**Christina Nacos, P.E.**

(720) 217-7558 cmn529@gmail.com

**Senior Supply Chain Strategy and Business Development Leadership**

**Pharmaceuticals / Biotechnology / Technology Transfer / Network Optimization Regulatory Strategy / Global Supply Chain / Strategic Alliances / Sourcing / Engineering Strategy Development / Program & Project Management**

Global technical, business and regulatory expertise in developing strategies and alliances for supply assurance and cost reduction in the pharmaceutical industry. Especially strong in supply chain risk management to address weak areas and seize growth opportunities. Adept at…

* **Optimizing API network performance**
* **Anticipating and planning for short and long term needs and opportunities**
* **Evaluating and selecting international vendors and partners**
* **Enhancing top- and bottom-line revenue**

BS, Chemical Engineering, emphasis in Biotechnology, University of Colorado, 1997. Graduate Certification Engineering Management with Quality Emphasis, University of Colorado. PE, Chemical Engineering, Colorado. Project Management Certification, ESI International/George Washington University, 2013. Regulatory Affairs Certificate, RAPS, 2017.

**History and Highlights**

**Process & Project Engineer- Oligonucleotides**

Corden Pharma Colorado

2016 to Present

Temporary contract

Lead startup of the oligonucleotide program, implementing at medium to large scale manufacturing. Serve as SME for specifications and design of large scale oligo equipment for $15M+ capital project. Guide and contribute to several project teams.

**Senior Manager, Active Pharma Ingredient (API) Strategy**

Pfizer/Hospira

2013 – 2016

Promoted to create an API master strategy to optimize API network. Focused on capital investments, vertical integration, strategic partnerships, alternate sourcing, JV’s and divestures. Provided strategic API and KSM sourcing, and technical due diligence, covering companies worldwide. Served as API SME for corporate initiatives, forecasting, and troubleshooting.

* **Supported global expansion.** Created Hospira’s first API long range forecasts**. E**nsured API needs and supplies were aligned to support Global Expansion (GE) initiative. Provided senior corporate decision makers with API long range planning, supply chain strategies and global expansion markets guidance.
* **Regained control of spiraling costs**. An internal API site’s manufacturing costs were rising. Arranged a stop-gap measure to lower the cost. The KSM (key starting material) was approximately 50% of the manufacturing cost and came from biomass extract. Negotiated a deal to purchase the biomass directly from the seller, transport it to an Indian extractor, and ship the final KSM to the Hospira site. Overcame significant logistical, technical and regulatory hurdles. Dropped the KSM price by 40%. Saved $1.5 M annually.
* **Orchestrated the shutdown of a money-losing manufacturing site.** An API manufacturing site was severely underutilized. Created a plan to produce key molecules (low volume, low cost APIs with high value) at CMOs. Arranged technology transfers. Found options, wrote RFPs, developed regulatory strategy for filings and transfers timing. Collaborated with finance and supply chain to develop an exit strategy. Developed a multi-faceted plan that included site closure and technology transfers that saved $21M annually while ensuring a ready supply of key API’s.
* **Solved a crucial capacity problem**. Analyzed network capacity to support long range plan. Determined the India facility would have huge capacity issues when Product X launched, the biggest launch and first-to-market opportunity in the pipeline. Under tight time constraints, devised a capacity model, regulatory strategy and project plan. Won corporate approval and appointment to champion the $8M project that was completed on time and to specification.

**Technology Transfer Manager**

Hospira Boulder, Inc.

2008 to 2013

Promoted to this new position to manage 11 API projects from development through commercial process validation. Coordinated EHS, Quality, Validation, capital project engineering, manufacturing, and development departments to achieve on-time and within budget start-ups.

* **Created a formal overarching Technology Transfer process**. Forged a group that included each site department that brainstormed all the tasks and deliverables required for a successful TT. Fostered accountability. Translated the technology transfer process into an SOP and working guidelines. All tech transfers that used the TT Process were successful.
* **Established relations with key starting material suppliers (KSM’s).** Lack of prescreened KSM’s gave rise to production shutdowns, excessive costs, rush deliveries and firefighting. Took over sourcing of KSM’s. Built a database of companies, samples, pricing, delivery terms, etc. For each project KSM, sourced one low cost 'riskier' supplier and one supplier from the western hemisphere (less risk). Integrated KSM sourcing and testing into the Tech Transfer business process. Filed multiple suppliers for KSMs at the initial ANDA filings, a first.
* **Managed one of the company’s largest technology transfer projects.** For a project that was a first-to-market opportunity and the biggest product launch for the company in the upcoming five years, navigated a complex global regulatory maze. Used the TT process SOP and checklists to organize the team and developed a global filing requirements matrix for the API. Achieved the most cohesive and productive tech transfer the site ever had.

**Process Engineer III**

Hospira Boulder, Inc.

2003 to 2008

Responsible for evaluating process safety and writing process safety guidelines for the site. Performed process fit and throughput analyses for potential projects. Analyzed data and statistical significance through design of experiments.

**Senior Process Development Engineer**

Roche Pharmaceuticals

1999 to 2002

Developed and supported clinical production for a peptide fusion inhibitor API. Responsible for process development, costing, throughput analysis, scaling, registration batches, and technology transfers on first and second generation active pharmaceutical processes. Designed equipment and operational solutions.

* **Supported an important technology transfer project.** Championed and designed the equipment for the chromatography and final isolation, a $1.2 MM project. Scaled the process from lab to a 15 cm chromatography column. Transferred technology to an overseas site.
* **Orchestrated a reclassification which yielded significant savings.** The entire plant site had an electrical classification of Class I Division 1, the tightest hazardous area classification making procurement of equipment excessively expensive. Developed a plan and collected date to support reclassification to Class I Div 2. Earned hazardous area classification Class I Div 2, realizing significant savings. Received an employee recognition award.

**Process Engineer**

Roche Pharmaceuticals

1997 to 1999

Scaled, designed, implemented, started-up, supported and optimized three chemical pharmaceutical synthesis steps in large scale manufacturing. Optimized processes in manufacturing to improve throughputs and yields. Performed proactive process troubleshooting to resolve potential operating problems.

**Additional Information**

**Education**

**Business Development/Strategy**

RAPS, Regulatory Affairs Certificate, 2017

CfPIE, Preparation of FDA Submissions and Communicating with the FDA, 2014

Technical Training : IBI - Intercultural Business Improvement, Chinese Business Culture, 2012

SkillPath Seminars, Mega Memory for Business Professionals, 1999

**Project Management**

ESI International/George Washington University, Project Management Certificate, 2013

George Washington University, Project Leadership, Management and Communications, 2013

George Washington University, Risk Management, 2011

George Washington University, Scheduling and Cost Control, 2010

Kepner-Tregoe, Kepner-Tregoe Project Management, 2001

SkillPath Seminars, Managing Multiple Projects, Objectives & Deadlines, 1998

**Technical**

CfPIE, Lyophilization Training, 2017

PrimaTech, Process Hazard Analysis for Team Leaders, 2010

Scientific Update, Chemical Development & Scale-Up in the Fine Chemical Industry, 2004

Novasep, Prep Chromatography Purification, 2002

AIChE, Reaction Kinetics for the Practical Engineer, 2000

Chilworth Technology, Inc., Understanding & Controlling Static Electricity, 2000

Chilworth Technology, Inc., Dust Explosion Prevention & Protection Techniques, 2000

Chilworth Technology, Inc., Gas & Vapor Explosion Hazards, 2000

Chilworth Technology, Inc., Thermal Instability Hazards, 2000

Chilworth Technology, Inc., Control of Exothermic Chemical Reaction Hazards, 2000

AIChE, Crystallization Operations, 1999

AIChE, Distillation in Practice, 1999

MixTech, Mixing Dynamics, 1999

Stat-Ease, Experiment Design, 1998

AIChE, Bulk Pharmaceutical, 1997

**Hobbies**

Adventure travel, ultra-endurance mountain biking, trail running and adventure racing

**Professional**

American Institute of Chemical Engineers, Regulatory Affairs Professional Society Membership

**Patent**

Methods and compositions for preparing peptides with excellent solubility characteristics in aqueous solution at physiological pH; US 20060167220 A1, Filed 2005

**Previous Travel**

Extensive (for work and leisure)- China, India, Spain, Belgium, France, Italy, Germany, Austria, Switzerland, Tanzania, New Zealand, Canada, Mexico, Brazil, Chile, Peru, Bhutan, Fiji

**Knowledge of other cultures**

Chinese culture training, knowledge of Indian, Bhutanese, and South American cultures