Anna Fallon, PhD

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Summary

I am a Biomedical Engineering professional with excellent leadership, communication, and project management abilities. My core competencies include CER writing, Risk Management and Technical File and Design History File remediation to meet EU MDR. I have firsthand knowledge of regulatory requirements for BLA, PMA, IND, IDE, 510K, HUD, and HDE submissions and CFR Title 21 requirements for medical devices manufacturing and reporting. I am experienced in the development and execution of biocompatibility and toxicology risk assessments and test plans for class I, II, and III medical devices and CMC plans for BLA products to satisfy FDA and CE regulatory requirements.

Skills & Abilities

MANAGEMENT

- Leadership of a team of project managers, technicians and scientists
- Plan and conduct monthly project reviews to communicate to Executive Board
- Translate Corporate objectives into department objectives for execution

PROJECT MANAGEMENT

- Management of projects for Class II and Class III devices and tissue based biotherapeutics
- CFR Title 21 and ISO 13485 guidelines for medical device design, development and production
- ISO 14971 for the application of risk management for medical devices
- Design, planning and execution of GLP animal studies for multiple medical devices and BLA products including protocol and report writing and study oversight
- PMP certified by PMI (Certification # 1846149)

COMMUNICATION

- Routinely present scientific data to support marketing and educational initiatives
- Provide input for Clinical Evaluation Plans
- Writing of Clinical Evaluation Reports in compliance with regulatory requirements
- Maintain interdisciplinary relationships within and outside the company
- Publish scientific findings in peer-reviewed journals to support basic science as well as marketing

REGULATORY

- Authoring of CERs to satisfy EU MDR requirements
- Authoring and maintenance of EU Technical Files including GSPRs to satisfy EU MDR requirements
- FDA and EU submissions for Class II and Class III devices and biotherapeutics
- Design and execution of potency and identity tests and authoring of CMC sections for BLA submissions
- Communication with FDA to respond to questions during interactive review phase
- Plan and conduct Regulatory meetings with the FDA to discuss regulatory plans
- Implementation of GMP manufacturing requirements for medical devices and biotherapeutics

Experience

ADJUNCT PROFESSOR | UGA, COLLEGE OF PHARMACY, INTERNATIONAL BIOMEDICAL REGULATORY SCIENCES PROGRAM | AUGUST 2022-PRESENT

- Teach courses on Medical Device Regulatory Submission and Maintenance
- Mentor candidates for the Regulatory Sciences Graduate Program

PRINCIPAL AND FOUNDER | RENOVO BIOMEDICAL | JANUARY 2019-PRESENT

- Provide consulting services for medical device and biopharma regulatory compliance and product development
- Services include:
  - Engineering support for Device Design and Bench Testing
  - Design, planning and execution of non-GLP and GLP Preclinical studies
  - Product Development support for Design and Development including new product development and DHF remediation
  - CMC development support for process characterization and product release testing development
  - Regulatory support for submissions, technical file updates, CER writing, and other activities related to EU MDR gap assessment and compliance
- Recent Consulting Experience
  - EU MDR remediation of DHFs, labeling, packaging, biocompatibility, post market clinical documentation, and technical files including execution of testing required per gap assessments
  - Project management for product design and commercial launch of enteral feeding devices (feeding tubes, enteral syringes, and accessories)
  - Biocompatibility risk assessment, planning and execution of test plans for medical devices (enteral feeding, implants and instruments)
  - FDA Q submission for wound care medical device
  - Pre-IND Submission for a BLA product
  - PAS and CBE-30 submissions and Regulatory assessments for Drug/Device combination product

DIRECTOR OF RESEARCH | MIMEDX | JULY 2016- DECEMBER 2018

- Directed research to support current and new product development of human placental products. Responsibilities included:
  - Developing annual department budget and timelines for critical deliverables
  - Providing timely updates to the executive team on all ongoing research studies; maintaining data and reports per document control procedures
  - Interfacing with clinical PIs, KOLs, and academic collaborators to drive development of new therapeutic applications
  - Investigating potential therapeutic mechanisms for human placental products for future BLA indications
  - Developing preclinical models and managing studies to address pharmacokinetics, pharmacodynamics, safety, and mechanisms of placenta derived biotherapeutics
  - Drafting CMC, Biocompatibility, and Pharmacology/Toxicity sections for regulatory submissions for orthopedic, soft tissue repair, and neurologic applications
  - Mentoring and developing scientists and engineers in the department

PROGRAM MANAGER | HALYARD HEALTH | SEPTEMBER 2015 – JULY 2016

- Program Manager for both new product development and sustaining engineering projects.
  - Led an interdisciplinary team to develop new products for ostomy care
  - Changed all products in respiratory health from the use of DEHP laden plastic to be non-DEHP
  - Worked with on-house toxicology team to evaluate biocompatibility and toxicology needs based on risk assessment per 10993-1 for radiofrequency ablation probe for Coolief technology

PRODUCT DEVELOPMENT MANAGER | CORMATRIX CARDIOVASCULAR | OCTOBER 2012 – SEPTEMBER 2015

- Grew the R&D department from two individuals to eight reporting to me
- Supervised design and build of the R&D lab and implemented improved design control procedures
- Cleared three products for 510K release, and two approvals for IDE clinical studies
- Managed the successful delivery of product development projects and implemented an overall product development strategy in conjunction with peers and executives
- Performed biocompatibility and toxicology risk assessments and executed test plans for all ECM-based implantable cardiac devices (cardiac repair patch, pacemaker envelope, carotid patch, and tricuspid valve) and injectable particulate ECM and injection device.

SENIOR RESEARCH SCIENTIST | CORMATRIX CARDIOVASCULAR | JANUARY 2010 – OCTOBER 2012

- Directed projects for ECM-based medical device development from feasibility to US and International regulatory approval and commercial launch in the cardiovascular arena.
- Developed innovative decellularization methods for various Extracellular Matrices (ECMs) for cardiovascular and neurologic applications
- Developed novel uses for our current ECM
- Performed biocompatibility and toxicology risk assessments and executed test plans

RESEARCH SCIENTIST | CR BARD | DECEMBER 2007 – JANUARY 2010

- Participated in projects for mesh and ECM-based urogynecologic and hernia medical device development from feasibility to US and International regulatory approval and commercial launch
- Utilized animal models to evaluate polypropylene mesh, ECM, and absorbable devices for urogynecologic applications
- Planned and executed all biocompatibility and toxicology test plans for implantable urologic devices for urinary incontinence and pelvic floor disorder

POSTDOCTORAL FELLOW | EMORY UNIVERSITY | AUGUST 2006 – DECEMBER 2007

- Independent research projects included:
  - Differentiation of adipose tissue into cartilage and bone cells
  - Development of a knockout mouse for a receptor that is important in bone development
  - Primary culture of osteoblasts and chondrocytes from human samples

RESEARCH ASSISTANT | GEORGIA TECH | AUGUST 2000 – MAY 2006

  - Teaching assistant for Kinetics and Reactor Design, Plant Design, Separations Processes, and Transport Processes.

- Conducting independent research, including writing manuscripts and giving research presentations. The Development of a Novel in vitro Flow System to Evaluate Platelet Activation and Procoagulant Potential Induced by Bileaflet Mechanical Heart Valve Leakage Jets
  - Used human blood in a steady flow loop containing microchannels to assess damage done by mechanical heart valves
  - Used radiolabeling to track platelets as they coagulate on surfaces in the blood flow loop
  - Visualized flow patterns through these channels using Particle Image Velocimetry

CHEMICAL ENGINEER | LOCKWOOD GREENE | OCTOBER 1997 – AUGUST 2000

- At Lockwood Greene (a chemical consulting firm), I was a Process group leader for a project to implement new beer filtration process at nine Anheuser Busch breweries and a team member for a purification facility to produce Caprolactam from recycled carpet.

Education

PHD | MAY 2006 | GEORGIA INSTITUTE OF TECHNOLOGY

- Major: Chemical Engineering
- Minor: Biochemistry and Cell Biology
- Related coursework: Cell Engineering, Cell Biology, Biochemistry, and Biofluids

BS | JUNE 1997 | AUBURN UNIVERSITY

- Major: Chemical Engineering
- Minor: Premedicine

Publications

Bullard JD, Lei J, Lim JJ, Massee MM, Fallon AM, Koob TJ. Evaluation of dehydrated human umbilical cord biological properties for wound care and soft tissue healing. J Biomed Mater Res B Appl Biomater. 2018 Sep 10.

Soucy KG, Smith EF, Monreal G, Rokosh G, Keller BB, Yuan F, Matheny RG, Fallon AM, Lewis BC, Sherwood LC, Sobieski MA, Giridharan GA, Koenig SC, Slaughter MS. Feasibility study of particulate extracellular matrix (P-ECM) and left ventricular assist device (HVAD) therapy in chronic ischemic heart failure bovine model. ASAIO J. 2015 Mar-Apr;61(2):161-9.

Fallon AM, Goodchild TT, Cox JL, Matheny RG. In vivo remodeling potential of a novel bioprosthetic tricuspid valve in an ovine model. J Thorac Cardiovasc Surg. 2014 Jul;148(1):333-340.e1.

Fallon A, Goodchild T, Wang R, Matheny RG. Remodeling of extracellular matrix patch used for carotid artery repair. J Surg Res. 2012 Jun 1;175(1):e25-34.

Wu J, Yun BM, Fallon AM, Hanson SR, Aidun CK, Yoganathan AP. Numerical investigation of the effects of channel geometry on platelet activation and blood damage. Ann Biomed Eng. 2011 Feb:39(2)897-910.

Fallon, A.M., Dasi, L.P., Marzec, U.M.,Hanson, S.R., and Yoganathan, A.P. Procoagulant Properties of Flow Fields in Stenotic and Expansive Orifices. Annals of Biomedical Engineering. 2008 Jan; 36(1):1-13.

Fallon, A.M., Marzec, U.M.,Hanson, S.R., and Yoganathan, A.P, Thrombin Formation in vitro in Response to Shear-induced Activation of Platelets. Thrombosis Research. 2007 May 25.

Yoganathan, A.P., Fallon, A.M., Jimenez, Jorge. "Heart Valve Mechanics." Encyclopedia of Biomaterials and Biomedical Engineering. New York, Marcel Dekker, 2007.

Fallon, A.M., Shah, N., Marzec, U.M., Warnock, J.N., Yoganathan, A.P. and Hanson, S.R. Flow and Thrombosis at Orifices Simulating Mechanical Heart Valve Leakage Regions. Journal of Biomechanical Engineering. 2006 Feb, 128(1) 30-9.

Yoganathan, A.P., He, Z., Leo, H-L., Fallon, A.M.,"Mechanical Heart Valves." Encyclopedia of Biomaterials and Biomedical Engineering. New York, Marcel Dekker, 2004, 737-745.