Timothy Lloyd Trapp

Senior Project Management Consultant

Core Competencies

- CMC Project Management
- RAC Certified
- Biologics
- Pilot Plant Design
- Design/Scoping
- Clinical Supply
- Construction Management
- Third Party PM
- Gantt Chart Design

Professional Summary

Mr Trapp is an experienced CMC and pharmaceutical project management professional with extensive knowledge in development, pilot, clinical, and commercial pharmaceutical operations. Over the course of his 39+ year career, he has gained extensive technology transfer, design/scoping, commissioning, qualification, validation, and construction management experience for FDA regulated facilities.

Mr. Trapp is also RAC certified with extensive Module 3 submissions in support of IND, NDA, BLA, PMA, and IMPD submissions.

Education

B.S.	Biochemistry	Loma Linda University

Professional Experience

Design Space Inpharmatics, LLC **2020 - Present**

Senior Project Management Consultant

- CMC drug development, process and program management, validation, and regulatory affairs consulting projects,
- Full-service design, engineering, construction management and validation,
- Project Manager for manufacturer of Class 3 implantable medical devices,
- Resolved ongoing and historical production bottlenecks through unit operation optimization.

Pharma Supply Chain Consulting, LLC **2015 - Present**

Principal Consultant

A consulting firm providing development of Supply Chain and CMO identification/selection for pharmaceutical, biotechnology, device, and dietary supplement manufacturers. Extensive Tech Transfer and process equipment changeover projects.

- Biological products, Preliminary Facility and Process design, CMO introductions/selection, Project Management,
- Pharmaceutical CMC/dose form, supply chain development, CMO management,
- Process validation, commercial supply chain, FSMA planning/auditing, FSVP validation planning and Execution,
- Antisense oligomer technology, CMC planning and CMO identification, analytical method and specification development.

Carbylan Therapeutics **2014 - 2014**

Vice President of Manufacturing Operations

A clinical (Phase III) stage pharmaceutical company with a combination product implantable Class III knee device. Responsible for internal and external pilot, development, and manufacturing operations in support of clinical trials worldwide, and development of commercial supply chain.

- CMO Identification, technology transfer, vendor contracting and management,
- Engaged process engineering firm to characterize and standardize hydrogel manufacturing,
- Generated and performed FMEA for product in support of transfer and validation programs,
- Pilot operations in support of scale-up and product transfer.

Heron Therapeutics **2012 - 2014**

Senior Director of Manufacturing

A commercialization-stage pharmaceutical company with proprietary controlled release polymer technology which received a CRL from the FDA on previous submission.

- Switched and qualified suppliers for all key intermediates,
- Managed tech transfer and validation programs,
- Scaled up bulk drug formulation and filtration to market entry size (12 - 20X increase) at new CMOs,
- Aseptic syringe filler upgrades to accommodate high viscosity formulations,
- Negotiated API supply contracts, saving 70% over previous best pricing.

ChemGenex Pharmaceuticals **2008 - 2011**

Senior Director, Manufacturing Operations

A commercialization-stage pharmaceutical company developing a new class of drug for Chronic Myeloid Leukemia (CML) treatment. Responsible for all manufacturing operations (API, Drug Product, reagents, kits). Authored all CMC content and filings for IND, IMPD, NDA, and MAA. Responsible for contract manufacturing and assembly (clinical and commercial), drug supply chain development and management, and program manager for subcutaneous to oral dose conversion program.

- Scaled up API and Drug Product production processes and met aggressive production targets in support of clinical trial expansion and inventory build in preparation for market entry,
- Wrote and developed CMC sections for NDA and MAA submissions,
- Prepared for and passed initial pre-approval inspections at ChemGenex, the first FDA inspections in company history,
- Prepared EU contract manufacturing operations for successful FDA audit by performance of external audits, mock inspections, consulting engineering for water systems, and regulatory guidance,
- Technology transfer, scale-up, and method transfer to new Contract Manufacturing Organizations for US and EU clinical trials sites and market launch,
- Developed project timelines, budget, and action plan for accelerated CMC filing,
- Developed commercial entry plan for US, EU, and ROW markets.

ALZA Corporation **2003 - 2007**

Director, R&D Operations

A drug delivery and pharmaceutical discovery firm. Responsible for validation, commercial and pilot manufacturing/scale-up, calibration/metrology, maintenance, and supply chain operations in support of oral solid dosage and transdermal materials.

- Responsible for commercial and pilot scale manufacturing for 2 commercial and 23 development programs in support of worldwide J&J drug development strategy,
- Commercial manufacturing for oral and transdermal products for 18 months post-introduction as process, equipment and technology transferred to Vacaville operation,
- Manufacture of two market entry programs for controlled release oncology drug delivery,
- Managed the outsourcing of the Calibration and Metrology functions, consolidated systems and tracking – ongoing savings of $4.6+ MM per year, received J&J Global Standards of Leadership award for project,
- Successfully incorporated new process technology (PAT, high-shear granulation, etc.) in pilot operations prior to introduction as commercial process,
- Managed technology transfer to CMOs and divestitures of technology to private firms,
- Implemented risk-based qualification and life cycle management through changes to qualification, change control, and design control systems and streamlined processes and paperwork,
- Standardized practices (qualification, requalification, change control) across functions and locations,
- Introduced new equipment and technology (i.e. digital dataloggers, wireless probes) to provide better support to ongoing activities.

Bovis Lend Lease, Pharmaceutical Division **2002 - 2003**

Project Executive/Vice President West Coast Operations

Design, construction management, consulting, and validation of FDA-regulated facilities and laboratories.

- Profit and loss responsibility for office of 100+ staff performing consulting, project management, and construction management services,
- Confidential Client, St. Louis MO – Phase II Expansion - Project Executive for $192M biotech facility renovation,
- Managed all aspects of project schedule, budget, and scope. Aligned delivery systems with client needs provided additional consulting services (startup, validation, regulatory) to complete project,
- ELAN Pharmaceutical, South San Francisco, CA – 21 CFR Part 11 Evaluation and Remediation,
- Confidential Client, San Rafael, CA – Conceptual design, cost estimating, construction contracting, startup and commissioning for human tissue transplant facility,
- Confidential Client, Boston, MA – Strategic planning, Construction Management, Validation Master Planning, and startup, commissioning and validation of a $33M research facility,
- Confidential Client, Cambridge, MA - Strategic planning, Construction Management, Validation Master Planning, and startup, commissioning and validation of a $28M research facility.

McGhan Medical Corporation **2000 - 2002**

Director of Technology

Managed Engineering, Process Development, Manufacturing Technical Support, Maintenance, and Calibration departments.

- Program manager for introduction of 3 new Human Collagen-based products. Responsible for program development, process and facility design, regulatory compliance, and transfer to manufacturing. This $27M fast-track project was 22 months from conceptual design to facility inspection, including the construction of a dedicated manufacturing suite. Project was delivered on time and on budget,
- Renovated existing facility and utility systems during planned shutdowns while maintaining project schedule,
- Hired, trained, developed, and integrated 8 new engineers and development scientists into the ongoing project,
- Increased the cGMP and Regulatory compliance of the entire facility through renovation and changes to the following systems: Change Control, Preventive Maintenance, Engineering Document Control, Calibration, Validation Documentation, Engineering Standards, PLC/control systems , aseptic systems,
- Resolved ongoing and historical production bottlenecks through unit operation optimization, component, facility, and equipment redesign projects,
- Increased manufacturing uptime and output significantly (+12%) through facility, process, equipment, and operational changes,
- Implemented new de-gassing technology and equipment which reduced filling scrap by 78%.

Industrial Design Corporation **1992 - 2000**

Director of Biopharmaceutical Operations

Full-service design, engineering, construction management and validation firm. Profit and Loss responsibility for West Coast Biopharmaceutical operations and satellite office performance.

- Formed Biopharmaceutical division of IDC,
- Business Development and Project Management of domestic and international design, construction, and validation projects,
- Authored and implemented BioPharmacetical Quality Assurance Program to track design, construction, regulatory, and validation project quality. Developed and implemented Quality Control systems for pharma,
- Developed internal training programs for cGMP, Validation, GLP, and DQ programs,
- Managed the submission of DMF, NDA, ANDA, and 510(k) documents for client companies,
- Familiarity with design, operation, and validation of API production processes including synthesis, fermentation, cell culture, purification, clean utility systems, clean/mini/controlled/BSL/containment environments.

Project experience includes: Project, Process, and Program Management, Validation, and Regulatory Affairs consulting projects.

- OMYA-Superior, AZ. Project Manager for $43M USP grade CaC03 plant,
- Zymogenetics-Seattle, WA. Design and engineering services for a bio-waste inactivation system,
- Merck and Company, Danville, PA. Project Manager for design, engineering, and validation services to install a new site-wide deionized water system,
- Servier Pharmaceuticals-Arklow, Ireland. Project Manager for design, engineering, validation, construction management, and startup/commissioning for two new BPC process suites,
- Irotec Laboratories-Little Island, Ireland. Process design manager for design, construction, validation, and startup/commissioning of a 25,000 square foot pharmaceutical production facility,
- Amgen Inc.-Thousand Oaks, CA. Project Manager for sanitary piping manifold and pump replacement project in purification suites,
- Tokyo Kasei Kogyo-Portland, OR. Project Manager for design of new pilot facility for API,
- ProCyte Corporation-Kirkland, WA. Project Manager for design, construction and validation of 9,000 square-foot manufacturing and pilot facility for the production of intermediates and API.

Hybritech Inc **1985 - 1992**

Validation Manager

A manufacturer of monoclonal antibody-based diagnostic test kits.

- First validation manager in company history, responsible for all facility, process equipment and process validation activity companywide.

Production Manager

- Responsible for high-volume polystyrene bead extrusion operations, antibody coupling, and reagent manufacture. Received President's award for increasing manufacturing throughput.

Ciba-Corning Diagnostics **1981 - 1985**

OEM Product Manager

A manufacturer of liquid and lyophilized chemistry controls and reagents for the diagnostic products industry.

- Responsible for scale-up, pilot operations, and custom formulations for OEM clients.