Edward H. Murphy

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Biostatistician, Statistical Programmer, Data Analyst, Quality Engineer, and Analytical Chemist

Summary of Expertise

- Safety and efficacy analyses (design, execution, and summary) of clinical trials for IPs and medical devices at all phases (I-IV, including integrated studies) in therapeutic areas of diabetes, oncology, neurology, hepatology, cardiovascular, respiratory, psychiatry, and vaccines
- Generation of TLFs, source datasets per CDISC standards, and all supporting documentation for inclusion in trial study reports per industry standards, guidance documents, and regulations
- Use of statistical methodology for design and analysis of laboratory studies: study design using DOE principles, including defining process space; stability analysis; analytical method comparison, qualification and validation; statistical process control; development of specifications and manufacturing controls
- Process improvement and validation for manufacturing pharmaceuticals, biologics, and medical devices using large datasets of historical process output
- Regulatory experience in NDA and BLA submissions (clinical and CMC), clinical trial protocols and reports, and SAPs
- Team leadership of cross-functional groups including clients and other external stakeholders

Statistical Methodology

Generalized Linear Mixed Models	ANOVA/ANCOVA	Multivariate Analysis
Survival Analysis	Crossover Trial Analysis	Randomization
Sample Size	Multiplicity/Interim Analysis	Subgroup Analysis
Binary Response Data Analysis	Stability Analysis	Monte Carlo Simulation
Design of Experiments	Bayesian Methodology	

Software/Programming

SAS	R	Python
MatLab	C/C ++/CUDA C	Visual Studio
Linux (multiple distributions)	Windows and Office Applications	Oracle Virtual Box
VBA	Shell Scripting	MapReduce with Hadoop

Analytical Chemistry Methodology

HPLC	CE	UV-Vis
ELISA	PCR	Competitive Binding
Radiochemical Purity	SDS-PAGE	IEF
Karl Fischer	TOC	BCA

Education

M.S., Statistics, San Diego State University (including classwork at Claremont Graduate University)
B.S., Neuroscience, University of Pittsburgh (Phi Beta Kappa)

Work Experience

Quality Statistical Consulting Owner, 2015-present	Consult on statistical projects in pharmaceutical industry
Agility Clinical, Inc. (Carlsbad, CA) Manager, Biostatistics, 2013-2015	Promoted from Biostatistician I to Manager within 9 months. Involved in all levels of statistical support for CRO, including project management for external and internal stakeholders. Main statistician for *ad hoc* project work due to skill set (education and industry experience). Worked independently from project initiation (SAP development) through project completion (data deliverables and summary reports).
Althea Technologies, Inc. (San Diego, CA) Supervisor, QC Stability, 2008-2013	Lead team of HPLC analysts within department that generated over USD 1 million annually in revenue. Responsible for design of hundreds of analytical method validation protocols for products at various stages of clinical development and assay development. Formalized method transfer and qualification procedure, including sample size calculations, testing for equivalence and mixed modeling procedures for variance components analysis. Utilized discrete (Poisson, negative binomial) and continuous models in the analysis of microbiological and particulate data to set action and alert limits for manufacturing process controls. Collaborated with analytical and product development group to institute study designs based on DOE principles for process optimization and analytical method robustness evaluation.
Favrille, Inc. (San Diego, CA) Quality Control Analyst IV, 2004-2008	Responsible for submission of all validation documents for BLA-related activities; author of additional submissions accepted by FDA related to manufacturing comparability study. Created and monitored statistical process control system for all relevant assays to determine assay acceptability, set system suitability specifications, and demonstrate lot conformance. Supported CMC submission. Supported investigations of out-of-specification results by supplying relevant statistical data and supportive analytical data.
Biogen Idec (San Diego, CA) Biochemist II, 2002-2004	Routine stability testing of immunological and radioimmunological products.
Matrix Pharmaceuticals, Inc. (San Diego, CA) Quality Control Chemist, 2001-2001	Routine laboratory testing of manufactured drug substances and drug products.