DAVID LeBLOND

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CMC Biostatistician with 33 years industrial experience
in medical device and pharmaceutical R&D

Education:

2005	MS	Statistics	Colorado State University
1981	Ph.D	Biochemistry	Michigan State University
1974	MS	Dairy Science	University of Illinois
1971	BS	Chemistry	University of Illinois

Experience (Abbott/ Abbvie):

2012-present
CMC Statistics
Private Statistical Consultant
CMC Statistics, biosimilarity, drug stability, dissolution, analytical methods, validation, Bayesian methods

2009-2012
Drug Discovery
Principle Research Statistician
Bioassay development and optimization. Design and analysis of animal (pain, neurochemistry, cancer) model studies.

1997-2009
CMC R&D
Principal Research Statistician
Optimization and validation of pharmaceutical processes and analytical methods. Stability analyses. Sampling plan development. Application of Bayesian Methods in CMC,

1995-1997
In vitro diagnostics
Senior Statistician, Rare reagents manufacture
Cell culture monoclonal antibody process optimization and control. Design and analysis of test method and process validations.

1993-1995
In vitro diagnostics
Senior Statistician
Nucleic Acid Probe Diagnostic Business Unit. Study, design and analysis; clinical data management and preparation of graphics and reports for 3 new gene probe diagnostic products. FDA 510 (k) submissions. Management of SAS local area network system. Support to QC organization.

1991-1993
In vitro diagnostics
Statistical Consultant and Trainer
Diagnostics R&D Staff. Development of agenda, presentation materials, course booklet and computer exercises. Training of 300+ scientists and engineers. Design and analysis of process characterization and improvement studies. Pre-clinical statistical support. Technical service award in 1993.

1989-1991
Senior Research Scientist

In vitro diagnostics	Divisional R&D. Optimization of agglutination assay technology. Development of imaging system and data reduction for QC testing. Analysis of research clinical trials.
1987-1989	**Senior Systems Analyst**
In vitro diagnostics	Divisional R&D. Writing and validation of software design specifications for new diagnostic instrumentation. Development of algorithms for image analysis and assay data reduction. Outstanding performance evaluation. Promotion to senior scientist.
1981-1987	**Biostatistician**
In vitro diagnostics	Department of Biometrics, Divisional R&D. Pre-clinical and clinical statistical support. Writing of FORTRAN response surface analysis package. Experimental design course to 200+ Abbott scientists and engineers. $1,000 service award.
1979-1981	**Biochemist**
In vitro diagnostics	Physiology Diagnostics Venture. Kinetic modeling and optimization of enzymatic assay technology.

AFFILIATIONS:

American Statistical Association
American Association of Pharmaceutical Scientists
Member PhRMA statistical expert team (2000-2011)
Editorial Staff of Journals of Validation Technology, GxP Compliance, Statistics in Biopharmaceutical Research (2007-present)
USP Statistics Expert Committee (2011-present)

PUBLICATIONS:

40+ professional publications in various areas of Statistics, Pharmaceutical Science, Biochemistry and Clinical Chemistry (list available upon request). 2008-2013 publications listed below.

1. Gregory P Martin, et al. Lifecycle Management of Analytical Procedures: Method Development, Procedure Performance Qualification, and Procedure Performance Verification
2. Burdick RK, LeBlond D, Sandell D, Yang H. Statistical methods for validation of procedure accuracy and precision. Pharmacopeial Forum. 2013; 39(3).
3. LeBlond, David, Tan Charles, Yang, Harry (2013) Confirmation of Analytical Method Calibration Linearity, Pharmacopeial Forum, 39(5)
4. LeBlond, David, Tan Charles, Yang, Harry (2013) Confirmation of Analytical Method Calibration Linearity: Practical Application, Pharmacopeial Forum, 39(5)
5. Leslie Alessandri; Aima Acquah; Taro Fujimori; David Leblond; David Ouellette; Czeslaw Radziejewski; Mathew Rieser; Mary Saltarelli; Ivan Correia Increased serum clearance of oligomannose species present on a human IgG1 molecule. mAbs 2012;4(4):509-20.

6. Mockus L, LeBlond D, Basu PK, Shah RB, Khan MA (2011) A QbD case study: Bayesian prediction of lyophilization cycle parameters. AAPS PharmSciTech. 2011 Mar;12(1):442-8.
7. LeBlond, D, Griffith, D, and Aubuchon, K (2011) Linear Regression 102: Stability Shelf Life Estimation Using Analysis of Covariance, JVT 17(3), 47-68
8. LeBlond D (2010) FDA Statistics Guidance for Medical Device Clinical Trials – Application to Process Validation, JVT 16(4) 24-33
9. Smith, P, and LeBlond, D (2010) Sampling Error #10 – Data Error, JGxP 14(2) 83-92
10. LeBlond, D (2010) Review of the CDRH/ CBER Bayesian Guidance, JGxP 14(2) 53-59
11. LeBlond, D. (2009) Statistical Design and Analysis of Long-term Stability Studies for Drug Products, Chapter 23 in DEVELOPING SOLID ORAL DOSAGE FORMS: PHARMACEUTICAL THEO RY AND PRACTICE , pp539-561, edited by Yihong Qiu, Yisheng Chen, Geoff G.Z. Zhang, Lirong Liu, and William Porter, Academic Press, NY
12. LeBlond, D. (2009), "Understanding Hypothesis Testing Using Probability Distributions," Journal of Validation Technology, Vol. 15, No.1, pp 44-61, Winter 2009.
13. LeBlond, D. (2009), Risk Assessment of Drug Product Content Uniformity Release Failure: A Bayesian Approach, Presented at The American Statistical Association Joint Statistical Meeting, Washington, DC, August 1 - 6
14. LeBlond, D. (2009), Dissolution stability of a modified release product: A multivariate Bayesian approach, presented at the 32nd Midwest Biopharmaceutical Statistical Workshop, Muncie, IN, May 19
15. LeBlond, D. (2009) Hypothesis testing in pharmaceutical process and analytical development, Journal of GxP Compliance Vol. 13 Summer, pp 1-13.
16. LeBlond, D. (2008), "Data, Variation, Uncertainty, and Probability Distributions," Journal of GXP Compliance, Vol. 12, No. 3, pp 30-41, Spring
17. LeBlond, D. (2008) "Estimation: Knowledge building with probability distributions (Reader Q&A) Journal of validation technology, vol 12 Autumn
18. LeBlond, D. (2008), "Using Probability Distributions to Make Decisions," Journal of Validation Technology, Spring , pp 2 – 14,
19. LeBlond, D, Chang, M., Lin, T., El-Shourbagy, T. (2008) A statistical sampling approach to repeatability in bioanalysis, Oral presentation at Bioanalysis in Clinical Research, February 20, London.
20. Xuesong Liu; Joann Palma; Robert Kinders; Yan Shi; Cherrie Donawho; Paul A Ellis; Luis E Rodriguez; Milagros Colon-Lopez; Mary Saltarelli; David LeBlond; C Thomas Lin; David Frost; Yan Luo; Vincent L Giranda An enzyme-linked immunosorbent poly(ADP-ribose) polymerase biomarker assay for clinical trials of PARP inhibitors. Analytical biochemistry 2008;381(2):240-7.