

Charles Griswold

Director of Quality and Engineering

Cell: 619-683-2462 CGriswold@lion-dc.com

Two decades of experience strategizing, managing, and developing medical device technology. Key roles in the research, development, and production of patented medical devices. Effective management of teams up to 12 people, completing projects on time, and in budget.

PROFESSIONAL EXPERIENCE

LION DESIGN CONSULTING, INC.

5/08-Present

CEO, Contract Engineering Services

Design, Quality and Project Engineering management of dozens of medical products for clients on contract. Clients include Trinity Orthopedics LLC, Alere (Ameditech) and HipNav Technologies Inc.

Projects included:

Anterior Cage Implant R&D

UDI Project

Quality Manager

4.5, 6.0, fixed/pivoting Cannula

Primary on 3 FDA audits

10 Distributor/Internal Audits

Surgical Sterilization trays

-Dental Orthoscopic Camera

CE Mark Tech. File Submission

Lateral Cage Project

Vertebra Compressor/Distractor

Corex Bone Harvester Rev 2.5-2.61

SEABOTIX

10/06-12/07

Engineering Manager

Engineering Management of underwater ROV systems manufacturer. Installed PDM Works, Solidworks 2007 and Cosmos in department. Design refinement. Spearheaded 4 injection molded parts and at least 6 products through to production.

RIDGELINE ENGINEERING

10/04-4/06

Project Engineer/Quality Manager on underwater ROV system.

Committee Manager for company quality standards and practices. Revised/Created 12 company core process or procedural documents to bring the company up to ISO auditing standards.

Projects included:

- Biosite diagnostic sealer

-IntraLuminal Therapeutic catheter trimmer

- CSI Technologies Capacitor magazine/Loader

-Hunter Industries spin welder

SEQUENOM, INC.

11/00-8/04

Automation Engineer & Team Lead for in-house R&D prototypes.

Led 12 member MassARRAY(tm) Sample Tracking product team, from development to launch, resulting in 14 successful customer installations. Primary Mechanical Engineer for in-house R&D prototypes including Nano Chip, Resin Dispenser, and hME projects. Design projects yielded 9 marketed hardware items and patent applications including U.S. Patent Application 20020155587. Engineered 4 injection molded components 2 of which went into volume production.

Biological processing equipment developed:

- Liquid Handlers

-NanoCycler

-Nanodispensor

-100K PCR line

-MassSpectrometers

- LED lit inspection equipment

PRODOSYST AUTOMATION

3/00-11/00

Project Engineer supervising and designing automation projects.

PRODUCTION SYSTEMS

7/97-3/00

Project Engineer designing and project managing custom automation assembly lines and fixtures.

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EATON LEONARD, INC

7/93-7/97

Mechanical Engineer /Product Leader Lead Engineer on Vector Series measuring product.

DEVICES FOR VASCULAR INTERVENTION, INC. (Guidant)

6/93

Contract Design Engineer

Designed and documented 10 different blow-molded shipping packages for medical catheters of various sizes using CadKey 3D software.

GENERAL INSTRUMENTS

11/92-4/93

Senior Drafter

Design and Drafting of Electro-Mechanical test fixtures and enclosures. Successfully completed 3 multiple component, injection molded, assemblies. Designed and documented 2 complex electro-mechanical assemblies, including wire harnesses with wiring diagrams.

Gamma-Metrics (Thermo Gamma-Metrics)

5/92-11/92

Contract Senior Drafter

Design and Drafting of bulk material analyzers, using radioactive source mass spectrometers. Exotic Woods, Machine layouts and Computer Configuration documentation.

Chu Associates Incorporated

11/91-5/92

CAD Drafter

Computer aided design and detailing of Military Specification Radar Antenna

EDUCATION

Honors Diploma, Crawford High School, San Diego, CA	1987
B.S.M.E., University of California, Santa Barbara	1991
Courses FEA, MSC/NASTRAN, San Diego State University	1992
ISO 9001 Training Certified	1996
Advanced Assemblies for SolidWorks, National University	2003
Total Quality Management Training	2007
HVAC certification, City Community College	2008
CNC and EDM Technologies, City Community College	2008
ISO 13485:2016 Lead Auditor Certificate	2017
A.S.M.E Member	1991-2000
ASQ Member	2017- Present

TECHNICAL SPECIALTIES

Design Software: SolidWorks 97-2022, IronCAD 2001, Cadkey 2 through 98, AutoCAD 10-2007, Fortran 77, Direct Logic / Allen Bradley PLC Ladder Logic, Adobe Suite CS2 - CS4, Cosmos FEA and 2005-2015 MSC / Nastran FEA Microsoft Suite, Quickbooks, and MAPICS / MAS90 / DMA-MRP / ERP.

Standards: Geometric Dimension and Tolerancing (GDT) per ANSI/ASME 14.5M, DOD-100/1000, MIL SPECS, Good Lab Practices (GLP), ISO-9001/9002, FDA 21 CFR 820, MDD, MDR, ISO14971:2019 and ISO13485:2016.

Project skills: SPC, TQM, JIT, DFC, Product Configuration, Reverse Engineering, Pert/Gantt charts, Technical Writing, Costing/Quoting, 3D printing, Parametric CAD, Basic Mill, Lathe CNC