DAVID E. CHADWICK, Ph.D., RAC, FRAPS
Bloomington, IN 47402
(812) 335-3575, x102330 (office)

EXPERIENCE SUMMARY

- Multi-faceted, hands-on, scientifically trained, management-level regulatory/quality/clinical professional
- Well-rounded background in regulatory affairs, quality assurance, clinical trials, product and process development
- Member, Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee of the U.S. Food and Drug Administration, Industry Representative
- Board of Directors, Regulatory Affairs Professionals Society (RAPS)
- Fellow, Regulatory Affairs Professionals Society (FRAPS) from Regulatory Affairs Professionals Society
- Regulatory Affairs Certification (RAC) from Regulatory Affairs Professionals Society
- Entrepreneurial spirit/strategic thinker/problem solver
- Negotiation/Interaction with FDA, preparation and organization of 510(k)s, IDEs, PMAs and MAF submissions related to durable, disposable and implantable medical devices, combination products, *in vitro* diagnostics, and some drug experience
- Successfully implemented and achieved certification to ISO13485:2003
- Corporate HIPAA Privacy Officer for HIPAA Compliance
- Excellent communication skills (written, spoken & listening)
- Broad-based understanding of scientific and technical material, and very able to work effectively and efficiently in a team environment and across the organization
- Protocol preparation, clinical study design and execution, and pre-clinical studies
- Bench-top experience: hands-on laboratory work, product and process development and scale-up
- Odyssey of the Mind/Destination Imagination State Problem Captain and Regional/State/World Judge and Chair of the Minnesota Destination Imagination Advisory Board
- LEGO League (robotics program) organizing committee and Head Referee
- Invited speaker and organizer for multiple educational programs for Regulatory Affairs Professionals Society, Invited speaker for Medical Alley, Invited speaker for Food Drug Law Institute (FDLI)
- Adjunct faculty Purdue University and Ivy Tech Community College Bloomington
- Advisory Board, George Washington University, Regulatory Affairs Program
- Medical Device Committee member, FDLI
- Journal editor, FDLI

PROFESSIONAL EXPERIENCE

COOK, INC., Bloomington, IN **2006-current**
Director, Regulatory Affairs/Regulatory Science
Regulatory Research Scientist

- Develop and implement regulatory strategies for US and global product registrations
- Develop and maintain regulatory intelligence for US and global regulations and thinking
- Develop and prepare technical content of documents related to testing of Class III and higher complexity Class II medical devices submitted to global regulatory authorities
- Interactions with regulatory agencies and consultants, as necessary
- Write clear and accurate descriptions of pre-clinical testing and clinical studies of new medical products that will be used to support FDA and design dossier submissions
- Review requisite critical documentation for completeness and suitability for submission to regulatory authorities, both domestic and abroad, as required
- Maintain knowledge of federal, state and any local regulatory requirements applicable to pre-market submissions for medical devices and combination products

- Maintain knowledge of federal, state and any local regulatory requirements applicable to post-market submissions for medical devices and combination products
- Develop and implement testing and regulatory strategies for new medical devices
- Develop and implement testing and regulatory strategies for existing medical devices
- Assess new technologies for regulatory compliance
- Collaborate with product development, pre-clinical, and contract research organization teams
- Collaborate with business development on new product/technology opportunities

GYRUS MEDICAL, INC., Maple Grove, MN **2004 - 2005**
Director, Regulatory Affairs/Quality Assurance
Director, Regulatory Affairs/Quality Assurance/Clinical Affairs

- US Division of a UK-registered medical device company with primary products in the urological, gynecological and abdominal surgery areas
- Responsible as the contact/spokesman for all interactions with regulatory bodies, both domestic and foreign, including negotiation, coordination and writing of submissions, review of technical reports prior to submission
- Responsible as the contact/spokesman for all interactions with quality audits by regulatory bodies and OEM partners (Management Representative)
- Successfully implemented and received certification to ISO13485:2003
- Successfully implemented Agile Product Lifecycle Management documentation program
- Management of Quality and Documentation staff of nine persons
- Responsible for Complaint/MDR investigation and filing. Supported Technical Services Group, Customer Service Group, Product Return and Repair
- Primary contact point for interaction with UK parent organization, as related to product performance, design issues, customer complaints, complaint and repair trending
- Prepared and received market clearance/approval for multiple 510(k)s, Canadian registrations and other foreign registrations
- Responsible for document review and procedures
- Responsible for review of all labeling, advertising, technical and clinical reports

DISETRONIC MEDICAL SYSTEMS, INC., St. Paul, MN **1999 - 2003**
Director, Regulatory Affairs/Quality Assurance **1999**
HIPAA Privacy Officer (added responsibility) **2003**
Director, Regulatory Affairs **1999**

- US Division of a Swiss-based medical device company with primary products in the diabetes management and drug delivery areas
- Responsible as the contact/spokesman for all interactions with regulatory bodies, both domestic and foreign, including negotiation, coordination and writing of submissions, review of technical reports prior to submission
- Responsible for Technical Services Group, 24-hour Customer Service Group, Product Return and Repair, Complaint/MDR investigation and filing (Team of approximately eighteen persons)
- Primary contact point for interaction with Swiss parent organization, as related to product performance, design issues, customer complaints, complaint and repair trending
- Executed multiple 510(k)s, Canadian registrations and IDE for PMA
- Responsible for clinical trials design issues and trial execution, including protocols, IRBs, informed consent, center compensation, data analysis and publication of trial results
- Responsible for all document review and procedures
- Responsible for review of all labeling, advertising, clinical reports
- Assigned as Scientific/Technical Reviewer on potential corporate licensing and product technology purchase opportunities (due diligence activities)
- Responsible as Corporate HIPAA Privacy Officer for HIPAA Compliance

ANGEION CORPORATION, Minneapolis, MN **1996 - 1999**
Interventional Technology Division (IVT)
Director, IVT Clinical/Regulatory/Quality Systems 1998
Manager, Regulatory Affairs, IVT 1996

- Primary divisional contact/spokesman for all interactions with regulatory bodies, both domestic and foreign, including negotiation, coordination and writing of submissions, review of technical reports prior to submission
- Secured IDEs for division and managed progress, annual and final reports
- Responsible for clinical trials design issues and trial execution, including protocols, IRBs, informed consent, center compensation, data analysis and publication of trial results
- Spearheaded transition of IVT documentation system into ISO 9001-approved quality system
- Provided regulatory intelligence and strategy in project team environment
- Certified internal auditor and trainer for new employee orientation
- Reviewed manufacturing/quality/design documents for regulatory compliance

CONSULTANT, Regulatory / Clinical / Medical Devices and Drugs **1994 - 1996**

ORPHAN MEDICAL, Minnetonka, MN
Consulting and Writing Medical Device & Drug Regulatory Submissions / 510(k) / IND
Prepared and Submitted 510(k)s as needed
Supported pharmacokinetic studies for inclusion in IND

BETHEL COLLEGE, Arden Hills, MN
Adjunct Assistant Professor of Biology

MENTOR CORPORATION, Santa Barbara, CA and Minneapolis, MN **1992 - 1994**
Manager R&D/Engineering, Urology Surgical Products Division and
Manager, Program/Project Development, Minneapolis, MN 1993
Manager, Program/Project Development, Corporate R&D, Santa Barbara, CA 1992

Recruited to fill newly created position in Corporate R&D group with primary involvement with the Urology Surgical (Implantable) Products Division, then assigned/transferred to Minneapolis

- Primary responsibility to organize and motivate persons and teams necessary to support PMAs for FDA on two different product lines of implantable inflatable penile prostheses
  - Overall assembly of PMA studies and documentation for submission; coordination of PMA activities between manufacturing facility in Minneapolis and Corporate/Regulatory in Santa Barbara; initiation and coordination of all biological and chemical testing of raw materials and finished devices by contract laboratories, universities and internal laboratories; strong involvement with consultants, contract laboratories, regulatory groups and agencies, marketing group, R&D and other groups as related to the penile prosthesis projects
- Management of R&D staff of fourteen (Engineers, Technicians, CAD, Administrative Assistant), PMA and MAF preparation and submission, Engineering Change Order (ECO) review and signature, Material Review Board (MRB), Product Complaint investigation

DENTSPLY INTERNATIONAL INC., York, PA **1988 - 1992**
Director of Technical Research, Periodontal Products Division 1991
Manager - Biotechnology Group, Corporate Division 1988

Recruited with major responsibility to design and develop the PrognosStik® Elastase Test System enzyme-based fluorescent diagnostic test for periodontal disease detection and prediction of increased risk for disease progression

- Responsible for compliance of all aspects of final design, dimensions and specifications of the PrognosStik Elastase Test System; scale-up of manufacturing process for assembly and packaging of diagnostic test kit;

establishment of specifications for diagnostic test kit; identifying and qualifying vendors for components of diagnostic test kit; participant in product introduction to the periodontal community at national research meetings
- Preparation of Clinical Study Protocols; study Co-monitor; data collection/retrieval and clinical site visitation throughout the clinical studies; biostatistical analysis of study data with University Biostatistics team; review of study reports/manuscripts for publication
- Preparation of support documents for assembly and submission of PMA to FDA and presenter before FDA review group
- Development of Good Manufacturing Procedures (GMP) methodologies, validations and documentation related to all aspects of enzyme diagnostic test
- Responsible for specification and purchase of major research equipment to be used in laboratory

RICHARDSON-VICKS INC., Shelton, CT (subsidiary of Procter & Gamble Co.) **1985 - 1988**
Post-Doctoral Research Fellow/Consultant
Dermatological Research Group, Advanced Exploratory Research

Recruited to design, establish and implement the cell and tissue culture laboratory
- Primary responsibilities included: specification and purchase of major research equipment to be used in cell culture laboratory; development of radiochemical and enzymatic assays applicable to area of cosmetics research; screening of potential new ingredients for personal care products utilizing human skin cell cultures; establishment of outside contacts (area hospitals and university) to secure surgical or post-mortem specimens of human skin and hair follicles; development of tissue culture system able to support and maintain human hair follicles

UNIVERSITY OF PITTSBURGH, Pittsburgh, PA Awarded Ph.D. **March 1985**
SCHOOL OF MEDICINE
DEPARTMENT OF ANATOMY AND CELL BIOLOGY

- Trained with Dr. Irving Lieberman in areas of DNA, RNA, and Protein synthesis control

TEACHING EXPERIENCE

- Medical School teaching in Human Anatomy/Embryology and Histology courses
- Undergraduate and technical school teaching in Anatomy/Physiology and Cell Biology
  - Adjunct Professor of Biology, Bethel University, St. Paul, MN
- Adjunct Assistant Professor Regulatory Affairs, Ivy Tech Community College, Bloomington, IN
- Adjunct Faculty Regulatory Affairs, Purdue University
- Advisory Board, George Washington University, Regulatory Affairs Program

EDUCATION

Ph.D. University of Pittsburgh
School of Medicine
Department of Anatomy and Cell Biology
Pittsburgh, PA

B.S. Albright College, Reading, PA (Biology)

PROFESSIONAL MEMBERSHIPS (Past and Present)

Regulatory Affairs Professionals Society, Amer. Society Quality, Amer. Chemical Society, Amer. Assoc. for the Advancement of Science, Amer. Assoc. for Dental Research, and International Assoc. for Dental Research

PUBLICATIONS

Eleven peer-reviewed publications and abstracts

PATENTS

Two patents issued: US Patent #5,089,709 and #5,262,650.
Three additional patent applications submitted/abandoned

(Updated 09/17)