

Shannon L. Werner, Ph.D.

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EDUCATION

Ph.D. Biochemistry	University of California, San Diego Expertise: Systems Biology, Inflammation, Oncology Advisor: Dr. Alexander Hoffmann, Signaling Systems Laboratory	2009
B.S. Chemistry	Ithaca College, <i>Summa Cum Laude</i>	2003

SCIENTIFIC/CLINICAL WORK EXPERIENCE

**most recent work history listed below this section*

Biomarker Strategy Manager, BioPharma and Academic Partnerships Epic Sciences, San Diego, CA **2015**

- Recruited and managed the Biomarker Strategy team (3 Ph.D.-level and 1 M.S.-level direct reports) in the development of circulating tumor cell (CTC) biomarker strategies in collaboration with BioPharma and Academic partners for oncology therapeutic programs in clinical development (Phase I-III clinical trials)
- Developed and nurtured relationships with BioPharma and Academic collaborators, including Clinical Operations Managers, Biomarker Scientists, Biostatisticians, Principal Investigators/Clinicians, Medical Directors, and KOLs for CTC clinical testing strategies to support companion diagnostic development
- Served as technical/scientific lead for the Business Development team for sales development, including contract/budget preparation and review, advising on clinical testing strategy, and scientific presentation of Epic Sciences' CTC Technology platform
- Collaborated cross-functionally and provided scientific expertise to internal stakeholders, including Assay Development, Clinical Operations, Translational Research, IVD/Product Development, Quality Assurance/Regulatory Affairs, Finance, and Marketing teams to allow for efficient development, rigorous clinical validation, and sales/marketing of the Epic Sciences' product pipeline
- Reviewed/contributed scientific content and managed efforts related to the preparation of clear, articulate and impactful abstracts, posters, and scientific manuscripts
- Oversaw team's clinical data interpretation and clear, concise data presentation to clients to ensure all Pharma contract deliverables were met on time and on budget
- Strategically reviewed Clinical Biomarker team's project portfolio, performed risk mitigation, and provided updates to senior management regarding status, issues, and portfolio changes
- Ensured appropriate resource deployment to meet project goals and deliverables

Project Manager, BioPharma and Academic Partnerships Epic Sciences, San Diego, CA **2014-2015**

- Managed Pharma Partner-sponsored CTC biomarker clinical testing projects from initiation through completion for small clinical feasibility studies through late-phase/Phase III clinical trials
- Successfully managed 6-8 Pharma partner-sponsored clinical projects simultaneously
- Collaborated with internal Clinical Project Coordinators to ensure successful clinical trial initiation, sample receipt, processing, and clinical testing of patient samples, data analysis, and study closeout according to clinical trial protocols/SOPs.

- Co-coordinated and maintained Epic Sciences' sample/clinical testing tracking systems
- Performed qualitative and quantitative clinical sample/CTC data analysis; prepared and presented cumulative project data to Pharma clients
- Interpreted preclinical/translational research related to clinical testing projects in support of biomarker assessment and development strategies in collaboration with Pharma partners
- Collaborated with Pharma partners, Data Managers, and clinical CROs to co-create clinical trial data transfer specifications
- Performed clinical data transfers as per the agreed upon specifications
- Created and submitted final study reports upon the conclusion of clinical testing activities
- Ensured accuracy, timeliness, and quality of all project deliverables (study initiation, clinical sample receipt, assay testing, reports, data analysis, internal/external data presentations, data transfer, study closeout)
- Ensured all aspects of clinical testing activities meet established technical, quality and regulatory standards, depending on the regulatory level of the project (GCP, CLIA)
- Identified project challenges including changing priorities and communicating to key internal stakeholders
- Contributed to the preparation of abstracts, poster presentations and manuscripts in collaboration with internal stakeholders and Pharma partners
- Experienced in creating more streamlined/efficient workflows with respect to clinical sample collection, shipment, testing, data analysis, and data presentation (from start to finish of clinical sample testing lifecycle)
- Collaborated with Quality/QA team to prepare detailed protocols, procedures, and SOPs and document SOP deviations for all clinical trial processes (sample receipt, clinical testing, data analysis, data reporting, data transfer)
- Collaborated with Business Development for the preparation of budgets and contracts
- Collaborated with Finance to assist in clinical testing forecasting, budget, and invoicing
- Collaborated with Assay Development for transferring assays into the clinical testing phase and providing scientific input for assay troubleshooting and optimization
- Experienced with Project Management software including SmartSheets
- Provided scientific input, mentorship and guidance to junior staff

Scientist & Senior Scientist

Merrimack Pharmaceuticals, Cambridge, MA

2010 - 2014

- Experienced in the drug development process from early-phase discovery, target-selection, and optimization of therapeutic design criteria through initiation of Phase I clinical studies
- Experienced in project management, strategic decision-making, and mentoring junior scientists in driving the development of an oligoclonal anti-EGFR antibody therapeutic (MM-151) using Merrimack's Network Biology (Systems Biology) platform
- Developed and validated clinical pharmacokinetic assay reagents used in MM-151 phase I clinical studies, and worked closely with the Assay Development/QC team to ensure delivery of clinical assay reagents in a timely manner
- Designed and executed preclinical assays for the lead selection and characterization of the MM-151 therapeutic campaign
- Contributed to the filing of the MM-151 Investigational New Drug (IND) submission to the FDA, the MM-151 drug and diagnostic patents, and to scientific research manuscripts
- Experienced in engagement of project stakeholders (internal and external) via scientific presentations and initiation of academic research collaborations
- Fostered collaboration with computational biologists, protein engineers, and *in vivo* biologists to elucidate drug mechanism-of-action, identify and validate clinical biomarkers, and examine PK/PD relationships

Postdoctoral Fellow

University of California, Berkeley, Berkeley, CA

2009 – 2010

- Awarded a NIH National Research Service Award (NRSA) fellowship for the use of high-throughput siRNA synthetic lethality screens to dissect the role of protein ubiquitination in driving tissue- and cancer-specific cell proliferation

Doctoral Fellow/Ph.D. Candidate
University of California, San Diego, San Diego, CA

2003 – 2009

- Awarded a National Science Foundation Graduate Research Fellowship for the examination of the role of positive and negative feedback mechanisms in encoding the temporal control of NF-kappaB signal activation in response to inflammatory stimuli
- Collaborated with computational modelers to perform a parameter sensitivity analysis of the NF-kappaB pathway mathematical model to determine rate-limiting reactions within the pathway, and to predict network behaviors in response to pathway perturbations
- Co-authored the funded NCI R01 grant “IKK: Biophysical basis for dynamic regulation”
- Was the first graduate student of the laboratory, which provided excellent experience in the project management of laboratory operations, development and organization of lab protocols, and subsequent training of incoming graduate students

ENTREPRENEURIAL, CLIENT SERVICES, & HOLISTIC WELLNESS EXPERIENCE

Founder, Mindful Movement Instructor, Transformational Nutrition Coach, & Reiki Energy Healer
Shannon Werner Energy & Relevate LLC, San Diego, CA

2017 - 2020

- Founded Relevate, a Mindful Movement and Wellness Studio dedicated to raising the health and wellbeing of clients' minds, bodies, and spirits
- Curated mindful movement and healing offerings including group and private instruction in Barre, Yoga, STOTT PILATES®, Reiki Energy Healing, and Transformational Nutrition Coaching
- Received high acclaim, including 5-Star Google Rating, ClassPass 2019 Best Instructor in San Diego Award, and invitations to teach Master Classes/Workshops locally, nationally, and internationally
- Highly experienced in training/teaching/educating clients in movement and wellness practices through group and 1x1 coaching
- Performed all roles of the organization including class instruction, curriculum development, event planning, customer service/retention/communication, marketing/PR, financial/budget management, and business operations
- Highly experienced with Small Business Project Management:
 - **Scheduling and Time Management:** stayed on time/on budget to ensure delivery of high quality client experiences
 - **Cost control and Resourcing:** ensured business profit/revenue growth without investor funds and limited personnel resources
 - **Effective Organization:** documented all business practices, files, projects, and client inquiries in a clear, organized way
 - **Risk Management:** strategically forecasted changes in the fitness market, local competition, and seasonal trends in client attendance to ensure stability and growth of the business; maintained flexibility in adjusting strategic plan as needed
 - **Leadership and Effective Communication:** regularly exercised influence without authority with regard to customer service/communication/retention, exhibited outstanding public speaking skills, and led clients through powerful movement experiences; highly experienced with tailoring client communication based on their needs and communication style
 - **Collaboration:** Co-created and planned successful experiential events with global brands and local fitness partners

Studio Manager, Lead Instructor, & Instructor Mentor
Barre3, San Diego, CA

2015 - 2017

- Served as Lead Instructor, Manager, and Mentor to the instructor team and staff (15 total staff) at barre3, a mindful movement studio whose classes are inspired by ballet barre, yoga, and Pilates
- Managed all studio operations, including marketing/PR/social media, client retention, customer service, retail (stocking/inventory), staff/instructor recruitment and training, class scheduling,

studio maintenance, event planning, and strategic planning

PROFESSIONAL DEVELOPMENT

Project Management Professional (PMP) Certification Exam Prep Course (2020)

Completed 35 PDU contact hours of training to prepare for the PMP Certification through the Technical Institute of America. PMP Exam planned for late 2020.

UCSD Extension In Vitro Diagnostic Development Course (2015)

Learned the requirements for moving an IVD product from concept to regulatory approval and market launch. Topics included setting product requirements & specifications to meet customer needs, critical path management, resource planning, principles of assay development, instrumentation, role and composition of the product development team, risk analysis, and IVD clinical and regulatory issues including compliance and complaint handling.

Biotech Employee Development Coalition (BEDC) Management Academy (2015)

Was selected for and completed a 7-week manager development course designed to address practical, real work situations, including Strengths-Based Leadership, building effective teams, communication styles, communication for impact, building strategic relationships, and career building.

TECHNICAL & MANAGEMENT EXPERIENCE

Project Management and Communications: Project Management according to PMP certification guidelines, expertise with Smartsheets Project Management software, Scientific writing and editing, preparation and submission of academic grants/fellowships, manuscripts, patents, and Investigational New Drug submissions, preparation and presentation of scientific presentations (Teleconference or in-person), development and nurturing of customer relationships, management of assay transfer from research to clinical settings.

Leadership & Management Skills: Clifton Strengths Finder Qualities (Achiever, Self-Assurance, Relator, Strategic, Learner), goal setting, research, forecasting, project prioritization, time management, multi-tasking, negotiating, networking, delegation, mentorship and management of junior staff/direct reports, effective and conscious communication, collaboration, active/empathetic listening, reflecting/mirroring, flexibility, constructive feedback, motivation/empowerment, public speaking, conflict resolution, problem solving, recruitment, performance evaluation.

Laboratory/Software Skills: Molecular Biology, Protein Purification, Tissue Culture, Biochemistry, Immunoassay, Immunofluorescence Microscopy, Analytical Chemistry, Bioinformatics, Data Analysis, BLAST, Primer Design, Cell Profiler, Cell Profiler Analyst, MetaMorph Imaging, ImageQuant, Photoshop, Prism, FilemakerPro, Adobe Illustrator, Endnote, Microsoft Office Suite (Word, Excel, Powerpoint), Project Management Software (Asana, Smartsheets), Salesforce.

Small Business Operations: programming/class format development, customer service, client retention, community outreach/events, advertising/marketing/PR, social media marketing, accounting/budgets, strategic planning and revenue forecasting, goal setting, planning, studio maintenance, retail/inventory, studio schedule management, staff training/mentorship, collaboration with brands, corporations, and charities.

Additional Soft Skills: Clear, confident, and respectful communication, cooperative teamwork, calm, curious, and optimistic outlook when facing challenges, self-starter/motivated, balanced use of intuition and logical thinking, persistent, committed, takes initiative, holistic/systems thinking,

innovation-minded, integrity, authenticity, dependable, emotional intelligence, introspection, critical observation, attention to detail, thinks outside of the box

PUBLICATIONS (in reverse chronological order; *Equal author contribution)

Greene SB, Dago AE, Leitz LJ, Wang Y, Lee J, **Werner SL**, Gendreau S, Patel P, Jia S, Zhang L, Tucker EK, Malchiodi M, Graf RP, Dittamore R, Marrinucci D, Landers M. (2016) "Chromosomal Instability Estimation Based on Next Generation Sequencing and Single Cell Genome Wide Copy Number Variation Analysis." PLoS One. **11**: e0165089.

Punnoose E, Ferraldeschi R, Szafer-Glusman E, Tucker EK, Pandita A, Flohr P, Riisnaes R, Miranda S, Figueiredo I, Rodrigues DN, Omlin A, Pezaro C, Zhu J, Amler L, Patel P, Yan Y, Bales N, **Werner SL**, Louw J, Marrinucci D, Attard G, de Bono J. (2015) "PTEN Loss in Circulating Tumor Cells (CTCs) Correlates with PTEN Loss in Fresh Tumor Tissue from Castration-Resistant Prostate Cancer (CRPC) patients." British J. Canc. **113**: 1225.

Kearns JD, Bukhalid R, Sevecka M, Tan G, Gerami-Moayed N, **Werner SL**, Kohli N, Burenkova O, Sloss CM, King AM, Fitzgerald JB, Nielsen UB, Wolf BB. (2015) "Enhanced targeting of the EGFR network with MM-151, an oligoclonal anti-EGFR antibody therapeutic." Mol. Cancer Ther. **14**: 1625.

Werner SL, Graf RP, Landers M, Valenta DT, Schroeder M, Greene S, Bales N, Dittamore R, Marrinucci D. (2015) "Analytical Validation and Capabilities of the Epic CTC Platform: Enrichment-Free Circulating Tumor Cell Detection and Characterization." J. Circ. Biomark. **4**: 3.

Behar M, Barken D, **Werner SL**, Hoffmann A. (2013) "The Dynamics of Signaling as a Pharmacological Target." Cell. **155**: 448.

Song EJ*, **Werner SL***, Neubauer J, Stegmeier F, Aspden J, Rio D, Harper JW, Elledge SJ, Kirschner MW, Rape M. (2010) "The Prp19-complex and the Usp4^{Sart3} deubiquitinating enzyme control reversible ubiquitination at the spliceosome." Genes and Dev. **24**: 1434.

Werner SL*, Kearns JD*, Zadorozhnaya V, Lynch C, O'Dea E, Boldin MP, Ma A, Baltimore D, Hoffmann A. (2008) "Encoding NF-kappaB temporal control in response to TNF: distinct roles for the negative regulators IkappaBalpha and A20." Genes and Dev. **22**: 2093.

O'Dea EL, Barken D, Peralta RQ, Tran KT, **Werner SL**, Kearns JD, Levchenko A, Hoffmann A. (2007) "A homeostatic model of IkappaB metabolism to control NF-kappaB constitutive activity." Mol Syst Biol. **3**: 111.

Basak S, Kim H, Kearns JD, Tergaonkar V, O'Dea E, **Werner SL**, Benedict CA, Ware CF, Ghosh G, Verma IM, Hoffmann A. (2007) "A fourth IkappaB protein within the NF-kappaB signaling module." Cell. **128**: 369.

Kearns JD, Basak S, **Werner SL**, Huang CS, Hoffmann A. (2006) "IkappaBepsilon provides negative feedback to control NF-kappaB oscillations, signaling dynamics and inflammatory gene expression." J Cell Biol. **173**: 659.

Cheong R, Bergmann A, **Werner SL**, Regal J, Hoffmann A, Levchenko A. (2006) "Transient IkappaB kinase activity mediates temporal NF-kappaB dynamics in response to a wide range of tumor necrosis-alpha doses." J Biol Chem. **281**: 2945.

Werner SL*, Barken D*, Hoffmann A. (2005) "Stimulus specificity of gene expression programs determined by temporal control of IKK activity." Science. **309**: 1857.

PATENTS

Kabbarah O, Szafer-Glusman I, Marrinucci D, Lee F, **Werner SL** (2020) "Compositions and Methods for Prostate Cancer Analysis." Pat.#20200200752

Kabbarah O, Szafer-Glusman I, Marrinucci D, Lee F, **Werner SL** (2018) "Compositions and Methods for Prostate Cancer Analysis." Pat.#20180209982

Bukhalid R, Nielsen U, **Werner SL**, Kearns JD (2012) "Monoclonal and Oligoclonal Anti-EGFR Antibodies for use in the treatment of tumors expressing predominantly high affinity EGFR Ligands or tumors expressing predominantly low affinity EGFR Ligands". Pat.# 20120308576

PROFESSIONAL PRESENTATIONS

American Society of Clinical Oncology Annual Meeting	May 2015
Clinical Data Presentations to Pharma Clients (on site, conference calls)	2014-2015
AACR-NCI-EORTC Int. Conference on Molecular Targets and Cancer Ther.	Nov 2011
Keystone Symposium for Inflammation, Microenvironment and Cancer	April 2008
11th Annual International TNF conference – Asilomar, CA	May 2007
Cell Signaling World Conference – Luxembourg City, LUX	January 2006

***REFERENCES PROVIDED UPON REQUEST**