CASSANDRA K. MACARTHUR, P.M.

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SUMMARY

Chemistry, Manufacturing, Clinical and Quality Control

- Strategic Development of small molecules, proteins, peptides, oligonucleotides, medical devices, combination products, OTC, generics, nutraceuticals and supplements in multiple dosage forms
- Manufacturing site evaluations, scale up for registration/validation API, Drug Product and Biologics
- GLP, GMP, GCP, ISO 9000 and/or ISO 13485 of US and International contract manufacturing and laboratories - All subsequently FDA approved sites
- Successful orchestration and development of multiple client manufacturing Sites (5 International sites) and CMOs, CROs for Drug Substance/Drug Product managed through product launch and commercial manufacturing
- Quality by Design development of multiple products from small biotech to large pharma including cGMP, CROs and multiple clinical sites for Phase 1 through Phase 3
- Experience in analytical chemistry, biochemistry, immunology, cell biology, molecular virology and all applicable techniques
- Designed Quality Systems and author of supporting documents (SOPs), etc.
- Environmental Protection Association EPA CMC interaction

Regulatory Affairs Submissions

- Project lead for the resurrection of previously acquiesced submissions for approval for all 5 modules of eCTD
- Post Marketing CMC support including submissions; supplements, annual reports, FARs, DMFs, compliance and regulatory authority reviews and all document reviews.
- CMC Consent Decree Support and Mitigation- review and gap analysis for international submissions, recalls, compliance, CAPAs, strategic planning, risk mitigation, etc.
- 3 PMAs; 17 510K's, 2 IDEs, OTC Registrations prepared/submitted – All filings approved
- 9 NDAs (1 Orphan Drug)/CTDs; 2 ANDAs, 5 BLAs, 20 INDs, 2 MAAs prepared/submitted-All filings approved-Use of multiple software and filing systems including Mosaic, SharePoint, Prism and other software programs
- Medical writer for clinical protocols, reports, investigational brochures, preclinical submission modules and summaries
- Author of clinical, preclinical and CMC submissions for multiple registration authorities including Canada (TPD), EU (EMEA), Australia, Asia and emerging markets including Russia, Hong Kong, Korea, Latin America and Mexico.
- Speaker and regulatory trainer - Drug Information Association (DIA -eCTD; Project Management)
- Sponsor's representative for various government meetings including FDA, Advisory Committee meetings, Schedule A, B and C, in addition to BARDA, DOD, EPA and NIH
- Project Manager for the development, review and approval process for all pre-commercial to commercial products.
- International authority submissions; author and regulatory representative
- US Regulatory Representative for international clients
- Interim Vice President of Regulatory and Compliance for multiple startups

Project Management

- Managed Clinical Operations for 10 Phase 1 through Phase 3 clinical studies and 2 Phase 4 clinical studies
- International product investigation and recall managed successfully resulting in product improvement, company acquisition and increased sales
- CRO, CMO management 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
- Managed research and development teams for biologics, pharmaceuticals, vaccines and submissions

PROFESSIONAL EXPERIENCE

BRIDGING SCIENCE TO HEALTH, LLC. (Consulting Firm **2015-Present**
(Formerly: Bridging Health Matters, LLC.) **2008 – 2015**
President of Regulatory Affairs, Drug Development and Compliance
Selected Indications: Oncology: Breast, Renal, Lung, Prostrate, Hepatology; Nuclear Imaging; Vaccines; Dermatology, Cardiovascular; CNS, Anti-Bioterrorism; (Pharmaceuticals, Biologics and Medical Devices)

- Main regulatory strategist and writer for international and FDA regulatory submissions
- Consultant for multiple large pharmaceutical, biotech, chemical, and OTC companies
- CMC Post Marketing Support including risk assessment and gap analysis
- Post Marketing Regulatory support; writing of submission of PAS, CBE 30 documents
- Project Manager for CMC, for drug substances/drug products for process and analytical development, product registration and market launch, diagnostics and formulation development
- Project and Quality Manager for US, EMEA, Canadian, Australian, Russian and 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 -correlating with financial development plans -due diligence-gap analysis
- Conducts multiple clinical site audits and clinical study report filing reviews
- Performs due-diligence for regulatory submissions and business acquisitions
- 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 including Quality assessment of radiolabeled materials and sites
- Colorado Bioscience representative at BIO International for 2010; 2011; 2012

CMAC, LLC, Aurora, CO (Consulting Firm) **1992 – 2008**
Independent Consultant for Regulatory/Quality Systems, Project 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)
- 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
- 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 for academic and commercial use (research, GLP, GMP)
- Trained medical technical staff on clinical biochemistry equipment and clinical accession of patient samples for a start- up clinical testing laboratory

CLEVELAND BIO LABS, INC.
Vice President for Regulatory and Quality Compliance
2009-2010

- Project Manager for International Preclinical studies in China
- Project lead for Russian based products
- Project Negotiations with the Chinese Government based for preclinical anti-bioterrorism

ARCA DISCOVERY, INC. **2006–2007**
Senior Director of Regulatory, Non-clinical- Gene Targeted Cardiovascular Therapy

- CMC project lead for registration/validation batches for tablet dosage for lead compound
- 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 clinical/non-clinical and CMC sections of the eCTD submission.

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 supporting corporate goals
- Provided a due diligence plan and quality assessment for an international medical device acquisition
- Coordinated development of QA/Regulatory systems according to ISO and ICH Guidelines

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 and Clinical Operations, 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.in an injectable format

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 grant 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

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

SYMBIOTICS, San Diego, CA **1983 – 1984**
Senior Research Associate

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

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 cyclosporine A that resulted in the identification of advanced therapies for patients
- 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 a monoclonal for each protein including bioassay development for complement mediated diseases -Dr. Hans Mueller Eberhardt's laboratory

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

EDUCATION

Bachelor of Science in Biology and Chemistry, 1978, 1985
METROPOLITAN STATE COLLEGE, DENVER CO
Graduate Studies in Biochemistry and Cell Biology- Ph.D. program, 1985-1987
UNIVERSITY OF TEXAS, GSBS, BAYLOR MEDICAL SCHOOL, Houston, TX
Graduate Studies in Molecular Virology and Biochemistry- Ph.D. Program, 1991-1995
COLORADO STATE UNIVERSITY, Fort Collins, CO
Project Management Certification; 2000
UNIVERSITY OF COLORADO AT DENVER; Denver, CO

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. XXVII, 640