**Connie Tolman**

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**Senior Sustaining Engineer**

 **Silver Lean Certification |PMP | Six Sigma Black Belt**

**Experienced Professional with 24+ years of experience in all facets of Medical Device Quality and Manufacturing.**  Focus on problem solving resolutions, manufacturing support, NCMRs, Deviations, CAPA/SCARs, FMEAs, change orders, Quality audits, supplier audits and supplier change notifications. Assures compliance with 21 CFR Part 820/ISO 13485 to achieve company objectives. Transfer of products from development/R&D.

**Core Strengths**

Cross-functional team leadership ◦ Sustaining ◦ Process Improvement ◦ Quality Tools◦ Change management ◦ Problem Solving ◦ Root Cause Analysis ◦ Data Analysis

**Professional Overview**

INOVIO Pharmaceuticals – *San Diego, Ca* (06/20 – 7/22)

**Sustaining Manufacturing Engineer, Senior**

Class III medical device in the clinical trial process, supporting three (3) product lines interfacing with supplier for the consumable product assisting with qualification, validations and change management.

* Managed the problem resolution process utilizing NCMR, CAPA, deviations, root cause analysis and rework instructions for diverse mix of electroporation medical device product lines utilizing 5 Whys, fishbone diagrams, and resulted in the successful production of 3PSP handset, applicators, and arrays within 6 months from starting with company.
* Completed continuous improvement project for updating the complicated labeling process - reducing steps from 18 to 9 steps and reduced resources from 4 to 2 and reinvigorated the continuous improvement companywide team participation.
* Worked with suppliers to achieve timely resolution of issues related to sterilization process both internal and with outside suppliers by releasing Standard Operating Procedures.
* Completed protocols, reports, and IQ/OQ/PQ for new product line (FFS Blister and 3PSP pouch array) which resulted in readiness for full scale production for device and consumables.
* Coordinated quality documentation for response to TUV audits for yearly sterilization requirements resulting in approval from auditor.
* Worked with team to complete supplier audits and modifying Supplier Approval list including incorporation of the supplier portal enabling the team to get real time feedback for production status.
* Worked closely with R&D in the transfer of products for packaging and updating PFMEA and DFMEA as product moved into production.

Secure It – 05/16 – 06/20

**Operations Management Consultant** I

**Business Consultant (Dexcom)** *– San Diego, Ca* 06/19 – 09/19

Enterprise-wide European rollout of implementation of SalesForce.com and Fusion Oracle ERP system. Worked closely with European counterparts to define and document enterprise-wide process steps from lead generation through to returned goods authorization for 4 countries in preparation for “go live”.

**Operations Project Manager Consultant (Jenavalve)** – *Irvine Ca.* l 11/18 – 03/19

* Worked with the development manufacturing in the UK for the class III transcatheter aortic valve replacement device assisting with the preparation for FDA approval evaluating all of their products for consistency for their work instructions and verifications.
* Working with the Brea facility that manufactured the delivery system in the startup phase utilizing value stream mapping and business assessment processes for new orders, clinical trials, manufacturing, and delivery of product to hospitals.

Decision Sciences – *Poway, Ca*12/16 – 06/18

**Manufacturing/Quality Engineering**

Hands on manufacturing engineer for company that is a provider of advanced security and contraband detection systems.

* Created test station, software for final acceptance test for product which enabled the company to receive the first payment for shipment of Security system to Singapore.
* Worked with Contract Manufacturing supplier to document work instructions and improve workflow for 6 critical processes.

Becton Dickinson Life sciences – *San Diego, Ca*3/14 – 9/16

**Continuous Improvement Manufacturing Engineering Manager**

Reagent biotech manufacturing for research industry. Over 1500 SKUs in full scale production. Worked with biotech teams from tissue culture, purification, conjugation, and packaging to improve processes.

* Performed audit for GMP compliance all laboratory groups.
* Led Executive Steering Committee weekly to review the open NCMRs and CAPAs. Hosted the monthly CI Council with representative from each department to review their CI ratings posted on their daily information board.
* Initiated cost savings implementing bar code system for moving material between locations that reduced throughput from 5 days to 2 days.

Viasat – *Carlsbad, Ca*6/10 – 12/13
**Manufacturing Engineering Manager**

Hands-on Manufacturing Engineering Manager responsible for developing new manufacturing methods for electro-mechanical satellite communications systems.

* Identified capital equipment acquisition of Aqueous Technologies printed circuit board capital equipment which improved cleanliness from 19.39 μg per in² to 0.01 μg per in².

L3 communications – *Anaheim, Ca* 2/07 – 5/10

**Principal Manufacturing Engineer**

Manufacturing engineer for Air Force contract for GPS receiver.

* Recognized and leveraged best practices and brought them to the external customer, GPS Wing for Modernized User Equipment, and internal customer L3 Program Office, which resulted in business process improvements and 100% on time delivery to the customer
* Supported key business improvement projects which drove cost, efficiency, and quality for the transfer of data in the ERP system between Design group and Operations reducing transfer time by a minimum of 54%.

Dexcom – *San Diego, Ca* 9/05 – 1/07

**Manufacturing Engineering/Manufacturing Manager**

Led Facility and Operations team to successful build of clinical trials performed in New Zealand while managing the facilities move of the R&D, Operations and Chemical laboratory to new building utilizing ERP system.

* Identified and implemented production equipment resulting in yield improvement from 60% to 90%.
* Renegotiated the contract with contract manufacturers for printed circuit board assemblies, which resulted in savings of $500K per year.

Medtronic heart valves **- Principal Manufacturing Engineer** 6/04 – 9/05

* Class III implanted tissue valve on market manufacturing facility working with transfer of the sewing process to Mexico maquiladora and evaluating the stent machine qualification of new supplier in Northeast.

GE Healthcare (ex VitalCom) **Manufacturing Engineering/Service Integration Manager (**12/98 – 6/04)

* Class I in-market distributed networked monitoring device for hospitals overseeing three product lines. Failure analysis activity for new product launch that included Fishbone diagram, DMAIC analysis, CAPA involvement working with Regulatory on FDA audit representing Manufacturing.

**Education & Credentials**

**Bachelor of Arts (BA)** (2007) – University of California *– Berkeley,* *CA*

**Six Sigma Black Belt** #1014 (2003) – American Society of Quality

**Silver Lean Certification** #14819241 (2015) – SME / ASQ / AME / Shingo Prize

**Project Management Professional** #204653 (2004) – Project Management Institute