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**PROFESSIONAL SUMMARY**

Over 18 years as a Chemistry, Manufacturing, and Controls (CMC) statistics specialist to support drug development and manufacturing. Highly familiar with regulatory guidance and international standards, experienced in US and global regulatory submissions. Member of the USP Statistics Expert Committee since 2020.

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**PROFESSIONAL EXPERIENCE**

**Amgen Inc., Remote** Jan 2022 - Current  
*Principal CMC Statistician*

- Contribute to replies to questions from international regulatory agencies
- Developing SAS code to generate “automated” reports for several types of statistical analyses

**Akebia Therapeutics, Remote** Sep 2021 – Dec 2021  
*Associate Director, Head of CMC Statistics*

- Assisted in the development of the Continued Process Verification program for Auryxia® and Vadadustat

**Seagen Inc., Bothell, WA** Oct 2015 – Sep 2021  
*Senior Principal Scientist, CMC Statistics Mar 2019 – Sep 2021*  
*Principal Scientist, CMC Statistics Oct 2015 – Mar 2019*

- Performed statistical assessments to support regulatory filings, including approval of TUKYSA® under FDA initiative Project Orbis
- Developed and implemented the statistical strategy for Continued Process Verification of Seagen's three commercial products: ADCETRIS®, PADCEV® and TUKYSA®

**Juno Therapeutics, Seattle, WA** Jan 2015 - Oct 2015  
*Principal Non-Clinical Statistician*

- Contributed to CMC statistical topics in the Process and Analytical Development, then Biometrics group
- Performed graphical and statistical analyses to assist in technology transfer activities and determination of specification acceptance criteria

**Amgen Inc., Seattle, WA** Sep 2006 - Dec 2014  
*Principal Quality Engineer Mar 2009 – Dec 2014*  
*Senior Quality Engineer Sep 2006 – Mar 2009*

- Contributed to the development of Amgen's biosimilar program, including a face-to-face discussion in June 2014 with the FDA on statistical strategies for Tier 1-3 biosimilarity assessments
  - Authored content for regulatory filings including marketing applications
  - Generated SAS code, executed and documented calculations for multiple analyses including comparability and specification acceptance criteria determination, and shelf-life extensions
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**TEACHING EXPERIENCE**

**University of Washington, Seattle, WA** Jan 2015 - Mar 2020  
*Affiliate Assistant Professor*

- Statistical Topics for Regulatory Affairs Professionals, Jul 2016 – Mar 2020
- Statistics and Experimental Design, Jan 2015 – Mar 2017

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## EDUCATION

Master of Science in Quality Management and Productivity, University of Iowa, Iowa City, USA

Bachelor of Science in Mathematics with Economics, University of Strathclyde, Glasgow, UK

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## SELECTED PUBLICATIONS

All publications listed at [cmcstatistics.com](http://cmcstatistics.com)

- Bower, Keith M. 2000. "Using Exponentially Weighted Moving Average (EWMA) Charts." Asia Pacific Process Engineer.
- Bower, K.M. and Touchton, M.E. 2001. "Evaluating the Usefulness of Data Using Gage Repeatability and Reproducibility." Asia Pacific Process Engineer.
- Bower, Keith M. 2001. "Using CUSUM Charts to Detect Small Process Shifts." International Society of Six Sigma Professionals: EXTRAOrdinary Sense 2, no. 3: 1; 8.
- Colton, J.A. and Bower, K.M. 2002. "Some Misconceptions about R-Square." International Society of Six Sigma Professionals: EXTRAOrdinary Sense 3, no. 2: 6-7.
- Bower, Keith M. 2003. "Some Misconceptions about the Normal Distribution." American Society for Quality: Six Sigma Forum.
- Gorman, D. and Bower, K.M. 2002. "Measurement System Analysis and Destructive Testing." American Society for Quality: Six Sigma Forum Magazine 1, no. 4: 16-19.
- Bower, Keith M. 2003. "When to Use Fisher's Exact Test." American Society for Quality: Six Sigma Forum Magazine 2, no. 4: 35-37.
- Tebbs, J.M. and Bower, K.M. 2003. "Some Comments on the Robustness of Student t Procedures." Journal of Engineering Education 92, no. 1: 91-94.
- He, F., Woods, C.E., Trilisky, E., Bower, K.M., Litowski, J.R., Kerwin, B.A., Becker, G.W., Narhi, L.O. and Razinkov, V.I. 2010. "Screening of Monoclonal Antibody Formulations based on High-Throughput Thermostability and Viscosity Measurements: Design of Experiment and Statistical Analysis." Journal of Pharmaceutical Sciences, Vol. 100 No. 4: 1330-1340.
- Bower, K.M., Germansderfer, A., Kerwin, B.A., Kleemann, G.R., and J.R. Litowski. 2011. "Designed Experiments with Binary Responses." Journal of Pharmaceutical Sciences, 100: 5078-5079.
- Bower, Keith M. 2012. "Practical Interpretation of Equivalence Acceptance Criteria." Genetic Engineering and Biotechnology News, Vol. 32, No. 4.
- Bower, K.M. and A. Germansderfer. 2012. "Assessing Comparability Based on Limited Data." Quality Progress.
- Coffey, T. and Bower, K.M. 2017. "A Statistical Approach to Assess and Justify Potential Product Specifications." BioProcess International.
- Bower, Keith M. 2018. "The Relationship between R-Square and Precision in Bioassay Validation." BioProcess International.
- Bower, Keith M. 2018. "Statistical Assessments of Bioassay Validation Acceptance Criteria." BioProcess International.
- Bower, Keith M. 2018. "Certain Approaches to Understanding Sources of Bioassay Variability." BioProcess International.
- Bower, Keith M. 2019. "Determining Control Chart Limits for Continued Process Verification with Autocorrelated Data." BioProcess International.
- Bower, Keith M. 2020. "Biopharmaceutical Product Specification Limits and Autocorrelated Data." BioProcess International.
- Bower, Keith M. 2020. "Run Rules with Autocorrelated Data for Continued Process Verification." BioProcess International.
- Bower, Keith M. 2020. "Practical Considerations for Statistical Analyses in Continued Process Verification." BioProcess International.
- Bower, Keith M. 2021. "Using Prior Knowledge to Estimate Long-Term Variation." BioProcess International.
- Bower, Keith M. 2022. "Appropriate Estimation of Long-Term Variability: Using Biopharmaceutical Release and Stability Data." BioProcess International.
- Bower, Keith M. 2023. "Analytical Method Precision Comparisons—A Special Case." USP Stimulus Article.