Xuesong Scott Li 9 Bartkus Farm, Concord, MA 01742 • Cell: (339) 221-2117 • scottli888@gmail.com

SUMMARY

Veteran statistician with 20+ years of experience in teaching and application of statistics. Passionate about mentoring to non-statistical professionals and arm then with tools that they understand.

EXPERIENCE HIGHLIGHTS

Senior Principal Statistician, Process Development, Shire Pharmaceuticals, Lexington, MA 02421. 2012 – Present
Duties: Responsible for Statistical support to pharmaceutical process development, drug formulation, analytical method development, quality control, manufacturing and regulatory filings.

- Established best practice of qualification and validation of analytical method. Applied statistics to bioprocess development. Designed experiment with adequate resolution and statistical power, identified critical variables, recommended operation ranges and acceptance criteria. Maximized effectiveness and minimized risks.
- Successfully developed a new statistical approach to resolve a long standing quality issue concerning stability of Primary Reference Standard (PRS). Developed a scheme and an algorithm for qualifying and monitoring future Reference Standards. Received approval with fully satisfactory comments from regulatory agencies.
- Identified root cause of increased invalid rate of a bioassay by analyzing data with right statistical tools. Proposed and validated solution (that reduced invalid rate from 38% to < 3%) and received approved from FDA.
- Developed Similarity Score that quantifies similarity between subjects that had only been "eye-balled". Utilized advanced mathematics and developed robust algorithm for the determination based on measurement.
- Developed maturity model for statistics with company; assessed status of understanding/application of statistics; laid out a road map to advance level of application of statistics with effectiveness, efficiency and risk reduction.
- Initiated/conducted very successful statistics training program within Shire. Significantly improved knowledge of statistics and understanding of ICH guidelines. Influenced strategic decisions by Leadership Team. Achieved measurable improvement in effectiveness and efficiency of drug development.
- Extensive teach and coaching. Training topics include DOE, comparability, stability, setting acceptance criteria, robustness, ANOVA, sample size and power calculations, multivariate regression (modeling), process characterization and simulations, interpretation of result and drawing conclusions. Ensured compliance with regulatory guidelines.
- Authored several internal guideline documents in areas of statistical analysis, DoE and comparability. Published monthly educational Statistics Corner articles.

Principal Process Engineer, R/D, Instrumentation Laboratory, Bedford, MA, 2009 – 2012
Duties: Technical lead role in development/improvement, validation and documentation of manufacturing process of sensors; Determine root cause and provide cost effective solutions in the timely manner. DFM. DFR.

- Developed a model/algorithm that resulted in a novel sensor to monitor UV curing of membrane on pO2 sensor; improved product yield from ~60% to high 90%. Optimized and validated process parameters (UV intensity, curing rate, temperature, uniformity, exposure time, etc.); implemented statistical process control.
- Identified root cause of bonding failure of sensors and solved a long-unsolved "mystery" regarding membrane performance and surface treatment. Implemented and verified solution.
- Mentored engineers/interns in statistics, modeling, troubleshooting techniques, math and physics.

Manager, Department of Product Support and Development, AgaMatrix Inc. Salem, NH. 2006 – 2008
Duties: Responsible for development of new products, support and improve existing products; Implement scientifically sound principles in product development, quality control and regulatory filings.

- Created a non-linear model (by solving physics based differential equation and analysis of clinical data) and provided guidance to resolving performance issues of BGM system and to manufacturing process, resulting in significant quality improvement and cost reduction. Extensive statistical analysis and data mining practice.
- Led the development of No-code blood glucose monitors, from concept to launch. Developed algorithm for signal processing/linearization; determined manufacturing metrics by modeling and statistical analysis. Analyzed clinical result, drew statistically sound conclusions and received FDA clearance. Completed project on time, on budget and to the spec.
- Identified root cause of very high type-I error (false positive) in statistical analysis of QC data. Introduced Bonferroni correction and reduced error from 32% to 3%.
- Streamlined QC process. Led cross-functional team to define goals, identify issues; designed and executed DOEs and statistical analysis; Optimized QC process (sampling procedure, range and sample size, regression techniques); validated and documented changes. Improved reliability and shortened process cycle by ~40%.

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Technology Leader, Department of Analytical Sensors, GE Sensing, Billerica, MA. 1999 – 2006
Duties: Responsible for new sensor development, including high accuracy oxygen (PPB), moisture (PPM and PPB), combustible gases, and ultrasonic flow rate measurement

- Developed Derivative Fast Response (predictive) Algorithm to overcome long-standing technical limitations of moisture sensors and created low cost solution for high end applications. Increased 20% revenue for Hygrometer product line.
- Developed physics based model for ITMS (Ion Trap Mobility Spectroscopy), and several algorithms/numerical methods for instrument calibration, statistical analysis and error propagation based on first principles. Extensive data tracking, experimentation on drug substance, statistical analysis/non-linear regression and mathematics.
- Developed a novel algorithm for volumetric flow-rate measurement (patented), conducted extensive simulation and testing for validation of the algorithm. Significantly improved accuracy demanded by increasingly challenging market.
- Developed the world's first ultrasound transducer that measures gas flow rate from the outside of the pipe. The development ensured GE Sensing's leadership position in ultrasound flow measurement market and generated hundreds-million dollar revenue. Received multiple awards from prestigious organizations.
- Taught statistics to Six Sigma Black Belts.

Senior Engineer/Physicist, Analogic Corporation, Peabody, MA. 1994 – 1999
Duties: Development of ultrasonic imaging transducers for OEM customers.

- Developed world-class ultrasonic array transducers for medical imaging applications using new piezoelectric composite material. Modeling and simulation of ultrasonic field profile guiding design of imaging systems.
- Played key role in development of Ultrasonic Immunoassay technology. Modeled backscattering profile of sound off blood cells.

EDUCATION AND CERTIFICATIONS

PhD in Physics, Brandeis University, Waltham, MA. 1992
Microstructure of materials, such as glassy polymers and high Tc superconductors using positron annihilation spectroscopy. Math modeling, Monte Carlo simulation and statistical analysis. Gamma ray detection, light scattering.
Published papers in peer reviewed journals
Post-Doctoral Associate, Mechanical Engineering, MIT, Cambridge, MA. 1991 – 1994
Studied microstructure of glassy polymers. Extensive statistical analysis and mathematical modeling. Taught and mentored students on variety of scientific subjects including statistics. Published papers in peer reviewed journals

Certificates
•Six Sigma Green Belt, 2002; •Design for Six Sigma (DFSS), 2005; •Project Management, 2004
Patents

- 5,853,994, Dec 29, 1998. Particle Agglutination Assay System
- 7,058,521, June 6, 2006. Low Power Ultrasonic Flow Meter
- 7,523,676, April 7, 2009. Ultrasonic Flow Rate Measurement Method and System