

Cassandra K. MacArthur

www.bridginghealthmatters.com

12531 Revere Court
Aurora, CO 80011

E-mail: cassandra.macarthur@bridginghealthmatters.com
Telephone: (w) 303-364-4139; (c) 720-530-4457

Selected Major Accomplishments

- 7 NDAs (1 Orphan Drug)/CTDs; 16 INDs, prepared/submitted and filed
- 3 BLAs prepared/submitted – All filed and or approved
- 1 PMA; 8 510K's; 2 IDEs; 2 ANDAs prepared/submitted – All approved
- Site evaluations for GMP, GLP, ISO 9000 and/or ISO 13485 of US and International contract manufacturing and laboratories - All subsequently FDA approved sites
- Successful orchestration of multiple manufacturing Sites (3 International) for drug Substance/drug product managed through product launch and commercial manufacturing
- International product investigation and recall managed successfully resulting in product improvement, company acquisition and increased sales
- Speaker and regulatory trainer - Drug Information Association (DIA -eCTD)
- Chemistry, Manufacturing and Quality Control Regulatory Consultant for development of small molecules, proteins, peptides, oligonucleotides, medical devices and supplements
- Reorganized an academic center including staffing, grants and funding systems, and overall administrative functions according to NIH and FDA quality standards
- Interim VP of Project Management, Regulatory and Quality Assurance for an international (China) anti-bioterrorism project-successfully initiating preclinical monkey supportive care studies including hands-on training to support significant BARDA and DOD contracts
- Developed assays and GMP systems for supplement and herbal manufacturers to support changes in FDA guidelines

Professional Experience

Bridging Health-Matters, LLC.

CEO and President of Project Management and Compliance

2008-Present

Selected Indications: Oncology: Breast, Renal, Hepatology; Nuclear Imaging; Cardiovascular; CNS, Anti-Bioterrorism; Pharmaceuticals, Biologics and Medical Devices

- Main regulatory strategist and writer for international and FDA regulatory submissions
- Project Manager for CMC, for drug substances/drug products for process and analytical development, product registration and market launch, diagnostics and formulation development
- Project Manager for International Preclinical studies in China
- Project and Quality Manager for Asian based projects
- Quality systems development and implementation at client sites-Stability, CMC, QA, etc. programs,
- GCP, GMP, GLP auditor and trainer
- Provides successful strategic regulatory/quality development plans for innovative and developing biotech companies
- Conducts multiple clinical site audits and clinical study report filing reviews
- Performs due-diligence for regulatory submissions and acquisitions
- Investor relations and partnering of biotechs
- Attendee of FDA advisory committees and all client strategic FDA meetings
- Successful management of radioactive labeling and radioactive exposure projects
- Patent technical writer, U.S. Regulatory agent
- Quality assessment of radiolabeled materials and site visits

CMAC, LLC, Aurora, CO

1992-2008

Independent Consultant for Regulatory/Quality Systems, Project Management

- Senior Regulatory Affairs Consultant for all regulatory submissions, *Image Solutions, Inc*
- Successful submission and approval of FDA and EU clinical regulatory filings and subsequent IND updates, annual Reports and additional support documentation for biologics, pharmaceutical drugs and medical devices
- Provided regulatory/project management strategic planning for drug development product scenarios including labeling design, manufacturing and clinical trial management
- Reviewed and compiled the CMC sections of the INDs and CTX submission for three cardiovascular drugs (over 20 years of development- most analytical information in German)
- Interfaced with the FDA including pre-IND meetings, End of Phase 2, Pre-NDA, CTD/NDA filing response questions, “Ad-hoc meetings” and scheduled/unscheduled FDA visits
- Collaborated with global regulatory agencies to develop Standard Operating Procedures (SOPs), strategic Initiatives and activities for overall regulatory liaison function
- Developed in-house quality systems for drug and medical device Companies, ISO and ICH Standards
- Conducted audits and quality site qualifications for GMP, GLP, GCP regulatory standards
- Supported post-marketed products, CAPA systems, field actions and corporate due diligence
- Designed clinical and research laboratory space
- Trained med. tech staff on clinical biochemistry equipment and clinical accession of patient samples for a start up clinical testing laboratory

ARCA Discovery, Inc.

2006-2007

Senior Director of Regulatory, Non-clinical- Gene Targeted Cardiovascular Therapy

- Provided regulatory direction and leadership for CMC and other non-clinical aspects of the development and commercialization of bucindolol, a genetically linked beta blocker.
- Directed CMC, Quality and Regulatory for the registration/validation API manufacture and formulation of a small molecule cardiovascular drug for NDA submission. This included the development and review of all current and historical documentation, including the supporting CMC and Quality documentation for the synthesis, formulations, DMF, product development analytical methods to launch international contract manufacturing.
- Directed the review and assimilation of the non-clinical and CMC sections of the eCTD submission- (over 20 years of development information)

Medtronic Navigation, Inc.

2005-2006

Senior Regulatory Consultant- Surgical navigation medical devices

- Provided regulatory submission strategy for three lead computer based navigational products
- Developed corporate quality systems including CAPA and equipment recall to support corporate goals
- Provided a due diligence plan and quality assessment for an international medical device acquisition

Navigant, Inc. (Gambro BCT)

2002-2003

Senior Project Leader for Pathogen Reduction Technology Consultant - Blood Purification/ Medical Devices

- Coordinated all clinical programs for the two leading research and development projects – projects in Phase I/II international clinical trials
- Established biochemistry and microbiology objectives and strategies and trained the staff in direct activities for the commercial development of a medical device.

Ribozyme Pharmaceuticals Inc., Boulder, CO 1999-2002
Senior Project Manager of Regulatory and Clinical Studies,
Corporate CMC Liaison Consultant, Quality Control Supervisor
Indications: Oncology- Breast, Renal, Colorectal, Lung, Hepatology

- Senior Project Manager for all project team activities, (CMC, Regulatory, Formulations, and Clinical Development, Pre-Clinical and Clinical Operations) for an oncology drug.
- Clinical Project Manager for Angiozyme clinical studies; 3 Phase I and 5 Phase II; including breast cancer, colon cancer, lung cancer, and renal cancer
- Product development team liaison with corporate partner(s), Eli Lilly Pharmaceutical Inc. (Heptazyme) and Chiron Corporation, (Angiozyme) CMC corporate lead for successful \$1 million milestone completion of IND with Eli Lilly
- Responsible for regulatory/quality control compliance GMP program for 3 oligonucleotide APIs and their drug products.

The University of Colorado Health Science Center, Denver, CO 1998-1999
Program Administrator Consultant, Center for Human Nutrition-Obesity

- Restructured the Center for Human Nutrition to meet NIH and FDA compliance standards audited and reconciled system errors and redefined 81 Accounts for the annual budget of \$4.5 Million to compliance of federal regulations
- Assisted in the negotiations which resulted in the center receiving a \$1.25 million private gift

Symbiotics, San Diego, CA 1983-1984
Senior Research Associate

- Developed the Feline Leukemic Virus Agglutination Assay that resulted in a commercial product

Academic Research Experience 1980 - 1990

The University of Texas Health Science Center, Tyler, TX 1984-1990
Laboratory Director, Associate Research Specialist, Department of Biochemistry

- Conducted independent and collaborative research projects producing 10 major journal publications and a book chapter
- Isolated, fully characterized the clinical relevance of a novel cytokine, ERP, from human alveolar macrophage that causes neutrophils to release enzymes in the lungs of patients with ARDS.
- Awarded multiple grants for pulmonary research including ARDS, COPD, emphysema and lung damage mechanisms

Scripps Clinic and Research Foundation, La Jolla, CA 1981- 1983
Research Associate and Consultant

- Involved in the initial studies for the prevention of Graft versus Host Disease using cyclosporium A that resulted in the identification of advanced therapies for patients- Dr. Frank Chisari, MD
- The Scripps Clinic and Research Foundation Hybridoma Core consultant for the isolation purification, development and characterization of monoclonal antibodies for Scripps Clinic and Research Foundation
- Developed purification methodology for the Classic and Alternative Complement Pathway proteins and subsequent development of monoclonals for each protein including bioassay development for complement mediated diseases -Dr. Hans Mueller Eberhardt's laboratory
- Consultant for Elisa assay development for multiple scientific investigators

The Salk Institute for Biological Studies, La Jolla, CA 1979-1981
 Jonas Salk's Cancer Laboratory Research Associate

- Isolated and characterized Human Interleukin 1 and Interleukin 2 and their effects on Natural Killer Cells
- Involved with immunological research on the establishment and characterization of T-cells, B-cells, Natural Killer cells as long term prevention of tumor with the use of cloned Natural Killer lines in vivo and in vitro
- Responsible for the Salk Institute's Cell Line Core for International Research Studies which supplied the international research community cell lines

Education

University of Colorado at Denver, Denver, CO Project Management Certification 2000

Colorado State University, College of Veterinary Medicine, Fort Collins, CO 1991-1995

- Expression of Ovine Pulmonary Carcinoma Capsid Protein Gene in Escherichia coli; Production of Antibodies to the Purified Recombinant Protein for Analysis of Infectivity of the Retro virus by Enzyme-Linked Immunoassay-Graduate Studies MS and Ph.D. program

University of Texas, GSBS, Baylor Medical School, Houston, TX 1985-1987

- Graduate Studies in Biochemistry and Cell Biology- Ph.D. program

Metropolitan State College, Denver, CO- Bachelor of Science in Biology and Chemistry 1978

Ongoing Interdisciplinary Continuing Education to maintain current knowledge of Regulatory and Compliance Trends – Over 300 Continuing Education Credits

Personal Grants and Awards

Empire's Who's Who Among Executives and Professionals 2005

National of Conference of State Legislators, Denver, CO 1995

Internship - HIV/AIDS and Adolescents

Colorado State University: College Research Grant 1993, 1994

Outstanding Graduate Teacher, Department of Microbiology, Colorado State University, School of Veterinary Medicine, Fort Collins, CO 1991, 1992

University of Texas Leadership Grant 1990

Leadership Tyler Class IV and Leadership Texas and Leadership Tyler Award

Tyler Chamber of Commerce, Tyler, TX

American Hospital Scientific and Medical Ethics Grant for Community Outreach Programs 1989

American Heart Association Grant 1987

Fritz Blanc Medical Mycology Award, the American Medical Association 1978

Publications

1. Cohen, A.B., MacArthur, C.K., and James, H.L.: The control of neutrophil migrations through the lungs: an unexplored means of treating smokers with pulmonary emphysema. Pulmonary Emphysema and Proteolysis: 1986, Ed. J. C. Taylor and C. Mittman, Academic Press, 1986, pp 189-196.
2. MacArthur, C.K., Miller, E.J. and Cohen, A.B.: A peptide secreted by human alveolar macrophages which releases neutrophil granule contents. J. Immunology, 139: 3456-3462, 1987.
3. Idell, S., Gonzalez, K., Bradford, H., MacArthur, C.K., Fein, A.M., Mauder, R.J., Garcia, J.G.N., Griffith, D.E., Weiland, J., Martin, T.R., McLarty, J., Fair, D.S.: Procoagulant activity in bronchoalveolar lavage in the adult respiratory distress syndrome, Am. Rev. Respir. Dis., 1987; 136: 1466-1474.
4. Idell, S., Gonzales, K., MacArthur, C.K., Gillies, C., Walsh, P., McLarty, J., Thrall, R.: Bronchoalveolar lavage procoagulant activity in Bleomycin-induced lung injury in marmosets, Am. Rev. Respir. Dis. 1988; 136: 123-124.
5. Cohen, A.N., MacArthur, C.K., Idell, S., Maunder, R., Martin, T., Dinarello, C.A., Griffith, D.E., McLarty, J.: A peptide from alveolar macrophage that releases neutrophil enzymes into the lungs in patients with the adult respiratory distress syndrome, Am. Rev. Respir. Dis., 1988; 137: 1151 - 1158.
6. Peterson, B.T., Idell, S., MacArthur, C.K., Gray, L.D., Cohen, A.B.: A modified bronchoalveolar lavage procedure that allows measurement of lung epithelial lining fluid, Am. Rev. Respir. Dis., 1990, 141: 314-320.
7. MacArthur, C.K., Gray, L., Maunder, R., Martin, T., Idell, S., Cohen, A.B.: The secretion of high and low molecular weight forms of the enzyme releasing peptide (ERP) from the macrophage-like cell line, THP-1. American Journal of Respiratory Cell and Molecular Biology, 1990
8. Miller, E.J., MacArthur, C.K., Gray, L.D., Cohen, A.B.: Liberation of a neutrophil enzyme-releasing peptide from the surface of human alveolar macrophages, AJP, 258 (Lung, Cell. Mol. Physio., Pages L328 - L333, 1990.
9. MacArthur, C.K., Gray L, Cohen AB: Synthesis and secretion of high- and low-molecular weight forms of the enzyme-releasing peptide (ERP) from the macrophage-like cell line THP-1. American Journal of Respiratory Cell and Molecular Biology, 1991, Jan; 4 (1):18-25.
10. MacArthur, C.K. Sexually Transmittable Diseases and Adolescents, National Conference of State Legislatures State Stats, April 1996.
11. Cytokines of the Lung: New York: Marcel Dekker, 1993. xvii, 640 p.: Enzyme-releasing peptide / Allen B. Cohen, Edmund J. Miller and Cassandra MacArthur