

CV

Business Development
Quality Management
Disruptive Technology
Blockchain, AI, Stacking
Red Team, Web3 Dev.

Contact

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Top Skills

Regulation Compliance (Medical
Devices and Avionics)
Risk Management
Quality Management
Continuous Improvement
Project Management
Inclusion and Team Building
Business Development

Certifications

ASQ

Six Sigma Black Belt (2011)
Quality Manager / Operational
Excellence (2012)
Certified Medical Device Auditor
(2023)

APICS/ASCM

Certified in Production and Inventory
Management (2011)
Certified Supply Chain Professional
(2012)

IKO

Kiteboarding Instructor Level 1

Patents

US 6181394 · Issued Jan 30, 2001
US 6933991 · Issued Aug 23, 2005
TW 089100822 · Issued May 31, 2007
US 7405779 · Issued Jul 29, 2008
US 7649577 · Issued Jan 19, 2010



Diggy Breiling, ASQ CSSBB, CMQ/OE, APICS CPIM, CSCP

Leveraging experience in innovation, process improvement, organizational leadership, and ASQ's and APICS/ASCM certification, I have optimized operations, achieved business objectives, and enhanced supply chain management and inventory control within the medical device, aerospace, industrial and commercial industries.

As an experienced team leader, I have implemented and maintained quality management systems in compliance with ISO 13485, AS9100, and ISO 9000 standards, ensuring top-tier device production and quality control.

Applying ISO 14971 and IEC 62304 for risk management, I ensure the identification, analysis, and control of potential hazards throughout the Medical Electrical Device and Software product lifecycle.

My knowledge spans optics, electronics, mechanical, and software engineering, as well as business and quality assurance processes. With a strong business acumen, I have held P&L responsibility from 2003 to 2012.

My teams have designed processes and products, including electrosurgical generators, powered surgical staplers, and flat-screen display assemblies for cockpits, in-flight entertainment, and industrial applications that meet regulations, such as 21 CFR and 14 CFR, EU MDD/MDR as well as international and domestic standard.

I'm listed as inventor on 5 patents, and have contributed on innovation and trade secrets across a wide variety of products and fields.

Recently relocated to Venice, FL, I am open to 1099 and W2 opportunities, both local and remote, leveraging my leadership skills, ingenuity, and track record in business development and quality management to drive success within select organizations.

Manager - Technology and Development Energy

Applied Medical Resources, INC.

Rancho Santa Margarita, CA

<https://AppliedMedical.com>

December 2016 - September 2022 (5 years 10 months)

- Managed the Systems Team within the Technology and Development Group, focusing on risk management and regulatory compliance for the Energy and Mechanical lines including Voyant Intelligent Energy System and the KAIO Surgical Staplers and accessories.
- Ensured product compliance with international standards by proficiently applying IEC 60601-1 and collateral and specific specifications for safety and performance of medical electrical equipment.
- Coordinated closely with Notified Bodies such as UL and CE for product certifications in multiple regions like North America, Europe, and Asia, streamlining the certification process and developing strong working relationships with numerous UL compliance engineers.
- Ensured successful product registration and compliance in the European market by comprehensively understanding European Medical Device Regulations.
- Led the team in developing duFMEA (Design and Use/Mis-Use), working closely with the Process Development group on pFMEA (Process) to proactively identify and mitigate product design and manufacturing processes risks.
- Approved documents as the management representative for Design Engineering, ensuring compliance with regulatory requirements and adherence to internal quality management system procedures.
- Implemented and maintained quality management systems in compliance with ISO 13485, guaranteeing top-tier medical device production and quality control standards.
- Utilized advanced expertise in process improvement and organizational leadership, as demonstrated by ASQ-certified CSSBB and CMQ/OE, to optimize operations and achieve business objectives.
- Enhanced supply chain management and inventory control within the medical device industry by leveraging APICS-certified CPIM and CSCP proficiency.
- Applied ISO 14971 for risk management in medical device development, ensuring identifying, analyzing, and controlling of potential hazards throughout the product lifecycle.

Co-President

MobileCoat Global

Toronto, Canada; Menlo Park, CA; Shenzhen, China; Taipei, Taiwan

Jan 2012 – Aug 2021 (9 yrs 8 mos)

Developed and manufactured solutions for protecting mobile devices including screen protectors and plasma deposition nano-coating technologies to protect devices from the most common failures including screen breakage and liquid damage.

Vice President of Engineering / Business Development
Primeview Display Inc./DBA Interactive Display Solutions
Irvine California
Mar 2010 – Dec 2016 (6 yrs 10 mos)

<https://idsdisplay.com/>

- Established and grew the Value-Added Business Unit in Irvine, CA, specializing in the improvement of LCD displays for avionics, marine, and harsh industrial environments, resulting in a rise in service revenue from \$700k in 2010 to over \$3 million in 2012, and the enhancement of over \$10 million worth of materials through value-added services in 2012.
- Collaborated with customers to optimize their designs for enhanced durability and performance in harsh marine and avionics environments.
- Implemented automation of tasks using robotics and specialty tooling to increase efficiency and productivity in the production process.
- Oversaw Project/Program Management, Quality Assurance, Facilities, and Production Management.
- Launched contract assembly and kitting services for single board computers, cables, and supporting products
- Built and trained manufacturing, quality, and sales teams for the value-added services business unit.
- Managed production facility and equipment installation and maintenance, including ISO Class 4 clean room, laminar flow benches, vacuum systems, clean dry compressed air, HVAC, and automation systems.
- Spearheaded ISO9000 implementation and obtained certification.
- Conducted qualification and performed quality audits of vendors in accordance with ISO9000 system requirements.

Business Development / President
Flat Panel Display Solutions, LLC.
Hillsboro, OR
Oct 2003 – Mar 2010 (6 yrs 6 mos)

- Successfully executed a business plan for FPD enhancement company targeting niche markets, resulting in a consecutive doubling of business revenue in 2005, 2006, and 2007
- Grew the business from its inception in 2003 to over \$600k in service revenue by 2009, managing more than \$2 million in customer-supplied materials annually
- Formulated a custom optical silicone solution for the optical bonding of display elements, improving display performance and durability
- Developed high-reliability display systems for marine, avionics, and other applications, ensuring compliance with stringent environmental standards
- Designed and delivered comprehensive display training and licensing programs to companies in Taiwan, China, South Korea, and Oregon, fostering global partnerships

and collaboration

- Negotiated and finalized the successful sale of the company in March 2010 to Primeview Display Inc. of Irvine, CA

Project Manager / Principle Engineer
Via Optronix/White Electronic Design Corp.
Westborough, MA / Beaverton, OR;
Aug 1997 – Oct 2003 (6 yrs 3 mos)

<https://via-optronics.com/en/>

Devised a lean six sigma, single-piece flow, high-volume glass bonding process line, reducing labor time from 2 hours per unit to less than 25 minutes per unit

- Achieved a 50% reduction in selling price, doubled margin, and increased revenue for a 6-operator shift from under \$2 million to over \$5 million annually
- Decreased manufacturing defects by over 90%, resulting in savings of more than \$450k annually on rework and scrap
- Selected, installed, and tooled automated optoelectronic test equipment for accurate flat panel display measurement
- Played a significant role in the design of an 80,000 sq. ft. display value-added facility, including over 15,000 sq. ft. of class 10,000 clean room
- Managed military, avionics, industrial, and commercial LCD programs from RFQ review to final deliveries and long-term life-support, increasing revenue from bonding from \$3 million to \$6 million annually between 1997 and 2001
- Assisted in obtaining and maintaining FAA Part 21 Certification for Parts Manufacturer, ensuring compliance with industry standards
- Developed patented and trade secret intellectual property for innovative methods and materials to enhance the visibility and robustness of LCD displays, making them suitable for critical and harsh environments

Volunteering

- APICS-OC – Orange County Association for Operation Management
VP of Administration – Elected by BOD June 2011 to June 2012 Year
CPIM Instructor – Taught local classes on CPIM BOK

- OSEIA – Oregon Solar Energy Industries Association
Treasurer – Elected by BOD in 2006

BOD – Elected by organization membership in 2005

- Labdoo Educational Laboratory – <https://www.labdoo.org/en/>
Assisting amazing young folks in learning to repair and load Linux and Education software on donated notebook computers. To date over 42,000 notebooks computers have been distributed to school and facilities which could otherwise not afford them bringing educational opportunities around the world.