ionomer Systems: Using Nanoparticles to mimic Ionomer Morphology”

2004 American Physics Society, Montreal Qc – “Analytical Electron Microscopy Methods in Ionomer Systems”

Peer Reviewer

Macromolecules

Polymer

Journal of Polymer Science B: Polymer Physics