JANET A. TAMADA

Stanford, CA 94305
jtamada@scientiabioengineering.com

SUMMARY:

Strategic subject matter expert and technical leader with extensive expertise in developing medical devices and drug-device combination products from concept through launch. Successful in establishing and running engineering and scientific organizations in a variety of technologies and environments. Individual contributor with hands-on experience in design control, project management, nonclinical and biocompatibility testing, clinical studies, and regulatory submissions. Track record of bringing complex, technically-challenging projects to completion.

PROFESSIONAL EXPERIENCE:

CONSULTANT **2013 - present**
Scientia Bioengineering Consulting, LLC **Stanford, CA**

Provide consulting services relating to development of medical devices, drug delivery systems and combination products. Clients have included large and small companies for R&D, clinical, quality, and regulatory work and venture capital firms for technical due diligence. Projects include:

- Large pharmaceutical: Individual contributor for design control documentation for parenteral biologic-device combination products. Device representative for delivery of biologics into tissue via electroporation.
- Large pharmaceutical: Leader and individual contributor for quality compliance and data integrity activities in medical device testing laboratory for drug-device combination products.
- Small medical device: Project management, nonclinical, biocompatibility testing, and technical development consulting for implanted hydrogel sensors and electro-optical reader devices.
- Start-up medical device: R&D and clinical for medical device for digital health
- Big Tech company, medical division: Technical and clinical consulting on biological and chemical aspects of a glucose sensing contact lens. Advisor on nanoparticle delivery project.
- Large medical device: Nonclinical, CMC, and regulatory consulting for development of otic drug-device product to provide local anesthesia for ear tube insertion as an alternative to general anesthesia

VICE PRESIDENT, ENGINEERING **2007- 2012**
ArKal Medical **Fremont, CA**

- Led design and development of a microneedle-based continuous glucose monitoring device for diabetes management. Directed the technical effort, including establishing initial proof-of-concept, designing, testing, manufacturing and iterating prototypes, and completing clinical trials with an advanced prototype. Clinical trials established device performance in diabetic subjects that was superior to competitive commercial products.
- Built technical team from 11 to 30+ employees, and established core competencies in R&D, including formulation, sensor design, microfluidics, analytical testing, nonclinical and clinical operations.
- Secured $17 MM Series B funding as technical lead of the senior management team.

RESEARCH FELLOW / DIRECTOR, EARLY DEVELOPMENT **2005 – 2007**
Alza Corporation (a Johnson & Johnson Company) **Mountain View, CA**

- Led cross-functional team of over 25 people for second-generation IONSYS™, a novel iontophoretic transdermal fentanyl drug delivery system for pain management. Project resulted in two successful Phase I clinical trials that demonstrated improved pharmacokinetic profiles compared to the first-generation product. The updated IONSYS was acquired by Incline Pharmaceuticals, approved by FDA, and launched by The Medicines Company in 2015.
- Responsible for design control and risk management process. Wrote CMC section and managed IND amendments leading to successful Phase I clinical trials.
- Functional manager for biomedical engineering group focused on design of drug/device combination products, including transdermal, ocular and nasal routes of drug delivery.

SENIOR DIRECTOR, PRODUCT DEVELOPMENT **2004 –2005**
Alexza Molecular Delivery Corporation **Palo Alto, CA**

- Functional manager of multidisciplinary department of 16 scientists, engineers, and technicians for the mechanical and electrical design of two pulmonary drug delivery platforms and chemical characterization for four active pharmaceutical ingredients for products in Phase I to IIA development. The lead product, Adasuve® (loxapine inhaler), launched in 2014.
- Led project team of over 10 people developing an inhaled fentanyl product for pain management and prepared pre-IND package for meeting with FDA.

EXECUTIVE DIRECTOR, R&D AND MEDICAL AFFAIRS **1991 – 2004**
Cygnus, Inc. **Redwood City, CA**

Built group of 14 professional employees, progressing through positions of increasing responsibility from Research Scientist to Executive Director.

- Initiated and led technical effort from concept to U.S. and EU regulatory approval and launch of the first continuous glucose monitor with real-time glucose display. The GlucoWatch® G2 biographer was an innovative, non-invasive, transdermal medical device, which was marketed from 2002 through 2007.
- Managed research and development of chemistry, biology, algorithm, software and hardware development, and design control activities, leading to PMA approval and CE Mark. Managed interactions with contract design organizations for electrical, software, and mechanical design.
- Directed clinical operations and data management and analysis for clinical trials for next-generation product. Managed interaction with contract data management organization. Oversaw successful biological monitoring audits by FDA.
- Authored clinical and data analysis sections of the PMA submission and presented to the FDA Advisory panel, leading to unanimous FDA panel recommendation for approval. Published scientific articles as first author in peer-reviewed journals including *Nature Medicine* and *JAMA*.

POST-DOCTORAL RESEARCH FELLOW
Massachusetts Institute of Technology, Cambridge, MA
Harvard-MIT Health Sciences and Technology Program/Chemical Engineering
Research Director: Professor Robert Langer

- Demonstrated surface and bulk erosion of bioerodible polymers used in drug delivery, including the Gliadel® bioerodible wafer for brain cancer treatment. Published results in *PNAS*.
- Proposed and initiated the use of quasi-elastic laser light scattering to characterize protein stability. Published results in *PNAS*.

EDUCATION:

Ph.D. Chemical Engineering; Biotechnology minor
University of California, Berkeley, CA
Research Director: Professor C. Judson King

Publications resulting from doctoral dissertation work on extraction of carboxylic acids by amine extractants were voted as top 10 most influential articles of the decade and top 100 most-cited articles since 1975 for *Industrial and Engineering Chemistry*.

B.S. Chemical Engineering;
California Institute of Technology, Pasadena, CA
Graduated with honors; Caltech class rank: tied for first (GPA 4.0)

PATENTS, PUBLICATIONS, PRESENTATIONS, GRANTS, HONORS:

Full listing available upon request.

- Inventor or co-inventor on 41 issued U.S. Patents
- Author of over 40 publications and invited reviews in refereed journals. Invited lecturer to numerous academic, national, and international conferences
- Elected Fellow of the American Institute of Biomedical Engineering (AIMBE)
- American Chemical Society Industrial Biotechnology Award for Cygnus
- National Institutes of Health Postdoctoral Research Fellow and NSF Graduate Research Fellow
- Principal Investigator for National Institutes of Health Phase I and Phase II SBIR contracts