Lisa Maffei Luther, MS
Head of Regulatory and Founder

Lisa Maffei Luther is Head of Regulatory and a founder of Advyzom. Lisa provides regulatory strategic leadership and guidance on global and US development programs to biopharmaceutical companies so they are best positioned to successfully navigate through complex and evolving regulatory requirements. Lisa serves numerous clients where she provides strategic leadership to develop IND filing, development and registration strategies and manages the IND and NDA/BLA submission and approval process. Lisa leads FDA milestone, critical issue and Type A meetings across FDA Centers, Offices and Divisions and has long-standing relationships with senior FDA leadership. She provides many successful clinical and regulatory solutions for Boards, CEOs, Heads of Development and Heads of Regulatory Affairs. Lisa provides high-level strategic guidance across drugs, biologics, drug/device combination products, targeted therapies in a multitude of disease areas. She has a special interest and expertise in the areas of rare diseases and serious and life-threatening illnesses where she leverages her experience in FDA's expedited development strategies and processes including accelerated approval, fast-track and breakthrough designations, orphan designations and QIDP.

Lisa has over 30 years of regulatory and clinical development experience in the pharmaceutical industry predominantly in Regulatory Affairs at Hoffmann-La Roche. Prior to founding Advyzom in 2011, Lisa was an Executive Director, North American Regional Head where she led the Oncology, Virology, Cardiovascular/Metabolism, Advertising/Promotion, REMS and Regulatory Intelligence/Policy areas. Her regulatory expertise is broad where she served in senior management roles of increasing responsibility including Regulatory Group Leader positions, Global Regulatory Leader and US Regulatory leader for NME and line-extension development programs in Inflammation, Infectious Disease, Neurology, Pulmonary, Transplant and Dermatology. Throughout her regulatory career, Lisa has filed and received approval for over 100 INDs, 70 NDAs and line-extensions and provided regulatory leadership to 15 drug approval or Risk Management FDA Advisory Committee meetings.

Lisa was the recipient of the YMCA TWIN Award (Tribute to Women in Industry) in recognition of her significant contributions as a professional woman. Lisa also received Roche's "Pharma Development's Leadership Award" for advancing Roche drug development by developing best in industry standards and best practices for driving successful IND filings and clearances.

Lisa earned her Master of Science (with Honors) in Pharmaceutical Administration from Long Island University and holds a Bachelor of Science in Biology (Summa Cum Laude) from Montclair State University. Lisa also participated in a leadership development program affiliated with the London School of Business.