DREW NATHANIEL KELNER

2147 Kincaid Pl
Boulder, CO 80304
(303) 442-2769 (home)
(720) 625-1207 (cell)
dkelner42@gmail.com

QUALIFICATIONS SUMMARY:

- A proven scientific and business leader with expertise in biochemistry, immunology, cell biology and pharmacokinetics with 30 years of experience in the development and licensure of biopharmaceutical therapeutics

- Demonstrated expertise in process, analytical, formulation, and drug delivery development and commercialization for both innovator and biosimilar products

- Extensive experience in building highly effective, flexible, and responsive analytical and formulation development organizations in the biotechnology industry, at all stages of the product lifecycle

- Documented track record of improving inter-departmental interfaces, improving business processes to increase efficiency and reduce costs, and providing insightful solutions to challenging scientific, quality and regulatory issues

- History of technological innovation in analytical testing and product characterization for recombinant proteins from multiple expression systems, including monoclonal antibodies, fusion proteins, immuno-conjugates, and a therapeutic cancer vaccine

- Extensive experience with regulatory compliance and global regulatory filings at all stages of the product lifecycle, including successful Marketing Applications for 9 biopharmaceutical products and lifecycle management amendments/variations for 6 additional products
- Recognized scientific leader in the biopharmaceutical industry, with experience in drafting and/or serving as industry expert for pre-release feedback on regulatory documents (FDA and EMA), including guidance on monoclonal antibody production and quality control, analytical method development and validation, the application of Quality by Design to biotechnology product development, product specifications, and guidelines for product comparability and biosimilarity

EDUCATION:

- Haverford College, Haverford, PA, B.S., Chemistry, May, 1976.
- Duke University, Durham, NC. Ph.D., Biochemistry, June, 1983.
    - Dissertation Title: “Purification and Characterization of the Major Nuclear Porcine Histone Acetyltransferase Activity from Porcine Liver.”

PROFESSIONAL EXPERIENCE:

President, Colorado Biotechnology Consultants *July 2015- Present*

- Biotechnology consultancy focused on providing:
    - Expert opinion and testimony on biopharmaceutical patents, including process development, analytical testing, product quality/specifications, and biosimilar patent infringement
    - Scientific and business consulting services to biopharmaceutical companies in process, analytical, and formulation development, regulatory compliance, and quality control (e.g. specifications, control strategy, Quality by Design).

Executive Director, Global Analytical Sciences *May 2011- May 1, 2015*
Amgen, Longmont, CO

- Executive leader responsible for all Analytical Sciences (AS) activities, on a global basis, for Amgen’s large molecule late-stage commercialization (Phase III) pipeline; also responsible for analytical support for the large molecule commercial portfolio
- Consolidated a fragmented global AS organization into a functional network that effectively reduces redundancies, increases efficiency, and optimizes resource utilization across the enterprise in alignment with further corporate globalization
- Provided strategic leadership for global business initiatives, including:
    - improved AS/QC business operations to enhance efficiencies in method transfer, qualification and validation
    - a corporate-wide program to improve and standardize method system suitability criteria for the late-stage pipeline and commercial products with a goal of reducing invalid assay rates by 50%
    - corporate-wide initiative to optimize all analytical testing across the portfolio and lifecycle that will return savings by reducing the cost of in-process, release and stability testing, as well as reduce the costs of re-release testing of Drug Product as the products reach new global markets
    - Scientific guidance on comparability and biosimilarity strategies

- Advanced technologies for support of process development activities, enhancing robustness of method development, deepening molecular (product) understanding, and meeting evolving regulatory expectations world-wide
    - Examples include new applications of advanced mass spectrometry techniques to evaluate the physiological relevance of quality attributes to enable a more targeted testing strategy
    - Advanced biochemical, biophysical and biological characterization techniques applied to new modalities such as a therapeutic cancer vaccine ("TVEC") that is in Phase III clinical trials for advanced melanoma
- Scientific leadership of complex process and product-related investigations that leveraged the Amgen analytical network effectively to provide root cause identification and corrective action

Executive Director, Analytical and Formulation Sciences *Dec 2009 – April 2011*
Amgen, Thousand Oaks, CA

- Department head responsible for management of analytical development, product characterization, analytical comparability assessment and protein formulation development in support of clinical and commercial process and product development
- Improved efficiencies and reduced cycle times for analytical and formulation development in support of pipeline candidates
- Advanced platform formulation approaches for drug substance and drug product to improve stability and simplify drug product process development using a "universal formulation" approach
- Scientific expertise and guidance for corporate-wide CMC and specification strategies
- Co-led the Product Quality Attribute Assessment initiative of Amgen's Quality by Design program to provide the scientific basis, business process and the associated templates that are still used throughout the product development and post-marketing lifecycle to provide attribute severity scores for the process and product risk assessments

Director, Analytical and Formulation Sciences *January 2008-Dec 2009*
Amgen, Thousand Oaks, CA

- Department head responsible for management of analytical development, product characterization, analytical comparability assessment and protein formulation development for clinical and commercial process and product development
- Integrated formulation development work into analytical department, including development of platform formulation strategies

Director, Analytical Sciences *Sept. 2006-January 2008*
Amgen, Thousand Oaks, CA

- Analytical development department head, managing staff responsible for method development and qualification, product characterization, comparability assessment and support of bioprocess development
- Scientific expert to support corporate-wide regulatory and specification strategies, including participation on Amgen's Global Product Quality Board.
- Led development of universal methods strategy in support of multiple monoclonal antibody projects to reduce method development, qualification and transfer cycle times
- Scientific leader in the development of Amgen's Quality by Design strategy
- Amgen scientific adviser for WHO meeting in Geneva on *Nomenclature for Biologicals and Biotechnological Substances, including Biosimilars*
- Topic Leader for industry response to draft EMEA *Guideline on Production and Quality Control of Monoclonal Antibodies and related substances*

Associate Director II, Analytical Sciences *July 2005-Sept. 2006*
Amgen, Thousand Oaks, CA

- Department head responsible for management of protein project activities for analysis and characterization of bio-pharmaceutical development candidates and marketed products
- Critical reviewer and final draft contributor for Panitumumab (Vectibix) BLA filing
- Led development of business process to streamline and update method development, qualification and transfer practices
- Key contributor to design of product specification platform for monoclonal antibodies and *E. coli*-derived protein
- Lead author of Amgen's analytical platform strategy for *E coli*-derived protein therapeutics.

Associate Director, Analytical Sciences *March 2003-July 2005*
Amgen, Thousand Oaks, CA

- Managed analytical development group responsible for multiple protein bio-pharmaceutical projects, including support of commercial production and support of process development for Phase I, II and III projects.
- Completed development of commercial analytical methods and IND Amendment for Denosumab, Amgen's lead late-stage drug candidate for treatment of osteoporosis
- Contributed to regulatory responses to Palifermin BLA submission and Denosumab INDA

- Lead author of Amgen's analytical platform strategy for development of monoclonal antibodies.

Associate Director, Analytics and Formulation *Dec 1999-February 2003*
Bayer Corporation, Berkeley, CA

- Managed analytical development group responsible for assay development, structural characterization and formulation development for recombinant protein biopharmaceuticals
- Implemented assay /characterization testing to provide data for multiple biopharmaceutical development candidates
- Authored characterization sections for three IND submissions
- Provided analytical support and scientific guidance for marketed product, recombinant factor VIII

Principal Staff Scientist, Analytics and Formulation *April 1999-Dec 1999*
Bayer Corporation, Berkeley, CA

- Managed analytical development group responsible for assay development and structural characterization of recombinant proteins
- Developed assay panel for multiple biotechnology products in preparation for submission of two INDs
- Provided characterization support for licensed recombinant factor VIII and for completion of licensing of new sucrose formulated factor VIII product (Kogenate-FS).

Senior Staff Scientist, Biochemistry *July 1995-April 1999*
Bayer Corporation, Berkeley, CA.

- Established analytical development group to support Process Sciences development work to meet needs of increasing pipeline
- Developed and implemented characterization plan for licensing of second generation recombinant factor VIII
- Provided scientific guidance to troubleshoot production issues for recombinant factor VIII

Staff Process Development Scientist *June 1994- July 1995*
Manufacturing Process Development, Bayer Corporation, Berkeley, CA.

- Developed analytical assays for product and impurity characterization of recombinant factor VIII
- Scientific guidance for troubleshooting of manufacturing problems for rFVIII (Kogenate)
- Presented process development issues to senior management
- Contributed to responses to questions from regulatory agencies

Senior Process Development Scientist *May 1993- June 1994*

Manufacturing Process Development, Bayer Corporation, Berkeley, CA.

- Developed downstream unit operations for Kogenate purification that increased yield, process efficiency, throughput, and robustness relative to existing process
- Developed and optimized in-process assays for new Kogenate process
- Provided scientific guidance to solve host cell protein and nucleic acid impurity issues in manufacturing

Scientist II, Analytical Biochemistry *October 1991- May 1993*
Xoma Corporation, Berkeley, CA.

- Developed chromatographic, electrophoretic, and immunochemical assays for two new protein products
- Developed peptide mapping and mass spectrometric methods for analysis of protein micro-heterogeneity and post-synthetic modifications of bactericidal permeability increasing protein (BPI); identified heparin and lipopolysaccharide (LPS) binding domains of BPI

Senior Chemist, Product Development *October 1987- September 1991*
Beckman Instruments, San Ramon, CA.

- Developed new applications for high performance liquid chromatography (HPLC) of proteins, peptides, and amino acids
- Developed new chromatographic columns, instrumentation, and software
- Authored 27 technical reports on HPLC applications
    - Presented results at national and international meetings
    - Project leader for evaluation of Ultraspherogel SEC, a new size exclusion HPLC column launched in 1990
    - Developed protocols for use of RealTime Purity Algorithm of Beckman Diode Array Detector for assessment of peptide and protein purity

Research Associate, Laboratory of Dr. Salvatore V. Pizzo *August 1986- August 1987*
Professor of Pathology and Biochemistry
Duke University Medical Center.

- Purification and characterization of cell surface receptors for fibrinogen degradation products in macrophages.

Postdoctoral Research Fellow *July 1983- July 1986*
Laboratory of Dr. Peter Cresswell, Professor of Immunology
Duke University Medical Center

- Purification and characterization of biosynthetic intermediates of human HLA class II antigens in B lymphoblastoid cells. Recipient of Postdoctoral National Research Service Award from N.I.H.

Graduate Student, Laboratory of Dr. Kenneth S. McCarty *August 1977- June 1983*
Professor of Biochemistry, Duke University Medical Center

- Purification and characterization of the major nuclear histone acetyltransferase activity from porcine liver. Doctoral research published in the *Journal of Biological Chemistry*. Recipient of Predoctoral National Research Service Award from N.I.H.

RECENT PUBLICATIONS:

1. Kelner, DN, Krull, IS, Duff, RJ and Eris, T. Analytical Method Validation for Biopharmaceuticals, Part 1: Introduction and System Suitability. Institute of Validation Technology, Published on IVT Network (http://www.ivtnetwork.com), December 2016 (5 additional chapters available at IVT web site)
2. Apostol, I, Kelner, D and Krull, IS. *Analytical Method Validation for Biopharmaceuticals*, in Analytical Chemistry (on line book), InTech (Rijeka, Croatia), 2013. (This on line resource has achieved over 14,000 downloads as of August 29, 2017).
3. Apostol, I, Kelner, DN, et al*., Uncertainty Estimates of Purity Measurements Based on Current Information: Toward a "Live Validation" of Purity Methods*. Pharm Res 29: 3404-3414 (2012).
4. Apostol I, Kelner DN. *Managing the Analytical Lifecycle for Biotechnology Products*. BioProcess International, Sept. 2008, pp. 12-19.

RECENT PRESENTATIONS:

1. *Analytical Challenges in the Biotechnology Industry*. Webinar for Separation Sciences, Protein Analysis Methods for Biopharmaceuticals, October 1, 2015.
2. *From Peaks to Attributes: Leveraging Recent Advances in Analytical Technology to Enable a QbD-Focused Analytical Strategy*. WCBP 2013 (sponsored by CaSSS, the California Separation Society), Washington, DC, Jan 29-31, 2013.
3. *Advances in Glycosylation Analysis for Therapeutic Monoclonal Antibodies*. CMC Strategy Forum Japan, Tokyo, Dec 3-4, 2012.
4. *Comparability and Biosimilarity: Two Sides of the Same (or a Different) Coin?* Keynote presentation at IBCs 27th Antibody Development and Production Week, Huntington Beach, CA, Feb. 27-Mar 2, 2012.

References and Complete publication list are available upon request