Christopher Battles

Harvard, MA • 01451 • USA

Summary

- *25+ years' experience as both a core member of a successful medical device start-up and as a medical device design consultant spanning privately funded start-up companies to Fortune 500 corporations.*
- *Proficiency in DFSS/QFD tools, Critical Parameter Management techniques, and their application to Risk Management and Robust Product Design, with a strong background in first principles and analytic engineering analysis for front- and back-end design development.*
- *Prolific creativity demonstrated in conceptual systems development of medical device solutions for a broad range of applications including industrial design, ergonomic and human factors.*
- *Demonstrated ability to work in a fast paced environment to develop products quickly, as well as understand, manage and balance program risks in order to drive success.*

Experience

Christopher Battles Consulting — Harvard, MA

Principal — *Mar '25 – Present*

Consulting engineering for the medical device industry.
Sole-proprietor.

Vectis Amplification — Harvard, MA

Owner — *Jan '24 – Present*

Vectis Amplification designs, develops and manufactures audiophile amplification and related accessory hardware.

Currently developing a mixture of products including pre-amplifiers, power amplifiers, headphone amplifiers, input switching, Bluetooth streaming devices, etc. Stricly non-commercial at present.
Sole-proprietor.

Gentuity LLC — Sudbury, MA

Director of Engineering, Disposables — *Feb '21 – Jan '24*
Principal Engineer — *Sept '15 – Jan '21*

Gentuity LLC is a medical device manufacturer developing novel intravascular imaging solutions utilizing optical coherence tomography. Founded in 2015, Gentuity received FDA clearance for its first device, a cardiovascular imaging catheter and mobile system, in February 2020. A paradigm changing neurovascular imaging device that successfully completed first in human use is in development and has been presented at numerous conferences and in multiple journal articles.

A first round hire into the Principal Engineer role, I became responsible for the implementation of all aspects of catheter design and development, excepting the optics. Developed concepts for the neurology catheter architecture including human factors and ergonomics and implemented a robust design from concept through to manufacturing for the catheter hub and associated technologies for the cardiology product. Partnered with the electro-mechanical engineers to develop a unique interface with the capital equipment and oversaw the implementation of the catheter design into a new quality and regulatory framework developed at and for Gentuity.

As Director, I was responsible for improving the R&D organization including product testing, sustaining engineering and product development. Integrated four new hires into the team, enabling a shift in R&D from a start-up mentality into a full medical device company, improving throughput in our testing group, better data management, better test planning, and better program management.

Successfully acted as the technical lead on the first-in-human use of the neurology imaging system, including risk mitigation, build planning, testing requirements and lot release definition. This culminated in the first ever intravascular neurology imaging case in December 2022. The neurology product was subsequently spun off asS *Spryte Medical*.

Start LLC — Shelton, CT

Senior Project Manager — *Oct '12 – Mar '15*
Senior Project Engineer — *June '04 – Sept '12*
Project Engineer — *Sept '98 – May '04*

Start LLC is a medical device design consultancy which specializes in innovative design and creative solutions to complex medical industry needs. The underlying philosophy is to provide complete medical product design while providing its clients with robust solutions, elegantly designed to meet the desired goals while also generating valuable intellectual property.

Responsible for the total product-design process from conceptualization to realization, including project planning, ideation, technical assessment, concept design, ergonomics and industrial design, competitive benchmarking, CAD modeling, design engineering, mathematical simulations, CAE analysis, statistical design controls, DFM/A, test protocol development, production documentation, risk management, design verification and transfer to manufacturing.

Integral in the adoption and implementation of ISO 14971 for risk management, adherence to FDA 21 CFR Part 820, and the achievement of ISO 13485 certification in 2012. In-depth experience in risk management and DFSS methodologies and implementations. Familiarity with patent reviews, claims writing and the patent submission process.

Experience in product design for multiple areas of medical device technology including:

- Blood Collection and Handling Systems
- Needle Stick Prevention
- Femoral Artery Closure
- Minimally Invasive Gastroenterological Devices
- Cranial and Facial Reconstruction and Fixation
- Cranial Access Devices
- Surgical Cement Mixing Systems
- Wearable Drug Infusion Pumps
- Laparoscopic Access Devices
- Meniscal Repair Systems
- Gynecological Instruments
- Device Reuse Prevention
- Laparoscopic and Open Surgical Stapling
- Obstructive Sleep Apnea
- Neurosurgical Instruments
- Arthroscopic Instruments

Education

University of New Haven — West Haven, CT

Post Graduate Study — *2003 – 2005*
Concentration in Thermodynamics and Heat Transfer (15 Credit Hours)

Bachelor of Science – Mechanical Engineering
Summa Cum Laude — *1995 – 1998*

Stevens Institute of Technology — Hoboken, NJ

Mechanical Engineering — *1989 – 1991*

Skills

Technical Specialties: Proficiency in DFSS tools and techniques and their implementation to risk management. Over 24 years of design experience in molded plastic parts, elastomers, stampings, power transmission, fastening and joining, catheter development and manufacturing operations. Experience in statistical methods for design and tolerancing including Monte Carlo techniques, sensitivity analyses and optimization. Considerable experience in FEA simulation and analysis including non-linear materials and multi-body contact.

2D & 3D Modeling: AutoCAD, Draftsight, SolidWorks (CSWP), Pro/Engineer, Creo.

CAE and Mathematical Analysis: MathCad, R, SolidWorks Simulation, MSC.MARC, MSC.Patran.
Statistical Analysis: Minitab, RStudio, R.
Programming: C (a bit), Visual Basic (macros mostly), trying to learn Python, R, LaTeX.
Project Management: MS Project, Oracle SureTrak.
Creativity: MindJet, FreeMind, Inkscape, GIMP.
Office: MS Office Suite, Acrobat Professional.
Test and Measurement: LabView, TESAVista (vision), MTL-Windows & testXpert (tensile tester).

US Patents

12,364,385 - Imaging Probe with Fluid Pressurization Element • 11,684,242 - Imaging System • 12,090,476, 11,786,895, 11,351,535, 10,807,088, 10,456,782, 10,413,898, 10,376,879, 10,350,591, 10,343,157, 9,933,344, 9,919,309, 9,919,308, 9,919,307, 9,802,189, 9,731,290, 9,714,890, 9,700,886, 9,452,427, 9,364,828, 9,339,741, 9,333,445, 9,079,123, 8,998,000, 8,794,452, 8,747,781, 8,394,342 - Density phase separation device • 11,318,459 - Method and apparatus for microorganism detection • 10,271,716 - Endoscopic vacuum controller • 9,649,053, 9,427,180, 8,998,941 - Cam-actuated medical puncturing device and method • 9,492,195, 8,961,407 - Surgical port assembly • 9,314,267, 8,911,365, 8,888,695, 8,876,708 - Laparoscopic port assembly • 8,764,765 - Laparoscopic instrument and related surgical method • 8,696,704, 7,390,332 - Methods and devices for repairing tissue • 8,632,740, 7,736,593 - Device and methods for collection of biological fluid sample and treatment of selected components • 8,556,855 - Dual chamber syringe with retractable needle • 8,449,479 - Squeeze activated medical puncturing device • 8,414,486 - Portal apparatus with a finger seal assembly • 8,409,084 - Surgical portal apparatus including gear and lockout assembly • 8,328,717 - Seal device with adjustable aperture • 8,221,441 - Rotary-actuated medical puncturing device • 8,075,573 - Single intubation, multi-stitch endoscopic suturing system • 7,927,271 - Endoscope tool coupling • 7,232,448 - Minimally invasive stitching device • 6,929,645, 6,860,882 - Electro-surgical bipolar forceps • 6,702,455 - Bone cement mixing apparatus having improved gearing arrangement for driving a mixing blade • 6,921,192 - Bone cement mixing apparatus • 6,655,828 - Bone cement mixing apparatus having improved mixing blade configuration • 6,679,138 - Bottle opener

Interests

Non-exhaustive and in no particular order: Cooking, sailing, music, guitar, computers, electronics, open source, reading, art, bookbinding and gardening.