

**Tony Lubiniecki, ScD (USA)**

Board Member  
Treasurer



Anthony S. Lubiniecki, Sc.D, retired in May, 2017 as Senior Scientific Director & Fellow, CMC Strategy, Pharmaceutical Development & Manufacturing Sciences at Janssen R&D, LLC. During his 43 years in industry, he worked on development of over 50 recombinant derived investigational products using both microbial and eukaryotic expression systems, of which thirteen have become marketed products, including Simponi, Stelara, Sylvant, Tremfya, and Darzalez during his 13 years at Janssen R&D LLC. He also served as Vice President of Biopharmaceutical Development for GlaxoSmithKline, SmithKlineBeecham, and Smith Kline & French for 16 years, building a 400-person organization. He also spent 6 years at Genentech directing the development of tissue plasminogen activator and other recombinant DNA products in cell culture.

Tony also has been active in shaping regulatory policy by serving as a Pharmaceutical Research & Manufacturers of America representative to the International Conferences on Harmonization (ICH) Expert Working Groups for 6 Q5-Q7 guidance documents, and served as Rapporteur for two of them (ICH Q5D & Q5E). He has sat on review boards and advisory committees for the Department of Health & Human Services, Center for Biologics Evaluation & Research, and the National Academy of Sciences. He earned his Doctor of Science degree in Public Health Microbiology from the University of Pittsburgh in 1972, and his Bachelor of Science degree in Biological Sciences from Carnegie Mellon University in 1968. He is also Adjunct Professor of Chemical & Biochemical Engineering at University of Maryland Baltimore County since 1991.