

Micky Salgado-Gomez

When Micaela (Micky) Salgado-Gomez joined PharmaStat in 2012, she brought with her more than 14 years' experience in the biopharmaceutical industry — as a submission standards consultant, a statistical programmer, and an associate director of Statistical Programming.

Prior to joining PharmaStat, Micky worked at small pharma/biotech, mid-sized CRO, and large pharma companies. She has served as project manager as well as a statistical/quality control programmer in all clinical trial phases.

Micky's extensive experience with database integration includes working on a project to harmonize a decade's worth of legacy and current data for ongoing meta-analyses. Since 2006, she has been working with CDISC data standards where she has applied CDASH, SDTM, ADaM, and database documentation standards, such as blankcrf.pdf, and define.xml. Her project responsibilities also include planning, producing and overseeing deliverables.

Micky has conducted numerous training sessions about the theory and application of data standards for various technical audiences, including biometrics, clinical data management, and regulatory affairs. She is active in local biopharmaceutical industry users groups and CDISC. In 2011, she founded the San Diego CDISC Users Network (SDCUN) and is a frequent presenter on eCTD submission topics. Micky works out of PharmaStat's San Diego office.

Areas of expertise for Micky Salgado-Gomez:

- CDISC standards implementation
- eCTD strategies
- Production of Biometrics eCTD data and documentation
- Integration of databases
- Statistical programming
- Process planning
- Vendor selection oversight
- Management of outsourced projects

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