JAMES D. ISAACSON
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Highlights:

- Master's degree in Mechanical Engineering from **M.I.T.**
- Over **36 years' experience in Medical Device** R&D and Quality, encompassing cardiovascular, pulmonary, electrosurgical, drug delivery, radiology and renal disciplines.
- **Project management** skills focused on closure with Design Control compliance.
- Experience in developing new **Quality Systems** as well as Life Cycle Product Management from scratch
- Market-driven business approach, with targeted creativity resulting in strong IP protection (co-inventor of **27 patents** with others pending)
- Provides a unique balance of communication skills and customer interface experience with a strong technical background.
- Offers open, honest and direct two-way communication within company.

EXPERIENCE

Independent Consultant **2019 – Present**

Summary of Areas of Expertise:

- Creating and Implementing Quality Systems elements including Design Controls and Risk Management, with associated Training.
- Project Management with keen focus on both the critical path and getting it right the first time.
- Numerous Product Development aspects including (but not limited to) detailed review of designs, Statistics, Design of Experiments, Systems integration, Life Cycle planning, Shelf Life strategies and DHF audits.

Alucent Biomedical, Salt Lake City, UT **2020 – 2024**

Developer of proprietary technologies to treat Vascular Disease

Vice President of Quality and Engineering 3/21 – 4/24

Summary of Duties:

- Responsible for all Quality functions including creating and implementing Quality Systems suitable to support the development of Combination Products.
- Lead all device-based Product Development activities including the management of contract manufacturers.
- Hands-on Engineering and Design Assurance support of day-to-day development activities.
- Manage team of engineers and consultants

Sr. Director of Quality and Regulatory Affairs 10/20 – 3/21

Summary of Duties:

- Responsible for all Quality functions including creating and implementing Quality

Systems suitable to support the development of Combination Products.
- Hands-on Design Assurance support of day-to-day development activities.
- Working with consultants to manage various Regulatory strategies

JUUL Labs, San Francisco, CA **2018 – 2019**

Manufacturer of ENDS products

Sr. Director of Design Assurance 5/18 – 11/19

Summary of Duties:

- Create and Manage Design Assurance department, responsible for Quality Engineering functions in relation to new product development and design changes.
- Variety of other duties assumed in concert with a rapidly growing start-up.

Summary of Accomplishments:

- Led team in creating new and lean Design Controls and Risk Management process as an unregulated “best practice”.
- Initiated and led a team to create a Stability / Shelf Life program focused on disposable Pods and e-liquids.

Fresenius Medical Care, Ogden, UT **2013 – 2018**

Manufacturer of Dialysis equipment and disposables

Director of Design Assurance 3/13 – 5/18

Summary of Duties:

- Manage Design Assurance department, responsible for Quality Engineering functions in relation to new product development and design changes.
- Quality oversight responsibility for all disposable product development activities at multiple sites throughout North America as well as more global development efforts.

Summary of Accomplishments:

- Built new Design Assurance department, with responsibilities for all Quality functions as they pertain to New Product Development and Design Changes for medical devices throughout all North American facilities.
- Numerous new product 510(k)’s supported from Quality perspective for timely product release.
- Led team in creating new Design Controls process as part of FDA Warning Letter remediation. Remediation effort included the drafting and release of 10-15 Design Control SOPs on schedule and led transition to the new process including training.
- Led corporate wide effort to remediate all product Design History Files in response to an FDA Warning Letter.
- Zero 483's during tenure after numerous post-remediation FDA inspections.
- Supported numerous regulatory audits by internal and external entities.

GE Healthcare, Salt Lake City, UT **2007 – 2013**

Manufacturer of C-Arms - Mobile X-Ray Equipment

Lead System Designer 9/08 – 3/13

Summary of Duties:

- Responsible for system design and integration, including all product specifications, with traceability through V & V.
- Responsible for defect management and design change within the Installed Base of products.

Summary of Accomplishments:

- Validated cost reduced image chain components, saving $10-$15K per system sold.
- Completed Wireless Service Platform for 9900 Elite C-Arm. $3M Revenue projected for 2012. Accessory enables product to send images wirelessly to PACS and automatically sends system log files to home office for ongoing service diagnostics.
- Completed “Smart Power Switch” upgrade
- Completed UtilitySuite product, a SW-based configuration mgmt tool for all C-Arms

Project Leader, End of Product Life 7/07 – 9/08

Summary of Duties:

- Created and instituted new policy for Life Cycle Product Management, which assesses and coordinates service contracts, engineering support, product complaints, regulatory compliance and customer communication.

Summary of Accomplishments:

- New policy for Life Cycle Product Management approved on schedule.
- Completed “blanket” investigations of all complaints associated with “legacy” products for the purposes of making “end of life” declarations.
- Recommend Life Cycle status for legacy products to maximize service and new sales revenue, minimize regulatory liability and optimize engineering support.

IOMED, INC., Salt Lake City, UT **2004 – 2007**

Manufacturer of iontophoresis devices for active non-invasive drug delivery

Director of Design and Development

Summary of Duties:

- Evaluated new technologies and targeted new product research.
- Managed all product development personnel and activities.
- Responsible for all patent issues within the company; key interface with attorneys.

Summary of Accomplishments:

- Launched three new iontophoresis products.
- Instituted phased Design Control procedures at Iomed for product development.
- Filed numerous new patent applications.
- Feasibility agreement signed with a co-development partner in April 2006.

MEGADYNE MEDICAL PRODUCTS, INC., Draper, UT **1995 – 2004**

Manufacturer of reusable and disposable Electrosurgical accessories

Director of Engineering (including various promotions leading up to director)

Summary of Duties:

- Supervisory responsibilities all of Engineering including senior and junior engineers, technicians and designers.
- Responsible for all project management and engineering activities; oversaw approximately 20 simultaneous projects, including budget and schedules.
- Co-led business development activities and targeted new product research
- Responsible for all patent issues within the company; key interface with attorneys.
- AAMI / IEC Electrosurgery Standards Committee member (HF-18)

Summary of Accomplishments:

- Managed the successful design and development of various electrosurgical products, which contributed to over a 100% growth in Megadyne Medical Product's revenues over nine years (1995 – 2004).
- Recognized as top technical specialist in Electrosurgery, with an unmatched grasp of the scientific and clinical issues. Extensive worldwide travel in support of company's product lines reflects ease and success in front of the customer.
- Frequent customer interactions to support sales as well as investigate complaints.
- Managed the development team responsible for the patented Resposable MegaTip / Indicator Shaft Laparoscopic Electrode and the Mega 2000 Reusable Patient Return Electrode, Silver Award winner from the 1999 Medical Design Excellence Awards.
- Instrumental in creating a formal Design Control system for MegaDyne.

INNERDYNE, INC./CARDIOPULMONICS, INC., Salt Lake City, UT **1992 – 1995**

Manufacturer of radially expanding trocars and intravascular oxygenators

COBE LABORATORIES, INC., Arvada, CO **1988 – 1992**

Manufacturer of cardiovascular equipment for use in open heart surgery

DICONIX, INC., Dayton, OH **1985 – 1988**

Manufacturer of Ink Jet Printers

EDUCATION

M.S. Mechanical Engineering,
MASSACHUSETTS INSTITUTE OF TECHNOLOGY, Cambridge, MA

B.S. Mechanical Engineering,
UNIVERSITY OF MICHIGAN, Ann Arbor, MI

HONORS AND AFFILIATIONS

TAU BETA PI, National Engineering Honors Society
PI TAU SIGMA, National Honorary Mechanical Engineering Society
Cum Laude graduate from University of Michigan
Intellectual Property, co-inventor of 27 patents
Community Volunteerism, Current Board of Director and Executive Committee member of Jewish Family Service of Utah. Immediate Past-President of local religious congregation and past board member of multiple non-profit community organizations, including Past-President of local philanthropic organization.
Professional Artist, having exhibited and sold original acrylic paintings