

ROBERT BATTISTA

Engineering Manager



As the Engineering Manager at Modality Solutions, Robert Battista works to provide technical and regulatory guidance on all client engagements for cold chain validation. He has a successful track record with regulatory filings including over 15 successful commercial filings in the US, Europe, the UK, and Brazil for biologics and advanced therapies. Robert is an industry expert at validation master planning and implementation during the clinical stage, pre-filing preparation, and post-filing/launch changes. His expertise also extends to transport simulation design and Performance Qualification best practices.

Robert has developed industry-best methodologies for all modalities of product in the biopharma space. He has led successful cold-chain validation efforts for cell and gene therapies, monoclonal antibodies, antibody drug conjugates, and small molecules in capsules and tablets. His achievements have led to industry recognition with a speaking role at the 2023 Supply Chain and Logistics for Cell Therapies Summit.

Robert's experience also extends to the execution of clinical trial operations in challenging environments. Most recently he served as a Subject Matter Expert (SME) in the Democratic Republic of the Congo (DRC). In this high-security risk environment, he and co-founder Dan Littlefield ensured that three active Ebola Treatment Unit pharmacy depots met FDA and other international regulations regarding best practices associated with cold chain product storage, distribution, monitoring/controls, and documentation. Emergency backup and contingency plans were developed for all sites with local personnel trained on the response procedures. Robert has also assisted in training local Ebola response staff members on cold chain procedures and fundamentals of understanding the use and maintenance of the critical equipment at the sites.

The skills learned in these challenging environments have also translated to success in improving cold chain operations for domestic operations such as warehouses and manufacturing facilities. Robert evaluates the readiness of both active and pending sites for cold chain operations by performing gap analyses and assessing the existing cold chain processes, including the qualification of refrigerators, freezers, and cold rooms. He then creates and enacts mitigation strategies for any identified gaps across the facility network.

Robert attended The Ohio State University where he received his Bachelor of Science degree in chemical engineering with a minor in physical geography. Robert is also an active member of ISPE.

Education

Bachelor of Science, Chemical Engineering

The Ohio State University

