Curriculum Vitae

Lawrence Charles Dumont

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Summary

I have over 30 years diversified industry experience in pharmaceutical and diagnostic biotechnology product development. My scientific expertise includes biological, immunological, and physico-chemical analytical methods development. These methods have been applied to a wide range of areas including biopharmaceutical process development, non-clinical and clinical assays, protein and peptide characterization, and formulation and stability protocols. I have also developed *in vitro* devices for diagnostic testing. I have supervised, managed, or directed both small and large scientific staff in a variety of settings and have an outstanding record of success in achieving corporate goals. I am currently a bioanalytical consultant serving clients in the greater Boston Area and on the West Coast. My career objective is to continue to apply my technical expertise, excellent communication, team building, and leadership skills while contributing to the overall success bringing biotechnology products to market.

Employment History

BioSense Consulting Services, Newcastle, ME, formerly located San Ramon, CA (2002 to present)

Principal, Bioanalytical Consultant, Skills and Services Listed:

- Interim Management
  - Quality Control Manager
  - Analytical Development Director
  - Formulation Development Manager

- CRO Management
  - PK, Anti-Drug Antibodies, and Neutralizing Antibody Assays
  - Manage interface for three clients
  - Manage interface at three CROs
  - cGMP and GLP operations

Employment History (continued)

- Method/Instrument Validation
  - Prepared method qualification/validation protocols and reports
  - Prepared instrument qualification protocols and reports
  - Reviewed method and instrument validation packages for compliance
  - Prepared gap analyses with remediation plans

- Process Validation
  - Sampling plans
  - Analytical methods validation/compliance
  - Acceptance criteria review and justifications

- Regulatory Submissions
  - CMC sections for several INDs
  - CTD formatted CMC sections for BLA

- Analytical Development

  HPLC
  - Cation and Anion Exchange Chromatography
  - Size Exclusion Chromatography
  - Surfactant Analysis with Fluorescence Detection

  Capillary Electrophoresis
  - SDS-CGE
  - cIEF

  Enzyme Assays
  - Free drug in human serum
  - Drug activity assays

  Biological Assays
  - Drug Potency
  - Neutralizing Antibody

- Formulation Development (liquid dosage form for biologics)
  - Excipient Selection
  - pH and Solubility Optimum
  - Design of Experiments

Nuvelo, Inc., San Carlos, CA (September 2007 to March 2008)

Senior Director, Analytical Sciences

Directed a department with three main analytical functions: Characterization and Method Development, Bioanalytical Development, and Quality Control. Managed contract research organizations (CROs) to support characterization, lot release and stability testing, and non-clinical and clinical assays to support several protein and oligonucleotide therapeutics.

Employment History (continued)

Planned and implemented department budgets. Planned and implemented regulatory strategies and prepared regulatory document sections relating to the analysis of product quality attributes for biopharmaceuticals. Hired and maintained highly capable and motivated staff to achieve corporate and department goals and objectives.

Protein Design Labs, Inc., Fremont, CA (1992 to 2002)

Director, Analytical and Formulation Sciences, (April 1998 to February 2002)

Directed a department with four main functions: Protein Analytical Chemistry, Formulation Development, Bioanalytical Development, and GLP Assay Services. The department had a total of 30 scientific staff including six Ph.D. scientists. I was responsible for protein characterization and formulation development for early and late phase clinical studies including IND submissions. I was responsible for documenting key product development activities. I directed the development of bioanalytical methods for product quality, product impurities, product degradants, and product stability. I also established and directed the GLP assay services lab supporting non-clinical and clinical studies. I also maintained an annual operating and capital budget in excess of $2 million. During my career at Protein Design Labs, I participated in preparing relevant sections of two IND submissions, three IND amendments, one Type II Drug Master File (DMF) and three Clinical Trial Exemptions (CTX) with corresponding variations.

Associate Director, Bioanalytical Sciences, (August 1997 to April 1998)

Directed an analytical department with two main functions, biological and immunological development, and assay services (GLP operation). Directed a total of thirteen people, including two Ph.D. scientists. Responsibilities included providing validated analytical methods to the Quality Control laboratory for product identity, potency, trace impurities, and equipment cleaning validations. Many of these methods were used for lot release and stability programs. Also was responsible for developing GLP quality methods for pharmacokinetic, safety, and metabolism studies in animals and people. Immunochemical analyses were used to support non-clinical and clinical studies and were performed routinely according to GLP guidelines. Responsibilities also included deriving product testing strategies, analytical equipment purchases, and department budgets. Other responsibilities included written and verbal communications with the FDA including preparation of major portions of CMC and safety sections of IND submissions.

Senior Scientific Manager, Pharmaceutical Development, (November 1995 to August 1997)

Organized and managed a growing department including assay development and methods implementation. Developed and organized systems for method development, qualification, and transfer to Quality Control. Set up GLP systems including methods and documentation to support IND-enabling safety studies and clinical programs. Responsible for growing the department from 5 to 10 people while managing multiple projects. Involved in documentation for submission to the FDA for two major manufacturing IND amendments and one IND submission.

Employment History (continued)

Scientist, Process Development, (November 1992 to November 1995)

Designed and developed immunological and biological assays to support product lot release, stability, and safety studies for phase I clinical development. Methods development included ELISA, RIA, cell binding FACS, HPLC, and many related techniques. Developed assays to measure product potency, purity, consistency, and microheterogeneity. Methods supported fermentation, purification, formulation, quality control, and both non-clinical and clinical development activities. Managed a group of approximately five people.

SmithKline Beckman, Inc., (1985 to 1992)

Senior Scientist, Product Development, SmithKline Diagnostics, Inc., San Jose, CA (a subsidiary of Beckman Instruments, Inc.), (July 1990 to November 1992)

Applications Chemist, Beckman Instruments, Inc., Palo Alto, CA
(October 1987 to July 1989, includes a short hiatus)

Research Scientist, SmithKline Diagnostics, Inc., Sunnyvale, CA (January 1985 to October 1987)

Hygeia Sciences, Inc., Newton, MA, (formerly BTC Diagnostics, Inc.) (1984 to 1985)

Atlantic Antibodies, Inc., Scarborough, ME, (1982 to 1984)

Education

Bachelor of Arts, Biology
Secondary Education Teaching Certification in Biology/Chemistry
Colby College, Waterville, ME
1982

Continuing Education
Immunology / Molecular Biology / Biochemistry / Molecular Pharmacology
UC Berkeley Extension, Berkeley, CA (1986-1995)
Computer Information Systems for Managers / Introduction to Quantitative Business Methods
California State University in Hayward (2002)

Trained in cGMP, GLP, and GCP

Professional Memberships

American Association of Pharmaceutical Scientists
American Association for Clinical Chemistry

Publications

J.G. Jurcic, T. DeBlasio, L. Dumont, T.J. Yao, and D.A. Scheinberg, "Molecular remission induction with retinoic acid and anti-CD33 monoclonal antibody HuM195 in acute promyelocytic leukemia," Clinical Cancer Research, (2000) Feb; (6) 372-380.

G. Schlag, H. Redl, G.O. Till, J. Davies, U. Martin, and L. Dumont, "Anti-L-selectin antibody treatment of hemorrhagic-traumatic shock in baboons," Critical Care Medicine, (1999) Vol.27, No. 9, 1900-1907.

Yu Fang, Larry Dumont, and Brent Larsen, "Real-time isoform analysis by two-dimensional chromatography of a monoclonal antibody during bioreactor fermentations," Journal of Chromatography A, 816 (1998) 39-47.

P.C. Caron, L. Dumont, D.A. Scheinberg, "Super saturating infusional humanized anti-CD33 monoclonal antibody HuM195 in myelogenous leukemia," Clinical Cancer Research, (1998) Jun; 4 (6) 1421-1428.

Invited Presentations

Larry Dumont, "Drug Substance Preparation and Characterization: Integrated Strategies for Biologics Development," Arden Conference (AAPS), West Point, NY, (2011)

Larry Dumont, "Multi-Dimensional Chromatographic Analyses: Considerations for Method Development and Validation," Barnett International Conference on Chromatography Validation and Methods Development, Philadelphia, PA, (2002).

Larry Dumont, "Assessing product comparability in early phase clinical development when there are significant product differences," 4th Annual IBC Conference on Well Characterized Biologicals, Seattle, WA, (2001).

Larry Dumont and Lars Östberg, "Immunogenicity testing of a human monoclonal antibody that binds hepatitis B surface antigen," Second Annual Mason Laboratories Symposium on Biotechnology, Boulder, CO (1996).

Posters and Presentations

E. Kast, L. Dumont, P. Motchnik, H. Hundal, and H. Balasubramanian, "Isolation and characterization of the isoforms of a recombinant human monoclonal antibody," 4th Symposium on the Analysis of Well Characterized Biotechnology Pharmaceuticals (WCBP), San Francisco, CA (2000).

Posters and Presentations (continued)

E. Kaisheva, S. Gupta, M. Nguyen, A. Flores-Nate, R. Singer, and L. Dumont, "Development of a subcutaneous liquid formulation at 100 mg/mL for a humanized monoclonal antibody using experiment design techniques," Annual Meeting of the American Association of Pharmaceutical Sciences, New Orleans, LA (1999).

J. G. Jurcic, A. DeBlasio, L. Dumont, R.P. Warrel, Jr., and D A. Scheinberg, "Molecular remission induction without relapse after anti-CD33 monoclonal antibody HuM195 in acute promyelocytic leukemia (APL)," Annual Meeting of the American Society of Hematology, San Diego, CA (1997)

Yu Fang, Larry Dumont, and Brent Larsen, "Real-time isoform analysis by two- dimensional chromatography of a monoclonal antibody during bioreactor fermentations," 17th International Symposium on the Separation of Proteins, Peptides, and Polynucleotides, Rockville, MD (1997)

Larry Dumont, Yu Fang, Susan Klein, Robert Singer, and Brent Larsen, "Antigen binding comparison of two isoforms of a monoclonal antibody using high performance size-exclusion chromatography," 17th International Symposium on the Separation of Proteins, Peptides, and Polynucleotides, Rockville, MD (1997)

Lisa Hernandez, Joyce Chinn, Charles Bullock, Lewis Campbell, Maria Albano, Jennifer Contreras, Lawrence Dumont, and Corine Klingbeil, "Anti-CMV human monoclonal antibody, MSL 109: PK and safety of intravitreous delivery in rabbits," The Sixth International Cytomegalovirus Conference, Orange Beach, AL (1997).

P.C. Caron, J. G. Jurcic, L. Dumont, D. Tyson, and D A. Scheinberg, "High-dose infusional humanized anti-CD33 M195: Prospects for treating minimal residual disease ," Annual Meeting of the American Society of Hematology, Orlando, FL (1996)

C.K. Klingbeil, J. Guo, L.C. Dumont, Q. Zhu, P.I. Nadler, and E.C. Dunkel, "Human anti-cytomegalovirus monoclonal antibody (MSL 109), but not CMV hyperimmune globulin, reduced vitreoretinal pathology associated with HCMV retinal disease in the rabbit model," The Fifth International Cytomegalovirus Conference, Stockholm, Sweden (1995).

C.K. Klingbeil, L. Östberg, M.S. Co, C. Queen, L. Dumont, and P. Nadler, "Pharmacokinetics and immunogenicity of human and humanized monoclonal antibodies to herpes simplex virus," American Society for Clinical Pharmacology and Therapeutics, New Orleans, LA (1994).

Patent

US Patent #5,013,669
Mass Producible Biologically Active Solid Phase Devices, Issued 1991.
Inventors: Donald F. Peters and Lawrence C. Dumont