

## **Michael A. Santalucia**

**Michael A. Santalucia**, is the Vice President Global Regulatory Affairs for TerumoBCT, Inc. and is responsible for managing the global Regulatory Affairs function regarding the development and execution of product submission strategies for the company's medical devices, Regulatory compliance requirements and industry advocacy.

During his career Mike has develop global RA organizations, submission strategies, managed numerous regulatory body inspections and successfully addressed various compliance issues to resolution. Prior to TerumoBCT, Mike was the Regulatory Affairs Vice President for Terumo Cardiovascular Systems and the Vice President of Global Regulatory and Government Affairs for Bausch & Lomb, Inc. In each of his prior roles, Mike was responsible for global Regulatory Affairs management as well as Quality System management and compliance activities. He is familiar with global submission requirements including but not limited to: 510(k), PMA, IDE, CE Mark, as well as post market requirements. Mike is an active participant with various AdvaMed and industry working groups. He has participated in various international industry working groups, has been a member of standards committees and is an active contributor/speaker at industry forums. Mike holds a Regulatory Affairs Certification from RAPS and has a BS degree in Biology and Chemistry from LeMoyne College, Syracuse NY.