

Donna E. Supko R.Ph., Ph.D.

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Dr. Donna Supko is an Executive Director of Regulatory Strategy at Advyzom, where she advises clients on high-level regulatory strategy from pre-IND through NDA/BLA and global submissions. Donna has more than 25 years of regulatory and drug development experience, including senior regulatory leadership roles at global pharmaceutical companies and emerging biotechs. She has guided clinical, nonclinical and CMC strategy for small molecules, biologics, devices (including Class III and companion diagnostics), combination products, cell and gene therapies, and radiopharmaceuticals. She has more than 17 years of experience in oncology, along with immunology, neurology, metabolic, endocrine, cardiovascular and infectious diseases, with a focus on rare and difficult-to-treat patient populations. Donna has played a key role in many US, EU and global marketing approvals. She has hands-on experience with Breakthrough Therapy, Fast Track and orphan designations, accelerated approval, and priority review. She has also led FDA Advisory Committee preparation and meetings with health authorities including FDA, EMA, PMDA, Health Canada and TGA.