

Contact

www.linkedin.com/in/gregorydale
(LinkedIn)

Top Skills

Robotic Surgery

Printed Circuit Board (PCB) Design

Combination Products

Certifications

CSM - Certified Scrum Master

Honors-Awards

Intel / Regeneron Science Talent
Search Top 40 Finalist

ISEF (International Science
& Engineering Fair) - 3 years
participant yielding 15 first place
awards

Patents

Systems and methods for real-time
PCR

Method and molecular diagnostic
device for detection, analysis and
identification of genomic DNA

Real-time PCR in micro-channels

Microfluidic devices with integrated
resistive heater electrodes

Combined thermal devices for
thermal cycling

Greg Dale

MEDICAL DEVICE DEVELOPMENT | INNOVATIVE PRODUCT
DESIGN | QUALITY | MANUFACTURING

Boston, Massachusetts, United States

Summary

An entrepreneurial leader with experience in successfully commercializing consumer and technology products. Developed and manufactured more than 20 new products to date. A strategic and process driven thinker with the ability to visualize, create, and integrate novel ideas into practical, reliable products that the customer needs. Combining a unique skill set of development, quality assurance and manufacturing my expertise spans from start-up companies to the ramp-up of global manufacturing operations.

EXPERTISE AND SUMMARY

- Expert in medical device and in-vitro diagnostics product development
- Hire, build, and mentor high performance cross-functional and global teams
- Due diligence, intellectual property and patent strategy assessment
- Business plan and product roadmap development
- Product Commercialization and NPI
- Supply chain operations for products, reagents, assay kits, injection molded components, IVD consumables, medical devices and instruments
- Global manufacturing and offshore experience for high volume production automation, process engineering, aseptic filling, injection molding, sterilization, packaging and distribution
- Site validation leading to FDA and ISO approvals
- Inventor with 37 issued U.S. Patents
- Development experience with assays, instruments, microfluidics, sensors, optics, photonics, lasers, image processing, electronics, disposables, drug autoinjectors, reagents, wearables and implantables
- Inventor of optical sensors, organ-chips, glucose monitoring devices, microfluidic devices, POC platforms, PCR thermal technology and NGS Sequencing products

- Software development, GUI UX Design, Agile, JIRA, SW test and SW validation
- Quality Assurance & Regulatory – FDA audits, supplier audits, UL/CSA, CE, QSR, ISO 13485, 9001, 14971, 62304, 60601, 61010, 510k, PMA, validation, design control
- Inventor and designer of the Dale Beam and Flash Sequencer photographic products. Founder and CEO of company that created, manufactured and marketed electronic triggers, precision optical and flash control devices for photographers.
- Creative photography business - www.gregdalephotography.com. Photographer and contributor with the National Geographic Image Collection.

Experience

SemPresto, Inc
Chief Technology Officer
2025 - Present (1 year)

Vicarious Surgical Inc.
Director Hardware Engineering
2024 - 2025 (1 year)
Waltham, Massachusetts, United States

Sherlock Biosciences
Vice President Engineering and Product Development
2022 - 2024 (2 years)
Boston, Massachusetts, United States

Led the design, development and manufacturing scale-up activities for home use diagnostic platforms. Adept with low-cost, high volume and enhancing the customer experience design and development.

GENERAL FLUIDICS CORPORATION
Vice President Engineering
2021 - 2022 (1 year)

National Geographic
Photographer, National Geographic Image Collection
2009 - 2022 (13 years)

The National Geographic Image Collection offers the best of the National Geographic Society's rich 125-year history of storytelling. The image archive is one of the most comprehensive collections available around the world, its expansive moving image collection features thousands of photos and a unique roster of photographers and videographers.

LASE Innovation Inc.

VP Engineering

2020 - 2021 (1 year)

LexaGene

Vice President Product Development & Manufacturing

2018 - 2020 (2 years)

Developed a microfluidic PCR pathogen detection platform for veterinary, food safety and human clinical diagnostic markets including COVID-19 detection. Scaled design, engineering and manufacturing from lab prototypes to a commercial product.

Emulate, Inc.

Vice President Product Development, Manufacturing and Quality

2016 - 2017 (1 year)

Greater Boston Area

Led development, quality, and manufacturing activities for Organs-on-Chips technology pioneered by The Wyss Institute for Biological Inspired Engineering at Harvard University.

Selected Accomplishments:

- Led product activities for prototyping, design, software, instrument engineering and project management for microfluidic based 3D cell culture (organs-on-chips) that emulate the physiological environment of the human body. Developed a new CO2 gas mixer instrument from concept to 10 prototypes in record time (6 months).
- Manage and select all external contract manufacturing for the production and sterilization of high volume microfluidic organ-chips, injection molded plastics, reagents, and instruments.

QIAGEN

8 years

General Manager QIAGEN Boston

2013 - 2016 (3 years)

Greater Boston

Established the Boston division of companies developing Next Generation Sequencing systems and IVD products.

Selected Accomplishments

- Develop and manage a site budget including infrastructure, labs, quality assurance, investments, and people
- Grow site in 2 years from 20 to 80 people. Develop and communicate a site strategy.
- Oversee daily operations at the Waltham site
- Perform technical due diligence for external technology and acquisitions

Sr. Director, Instrumentation and NGS Engineering

2008 - 2013 (5 years)

Gaithersburg, Maryland

A leader in sample and assay technologies for molecular diagnostics, applied testing, and pharmaceutical research. I was hired to advance HPV diagnostic testing through new products and lab automation.

Selected Accomplishments

- Directed product development, technical, design control, engineering, software, reliability, software, manufacturing transfer, and verification/validation activities
- Supported product improvements, 510k / PMA submissions, and CE mark technical files
- Provided guidance through FDA audits for design control and verification/validation
- Developed POC device for HPV diagnostics in emerging markets
- Developed several high-throughput lab automation products

Canon U.S. Life Sciences

Director Product Development

2005 - 2008 (3 years)

Hired the engineering team and built a development department for a new Canon R&D subsidiary. Managed the design and development of microfluidic real-time PCR automated instruments for molecular diagnostics and personalized healthcare devices. Designed and patented new microfluidic diagnostic products. Coordinated system architecture and chip microfabrication with several global companies and OEM manufacturing partners.

Senseonics, Incorporated
Manager Quality Assurance
2002 - 2005 (3 years)

Company has developed an implantable continuous glucose monitor. Product is currently FDA approved.

Selected Accomplishments

- Managed the development of a wearable wristwatch glucose sensor and reader. Wrote and developed requirements, specifications, risk plans, and verification plans
- Selected and managed the development, software, and manufacturing partners
- Coordinated the animal clinical trials of the system
- Put in place the design control and quality management system (QMS)

Wilcoxon Research
Director of Research & Development
2000 - 2002 (2 years)

Managed the sensor development and engineering programs and department for vibration analysis, energy harvesting, and remote monitoring via Bluetooth wireless. Coordinated several SBIR grants and managed a multi-year NIST ATP program to successful completion.

Senseonics, Incorporated
Director of Development
1997 - 2000 (3 years)

- Designed and developed a miniature implantable glucose sensor and RF wireless monitor for a diabetes healthcare start-up company
- Developed and managed advanced microelectronic manufacturing processes and scale-up of an implantable fluorescence-based sensor
- Developed surgical tools for product
- Led sterilization validation, cytotoxicity, and biocompatibility studies for pre-clinical implant studies
- Developed an OEM oxygen sensor for a respiratory metabolic monitor device

CIBA Vision
3 years

Head of Manufacturing and Quality Engineering
1996 - 1997 (1 year)
Indonesia

A global manufacturer of contact lenses and eye care products.

Selected Accomplishments

- Led ISO and FDA inspections of the Asia manufacturing plant leading to site approval
- Managed R&D, manufacturing engineering, SPC, validation, and training activities
- Implemented new automated lens packaging and inspection lines and launched new product
- Audited suppliers and implemented global design controls
- Validated the MRP and CAPA systems

Manager of Quality Engineering, Validation and Site Support

1994 - 1996 (2 years)

Atlanta

Responsible for quality engineering, manufacturing engineering, global process validation, calibration, CAPA, sterilization, complaint handling, and the injection mold toolroom. Manufacture and package class II and III contact lenses in extremely high volumes. Manage a global department of 30 people. Interface regularly with FDA for audits, complaints, and recall matters.

Education

Virginia Tech

BS, Mechanical Engineering