

SKILLS

- Results-driven professional with experience managing projects and programs in a dynamic environment under strict timelines. Project and program types include new facility construction, existing facility improvements, quality system optimization, tech transfer, new product launch, new product introduction and FDA consent decree remediation.
- Extensive background working in a diverse range of life sciences companies including monoclonal antibody and recombinant protein manufacturers, providers of stem cell therapies, and medical device manufacturers.
- Experienced team leader with a solid track record of successfully managing and motivating cross-functional teams in a matrix organization.
- Analytical problem-solver with the ability to quickly adapt to change, assess the bigger picture, and analyze and mitigate risks.
- Strong verbal and personal communication skills with a demonstrated ability to guide and advise all levels of an organization from project teams to executive steering committees.
- Proficient in: Microsoft Project, Visio, PowerPoint, Excel, and Word.

PROFESSIONAL EXPERIENCE

Eastridge Workforce Solutions

Kansas City, KS

May 2018 – Present

Program Management Consultant

- Managed setup and qualification of an R&D and Pilot Plan clean room and clean utilities for production of clinical trial material. Developed a transition plan for transferring equipment and resources while continuing to support testing required for commercial production.
- Collaborated with R&D and Operations Engineering groups on design, procurement, and qualification of capital equipment and developed a multi-phase plan for moving from manual to fully-automated lines to support the product as it evolves from clinical to commercial production.
- Headed the effort to setup a new sterilization vendor to support demand growth and increase supply chain redundancy. Deliverables included forecast planning, development of new supply chain processes to support new transit routes, implementation of temperature and humidity monitoring devices to ensure cGMP compliance, and Quality systems modification to support remote lot release at contract manufacturers and distributors.
- Led the expansion of final packaging and product release capabilities to new facilities to increase efficiency and implement redundancy. Work included introduction and qualification of new equipment, process tech transfer, and modifications to the Quality System and FDA filing.

DexCom Inc.

San Diego, CA

January 2016 – April 2018

Principal Program Manager, held from January 2018 to Present

(Promoted from Senior Program Manager), held from January 2016 to January 2018

- Managed the build-out of a \$50M, 148,797 sq. ft. commercial manufacturing facility in Mesa, AZ from design through to full FDA approval. Represented end-users in design efforts, monitored construction, assisted in problem solving, and led execution of commissioning and qualification of the facility, utilities, and production equipment. Project was completed ahead of schedule and on budget.
 - Delivered bi-monthly, company-wide informational presentations on Mesa facility construction progress and quarterly update meetings for the CEO and Executive Leadership Team.
 - Supported Quality and Regulatory teams during Mesa-related filing of a 180-day site change supplement with the FDA and update of the company Tech File with the British Standards Institution (BSI). Received approval from both agencies with zero observations.
 - Built a cross-functional team comprised of Engineering, Manufacturing, Supply Chain, R&D, Finance, IT, Quality, and Regulatory departments to plan and execute the tech transfer of two products to the Mesa facility. Deliverables included procurement and qualification of all production and laboratory equipment and materials, execution of process validation and shipping studies, and development of new logistics methods for transit of in-process product to contract sterilizers.
- Led the conversion and retrofit of existing office space into qualified cGMP production suites for commercial production and R&D new product development at the San Diego campus and successfully filed a CBE-30 with the FDA and passed onsite BSI inspection.
- Oversaw all manufacturing facilities projects to improve capacity and production flow and to enable the launch of new products while minimizing impact and risk to production. Methods included clean construction and risk-based qualification and regulatory filing.

- Drove the onboarding and qualification of alternate suppliers for critical raw materials. Worked with Legal and Supplier Quality departments on agreement execution and with technical teams on design and execution of chemical and performance equivalency testing. This project improved business continuity and reduced cost by \$500K/year.

Sequoia Consulting Group

San Diego, CA

March 2015 – January 2016

Project Management Consultant

- Baselined departmental work load and resource utilization and created a prioritization tool to allow managers to focus resources and maximize return on investment.
- Guided project sponsor and leads in the initial planning phase of a tech transfer from a development site to commercial operations. Developed Work Breakdown Structure and resource tool to kick off initial communication and data gathering with impacted sites and departments.
- Took over management of an ongoing tech transfer project to introduce new fill/finish and packing technology. Improved project communication and stakeholder engagement leading to an increase in execution and accountability.

Genzyme Corporation

Allston, MA

May 2011 – December 2014

Senior Program Manager, held from January 2013 to December 2014

(Promoted from Senior Project Manager), held from May 2011 to January 2013

- Managed a site-wide utility shutdown while continuing to run critical manufacturing operations. Drove a multidisciplinary planning effort to successfully complete an on-time shutdown while safely continuing operations, resulting in a net gain of \$12 million.
- Drove the expansion of downstream manufacturing capabilities and facilitated collaboration between site departments and an external CMO resulting in a successful process development and regulatory filing.
- Selected by senior leadership to oversee the plant's Environmental Controls program. This program significantly reduced conflict and misalignment between projects and made it possible to successfully meet FDA consent decree verification dates.
- Developed communication channels between project teams and manufacturing personnel resulting in the ability to meet both production and project milestones in a timely and compliant manner.
- Led logistics planning and execution as part of a full maintenance shutdown. Worked with Supply Chain, Manufacturing, Validation, and Quality to identify and qualify storage for temperature sensitive material. This innovative solution enabled the continued processing of over \$6 million of work-in-process material.
- Designed a master transfer plan for the move and consolidation of all Genzyme's warehouses into one central location. Identified and classified products according to functional and regulatory criteria to define timing, order, and priority for relocation.

Israel Defense Forces (IDF)

Israel

January 2002 – February 2005

Logistics Office

- Co-commanded a company of 160 soldiers and led regiment logistics improvements resulting in a 35% logistics cost reduction.
- Planned and executed four transfer operations of the entire regiment consisting of 600 soldiers and 45 armored vehicles. Streamlined operations resulting in an 8% cost reduction.
- Managed \$5M of annual supply budget and validated the annual work plans for four regiments, decreasing the brigade's logistics expenses by \$1M.

EDUCATION - Degrees

UNIVERSITY OF MICHIGAN - **Stephen M. Ross School of Business, Ann Arbor Michigan**

Master of Business Administration, May 2011

- Awarded full merit-based scholarship.
- Volunteered for a non-profit project in Rwanda.

TEL AVIV UNIVERSITY - **Faculty of Life Sciences, Tel Aviv Israel**

Bachelor of Science in Biology, February 2008

- Dean's List Program for Excellent Students - Research Program.
- Graduated Magna Cum Laude, top 2% of class.
- Awarded Life Science Faculty Scholarship for academic excellence from 2006-2008.

EDUCATION - Certificates

PROJECT MANAGEMENT INSTITUTE - Project Management Professional (PMP) Certificate # 1882470, December 2015

WENTWORTH INSTITUTE OF TECHNOLOGY - Construction Project Management Certificate, August 2014