

Exponent®
Engineering & Scientific Consulting


# Martin Kane, M.S., CRE

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## Professional Profile

Mr. Kane provides consulting services related to analytics, statistics, and reliability engineering. He has extensive experience with product/process development and manufacturing in the fields of: biopharmaceuticals, consumer, optical fiber, telecommunications, electronic, commercial aircraft, and infant care products.

Mr. Kane's areas of statistical expertise include, response surface modeling (RSM), statistical process control (SPC), comparison testing, linear and logistic regression, Monte Carlo simulation and bootstrapping methods, failure modes and effects analysis (FMEA), and reliability analysis. He has particular expertise with design of experiments (DOE), measurement systems analysis (MSA), and exploratory data analysis.

Prior to joining Exponent, Mr. Kane was Director of Process Statistics at GlaxoSmithKline (formerly Human Genome Sciences, Inc.), where he provided statistical consultation services related to product and process development, assay development and validation, and analysis of manufacturing data. He was instrumental in developing a novel method for analyzing immunogenicity assay data, creating an intranet-based dashboard for simultaneously displaying multiple statistical control charts in the same window, and supporting the commercial approval of Benlysta (belimumab) and Abthrax (raxibacumab), products for the treatments of systemic lupus erythematosus and inhalational anthrax.

Mr. Kane also has extensive experience assembling and providing customized statistical training courses and he has been an invited speaker at more than 35 conferences. He has extensive knowledge and experience with JMP, the JMP Scripting Language (JSL), Minitab, R, Visual Basic (VB), and Visual Basic for Applications (VBA), and he is known to make full use of the VBA that is on the backside of Microsoft Excel and PowerPoint and JSL on the backside of JMP to automate analyses, simulations, or visualizations. He is also familiar with SAS, Weibull++, and S-Plus software for statistical and reliability analyses.

## Academic Credentials & Professional Honors

M.S., Mechanical Engineering, University of Arizona, 1994

B.S., Mechanical Engineering, University of Arizona, 1993

## Licenses and Certifications

ASQ Certified Reliability Engineer (CRE)

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## Prior Experience

Director of Process Statistics, GlaxoSmithKline (Formally Human Genome Sciences, Inc), 2002-2012

Statistical Consultant and Reliability Engineering Specialist, 3M, 1995-2002

Reliability and Maintainability Engineering Intern, Boeing, 1994

Mechanical Engineering Intern, Kimberly-Clark, 1991 and 1992

## Professional Affiliations

American Society for Quality - ASQ (senior member)

## Publications

Fairman J, Agarwal P, Barbanel S, Behrens C, Berges A, Burky J, Davey P, Fernsten P, Grainger C, Guo S, Iki S, Iverson M, Kane M, Kapoor N, Marcq O, Migone T, Sauer P, Wassil J. Non-clinical immunological comparison of a Next-Generation 24-valent pneumococcal conjugate vaccine (VAX-24) using site-specific carrier protein conjugation to the current standard of care (PCV13 and PPV23), Vaccine, Volume 39, Issue 23, 2021; 3197-3206.

Kumar S, DelCarpini J, Qu Q, Kane M, Gorovits B. Mitigation of pre-existing antibodies to a biotherapeutic in non-clinical species when establishing anti-drug antibody assay cutpoint. AAPS Journal 2017; Volume 19, Issue 1:313-319.

Grillo A, Kane M, Penn N, Perkins M. Characterizing the formulation design space. Biopharm International 2010; 23(3):30-39.

Kane M. Weibull analysis: A call for standardization. Proceedings, SPIE - The International Society for Optics and Photonics 2000; 4215:98-108.

Sloan D, Le Blanc S, Kane M. UV exposure and the tensile strength of optical fiber. Proceedings, SPIE - The International Society for Optics and Photonics Vol. 4215, pp. 191-200, 2000.

**Presentations**

Kane M. Dose-Response Curve Fitting for Ill-Behaved Data. Americas 2020 JMP Discovery Summit Conference, online (due to COVID-19), October 12-16, 2020.

Kane M. Integration of JMP with PowerPoint using Scripting and VBA. JMP Discovery Summit 2019 Conference, Tucson, AZ, October 15-18, 2019.

Kane M. Analytic Similarity: A Review of the FDA Draft Guidance on Evaluating Analytic Similarity. The 10th Annual CHI Immunogenicity and Bioassay Summit, Alexandria, VA, October 22 - 25, 2018.

Kane M. Parallelism and Constraining Curves: The 4-Parameter Logistic Function. The 9th Annual CHI Immunogenicity and Bioassay Summit, Alexandria, VA, October 23 - 26, 2017.

Kane M. Hosted Roundtable on Holistic Statistical Tools and Advancing Biomanufacturing. Cell Culture World Congress, San Diego, CA, May 24, 2017.

Kane M. Design of Experiments (DOE) for Product and Process Development. The 8th Annual CHI Immunogenicity and Bioassay Summit, Baltimore, MD, October 26 - 28, 2016.

Kane M. DOE and Predictive Modeling to Improve Decision on the Manufacturing Floor,. The 12th Annual IBC BioProcess International (BPI) Conference & Exhibition, Boston, MA, October 4 - 7, 2016.

Kane M. Characterization and Optimization for Quality-by-Design Using Design of Experiments. 11th Annual IBC BioProcess International (BPI) Conference & Exposition, Boston, MA, October 26 - 29, 2015.

Chunyk A, Spriggs F, Tabora J, Kane M, DelCarpini J, McCormack D, Kirchberg C, and Sokolnicki A. Workshop on Design of Experiments for Bioanalysis and Manufacturing, AAPS National Biotechnology Conference, San Francisco, CA, June 7-10, 2015.

Kane M. Risk-Based Approach to Immunogenicity Workshop and Characterization and Optimization Using Design of Experiments, IIR's 15th Annual Immunogenicity for Biotherapeutics, Boston, MA, October 20-22, 2014.

Arndt S. and Kane M. Product Safety from Concept to Mass Production. The 9th Annual Midwest Product Safety & Liability Prevention Conference, Chicago, IL, June 20-21, 2013.

Kane M. Statistical process control for assay development. 12th Annual CHI PepTalk: Formulation, Palm Springs, CA, January 21-25, 2013.

Kane M. Design of experiments—The primary tool in quality-by-design. American Society for Quality, Section 509, Biomed/Biotech meeting, Rockville, MD, December 6, 2012.

Kane M. How to develop a valid cutpoint—A cautionary tale. 8th Annual Bioassays and Bioanalytical Method Development, Berkeley, CA, October 1-3, 2012.

Kane M, Kubiak R, Zhang L. Intensive skill-builder for statistical analysis. 13th Annual Immunogenicity for Biotherapeutics, Baltimore, MD, April 17-19, 2012.

Kane M. Minimize error potential through firm establishment of acceptance criteria, baselines, cutpoints, and outliers. 7th Annual Cell Based Assays and Bioanalytical Method Development, Berkeley, CA, October 3-5, 2011.

Kane M. DOE 101: The basic principles of design of experiments. CHI The Bioprocessing Summit 2011, Boston, MA, August 22-25, 2011.

Kane M. Characterization and optimization using design of experiments. 34th Annual Midwest Biopharmaceutical Statistics Workshop, Muncie, IN, May 23-25, 2011.

Kane M. DoE 101: Basic principles of design of experiments. AAPS National Biotechnology Conference, San Francisco, CA, May 16-18, 2011.

Kane M. Validation methods for new critical reagents into assays—A round table discussion. 12th Annual Immunogenicity for Biotherapeutics, Washington, DC, April 4-6, 2011.

Van der Haegen B, Kane M. DoE and QbD: tools for optimizing the bioprocess. 10th Annual CHI PepTalk: Short Course, San Diego, CA, January 9-14, 2011.

Kane M. Statistical approaches for appropriate cut point determination. 6th Annual Cell Based Assays and Bioanalytical Method Development, San Francisco, CA, October 4-6, 2010.

Kane M. Use of DOE to determine process parameters for a robust design space in the formulation of a biopharmaceutical product. BioProcess International, Providence, RI, September, 20-24, 2010.

Kane M. Cut point for screening and confirmatory assays. 5th Annual Cell Based Assays in Drug Development for Biopharmaceuticals, Berkeley, CA, October 5-7, 2009.

Kane M. Clarify data and statistical analysis tool for cell based assays. 5th Annual Cell Based Assays in Drug Development for Biopharmaceuticals, Berkeley, CA, October 5-7, 2009.

Kane M. A discussion of the four-parameter logistic function. 10th Annual Immunogenicity for Biotherapeutics, San Diego, CA, May 4-6, 2009.

Kane M, Coleman D, Marsden R. Novel methods for improved statistical analysis. 10th Annual Immunogenicity for Biotherapeutics, San Diego, CA, May 4-6, 2009.

Kane M. Analysis of validation data. 13th Annual International Process Validation for Biopharmaceuticals, Carlsbad, CA, March 2-3, 2009.

Kane M. Statistical process control for improved assay development production and transfer. 4th Annual Cell Based Assays in Drug Development for Biopharmaceuticals, San Francisco, CA, October 6-8, 2008.

Kane M. Introduction to DOE concepts, steps and analysis. 3rd Annual IBC BioProcess International Analytical and Quality Summit, Cambridge, MA, June 2-4, 2008.

Kane M. Cut point determination when your data are not normal. 9th Annual Immunogenicity for Biotherapeutics, McLean, VA, May 19-21, 2008.

Kane M. Overview of commercial off the shelf statistical software packages. 3rd Annual Cell Based Assays in Drug Development for Biopharmaceuticals, Berkeley, CA, October 1-3, 2007.

Kane M. Effective statistical analyses: using benchtop tools, in-house statistician support and consultants. IBC Analytical Method Validation, June 4, 2007.

Kane M. Compare and contrast white paper screening cut point calculations. 8th Annual Immunogenicity for Biotherapeutics, San Diego, CA, May 8-10, 2007.

Kane M. Compare and contrast white paper screening cut point calculations for immunogenicity assays. SWE Strategies and Techniques for Immunogenicity Testing, San Diego, CA, March 8-9, 2007.

Kane M. Simplifying statistical analysis of cell based assay data for assay troubleshooting. 2nd Annual Cell Based Assays in Drug Development for Biopharmaceuticals, San Francisco, CA, October 4-6, 2006.

Kane M. Leveraging experimental design in process validation. 10th Annual IBC Process Validation for Biologicals, Carlsbad, CA, February 27-28, 2006.

Kane M. Scripting JMP for automated analysis of factorial design of experiments. 2nd Annual JMP Users Conference, Cary, NC, June 7-8, 2005.

Kane M. Utilizing measurement variability to set internal specifications. 8th Annual IBC Process Validation for Biologicals, March 7-8, 2005.