

David Perez, B.S.

Senior Director, Regulatory Operations and Submissions

David Perez is a Senior Director of Regulatory Operations and Submissions at Advydom. David provides leadership and support by directly handling submissions to the FDA. He has a proven track record in delivering projects with strict deadlines on time. Additionally, he can provide pre-submission document publishing while working with clients and their submission vendors. David has the skill set to efficiently manage multiple projects in a matrix Global environment and interacts effectively with executives, regulatory agencies, vendors and staff. He is responsible for the planning and preparation of regulatory submissions and support formatting, organization and structuring of major submissions in eCTD format and submitting advertisement and promotional materials to the Office of Prescription and Drug Promotion (OPDP). He is knowledgeable in eSubmitter for Center for Veterinary Medicine(CVM).

David has 23 years of experience in the pharmaceutical industry with 16 years in Regulatory Operations and Submissions. His career began as a Clinical Laboratory Scientist at Roche Laboratories. He held positions within the Regulatory Submissions Group and Regulatory Program Management at Hoffmann La Roche Inc/Genentech Inc. Subsequent to Roche, David held leadership positions with Regulatory Operations at Mitsubishi Pharma and Chugai.

David has a BS in Biology from the University of Puerto Rico. David has outstanding working knowledge of document management systems, publishing software, and technical capabilities which include Accenture Quantum/ViewPoint, Lipient InSight Publisher/Viewer, ISI toolbox, Adobe Acrobat, SharePoint, Lorenz docuBridge, Documentum/First Doc, Adobe Acrobat Pro 7, 9, 10 and 11, Compose for PDF, Lifecycle Management, Word Templates, Lipient/Accenture templates, Microsoft Office Suite 2007/2010/2013, Filezilla FTP Transfer, and Electronic Submissions Gateway (ESG).