Hany Selim

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SUMMARY:

- Expert in hands-on new product introduction of highly successful medical devices.
- Expert in running a manufacturing group within the process controls and documentation requirements of an ISO 13485 compliant environment.
- Both low and high-volume production experience in a regulated, medical device environment as well as a passion for working on a cutting-edge, life-saving product.
- Worldwide and Management Level Engineering, Manufacturing and Operations assignments with world leaders in Medical Devices.
- Proven track record in managing transition from R&D to Manufacturing, start-up operations, global new product introductions and developing business strategies to leverage market growth.
- Recognized expert in defining and developing complete manufacturing processes, advanced technologies injection molding, extrusion, precision machining and automation.
- Excellent knowledge of FDA, GMP and ISO 13485 & 9001.
- Verified and validated products and processes per CFR 21 FDA 820 regulations and ISO standards.
- Key qualifications: Board Level Presentations, Concept to Commercialization Management, Product Development, Process Innovation/Improvement, Fiscal/Project Management, Leadership Development.
- Abbott Labs QA Award (1988); Employee Excellence Award (1994); Chairman Award (1995).
- Master Black Belt 2012

EXPERIENCE:

BioCardia (San Carlos, CA) **Dec 2019- Present**
Stem Cell Catheter Manufacturer
Principle Manufacturing Engineer

- Successfully Qualified and released a new Accu-Seal Sealer.
- Reduced product build cycle time from 13 hours to 8.5 hour. This resulted in $162 per Catheter.
- Implemented and released PM procedure for the laserStar welder.

Auris Health (Redwood City, CA) **April 2019- Dec 2019**
Robotics Surgical Company
Staff Manufacturing Engineer

- Successfully expand the production line by adding 2400 SF to ramp up instrument production from 25 to 100 Bronch 1.0 a week.
- Establish cost savings plan to lean the Bronch 1.0 process and implement cost savings.
- Revamped the company PM and calibration program and eliminated unnecessary PM/calibration.

Nordson Medical Company (Sunnyvale, CA) **July 2017- April 2019**
Medical Device Contract Manufacturer
Value Stream Manager

- Successfully manage three product lines with 49 operators, three supervisors and four manufacturing engineers
- Improved Volcano yield from 70% to 100%, E-Sheath yield from 72% to 90% and Nevro yield from 87% to 96%.
- Delivered 24 million in company annual revenue
- Responsible for all aspects of the Value Stream including developing associates, budget planning, employment decisions and performance assessments of all direct and indirect reports.

- Ownership of the Value Stream P&L's, including cost analysis and opportunities, and manufacturing productivity.
- Act as the liaison between the business unit and the customer.
- Operations leadership including successful lean implementation resulting in productivity gains.
- Create a culture of continuous improvement by meeting with the Value Stream regularly to reflect on problems, solutions, and challenges.
- Lead the Value Stream in daily operations and continuous improvements which include but are not limited to supply chain productivity control, establishing manufacturing priorities, and coordination of activities with off-shift leadership.
- Emphasize the creation of continuous product flow, utilize pull systems where flow is not currently possible, and works to level the workload.
- Create the basis for continuous improvement and employee empowerment by ensuring that standardized work/processes are followed, countermeasures implemented, and compliance with safety requirements.
- Install and maintain a positive can-do team atmosphere within the Value Stream, holding regular team meetings and assigning team members tasks.
- Work to develop future state value stream maps and manages the plans to achieve it.

AirXpanders, Inc. (Palo Alto, CA) **OCT 2015- July 2017**

Developer of an implant device for breast reconstruction

Manufacturing Engineering Manager

- Transitioned V3.0 from R&D to Manufacturing in hands-on role leading small team.
- Own the development and documentation of manufacturing processes for V3.0, Class III medical device.
- Provided input to the R&D team to improve the manufacturability of the V3.0 design.
- Estimated and refined the performance, quality, and cost of the V3.0 primary manufacturing process providing input to, and receiving input from, Airxpanders business plan.
- Partnered with production and R&D groups to conduct technical training and introduce new Processes
- Collaborate with Quality to establish approved supplier base capable of producing devices for final V&V
- Managed the clean room expansion, layout and qualification
- Performed IQ's, OQ's & PQ for the V3.0 product and process
- Delivered annually, significant manufacturing continuous improvement and cost reductions.
- Project management leadership through direct reports and others.
- Derived the investments on new industrial initiatives and other changes necessary to improve Production efficiency, quality and operational safety.
- Participated in engineering design reviews; evaluate and approve drawings, routing, Specifications and other documents.
- Analyzed manufacturing process flows for continuous improvement opportunities in quality, Cost and throughput.
- Reviewed manufacturing processes, conceptualize improved equipment and processes, and Define requirements.
- Assisted in designing equipment, quoting equipment, deploying equipment, validating equipment And trouble-shooting equipment post deployment.
- Performed DOE-type engineering and optimization studies.
- Implemented UDI for Airxpanders V3.0 product.

VasoNova, a Teleflex Medical Company (Menlo Park, CA) **April 2011- June 2015**

Developer of a navigation system that places the PICC Catheter into the lower chamber of the heart.

Sr. Manufacturing Engineer

- Qualified and installed a compressed dry air system.

- Qualified and released product thermal printers to print all product labels in house. Designed all the labels using the Labelview 14 software. Printing the label in house resulted in a saving of $12/Stylet and annual cost saving of $840,000.
- Increased the Stylets production yield from 93% to 97%.
- Laid out 14,000 square feet addition to the existing site that included 3,200 square feet class 8 clean room, 2500 square feet stock room and 500 square feet ESD area for building the consoles. Worked with the architects to complete drawings and obtained permits. Reviewed the different contractors' bids and chose the one that finished the job. Supported the day-to-day construction until the project was completed. This project started with a budget of $927,000 and was completed $200,000 under budget.
- Laid out the production line in the new clean and purchased/qualified all the needed equipment. Qualified and maintained the monitoring of the new and old clean rooms.
- Prototyped / implemented $1,908,000 cost savings:
    - In house label printing $12/Stylet. Annual cost savings is $840,000
    - Pre-cut Santoprene $4/Stylet. Annual cost savings is $280,000
    - Automatic wire cutter $0.88/Stylet. Annual cost savings is $61,000
    - Coax wire threading $1.20/Stylet. Annual cost savings is $84,000
    - Pre-skived polyimide tubing $2/Stylet. Annual cost savings is $140,000
    - 8 pack dispenser box $0.98/Stylet. Annual cost savings is $70,000
    - Stylet distal Form $1.79/Stylet. Annual cost savings is $125,000
    - Automatic sensor attachment $ 4.40/Stylet. Annual cost savings is $308,000
- Completed and released the G4 front and back panel pad print.
- Completed and released the Flybook/Printer shipping box.
- Acted as the facility Manager. Managed all facility day-to-day activities and modifications.
- Acted as the safety officer of the site. Formed and led VasoNova safety team. Completed all employees' annual safety training. Completed all EHS corporate reports.

Medtronic (Santa Rosa, CA) **Sept. 2010-Mar. 2011**

Developer of Pre-Close device used in most of the cardiovascular surgeries.

Engineering Consultant

- Transitioned the Pre-Close device from R&D to Manufacturing.
- Eliminated two days from the device manufacturing cycle by replacing two epoxy cure 24 hours' cycles with an instant cure adhesive.
- Combined three machined parts with an injection molded part into one injection molded part. The new part resulted in $27 cost saving per device. With an annual quantity of 80,000 devices, this resulted in an annual cost savings of $2,160,000.
- Designed assembly fixtures using SolidWorks. This included the 3D models and detailed 2D drawings for the machined part.

Insound Medical (Newark, Ca) **Apr. 2010 - Apr. 2011**

Developers of invisible hearing assist devices for long term wear. HANDS ON since I was the only one in my department.

Manager of Sustaining Engineering

- Specified and sourced Insound parts, including setting the spec for the parts.
- Introduced the new Lateral Sizer assembly to production.
- Qualified the mold and the process for the new Lateral Sizer assembly.
- Improved the shipping package for the Lateral Sizer which resulted in an annual savings of $52K.
- Upgraded the design and the process for the Length Sizers using Statistical Process Control (SPC). This resulted in improving the yield from 70% to 99.2%.
- Supported all contract manufacturing activities to build all Insound accessories.
- Designed the new test head for the new flex board using SolidWorks. This included the 3D models and detailed 2D drawings for the machined part.
- Performed IQ, OQ and PQ for the new flex tester validation.
- Created the BOM for Lateral Sizers and Length Sizers.
- Ordered and qualified the injection mold for the Lateral Sizers.

- Managed the length sizer contract manufacturing in Costa Rica and the flex board contract manufacturing in China.

Biovitesse, Inc. (San Jose, Ca) **Nov. 2004 - Mar. 2009**

Developer of microfluidic diagnostic equipment for Rapid Bacterial Detection and Identification. BioVitesse was a six-person company including the CEO. HANDS ON, I did the mechanical design (solidworks), purchasing, document control and device/equipment assembly since I was the only one in my department.

Director of Manufacturing

- Specified and sourced all BioVitesse parts, including setting the spec for the parts.
- Established BioVitesse vendor base by managing the vendor selection, negotiating pricing, ordering and setting-up BioVitesse account.
- Created the fluidic diagrams and studied the flow rate through out the system.
- Built the first prototype on a wooden model to prove feasibility.
- Selected, tested and qualified the source and sample pumps.
- Modified an off-the-shelf prototype sheet metal box to house all valves and pumps
- Designed a second prototype box using SolidWorks. This included the 3D models and detailed 2D drawings for the sheet metal box and all the machined parts.
- Controlled all sheet metal boxes and machined parts revisions during development.
- Created the BOM for all products.
- Controlled all revision changes on the product, BOM and product cost.
- Reduced the cost of the disposable part, for concentration, from $65 to $5 per device.
- Molded the plastic cartridge that houses the chip. Before the injection mold was debugged and qualified BioVitesse was machining all the cartridges housings.
- Designed all the sample packages, solutions packages and attachments. Wrote assembly instructions for the disposable parts. Used mechanical drawings to assemble the system

Independent Business Start-Up (Sunnyvale, Ca) **Nov. 2001 - Nov. 2004**

Consumer product distribution

Consultant/Part Owner

- Assisted with the Business Planning and Day-to-Day Operations of this family business that processes a consumer product prior to shipment to distributors.

Gynecare, Inc. – A Johnson & Johnson Company (Menlo Park, Ca) **Jul. 1997 - Jul. 2001**

Developer of a gynecolgical product for the treatment of the uterine up normal bleeding.

Manufacturing Engineering Manager (Dec. 1998- Jul. 2001)

Managed technical staff, production and packaging of a Catheter Medical Devices in an ISO 9001 and FDA controlled operation. Clean Room environment produced over 300 devices daily and generated $80 million in annual revenue. Layout directed pilot line and new product development initiatives.

- Build and maintain a pilot manufacturing line for T2 Catheter development.
- Support all the V&V builds for T2 Catheter product
- Transitioned T2 catheter from R&D to Manufacturing
- Organized, implemented and executed total process and equipment validation for the T2 Catheter which was launched worldwide in November 1999 with no product complaints. Using the Statistical Process Control (SPC).
- J&J announced moving the T2 to Mexico after R&D completed the T2 V&V. Both R&D engineers left the company. I was the only engineer left at Gynecare. I did R&D and Manufacturing for six months to lunch the T2 catheter. Because I was in control of both sides of lunching the product, this product was launched with 96% yield first time in production.
- Performed IQ, PQ & OQ for the entire T2 Catheter assembly process validation, which was included in the PMA submission.
- Managed the design of fixtures, tooling and assembly aids for T2.0 catheters that decreased manufacturing assembly time significantly.
- Designed the shipping package for the T2 catheter.

- Qualified and validated the T2 tray and mold.
- Mold the T2 Handle using an injection mold for the hard plastic and an over mold for the soft rubber grip.
- Performed shipping test and T2 tray validation after the mold qualification.
- Conducted vendor and internal audits against ISO 9001 and FDA standards.
- Managed the calibration program for all tools, fixtures and equipments.
- Managed successful transition of operations to Mexico including a new start-up in Mexico.
- Managed the controller contract manufacturing in Denver.

Senior Manufacturing Engineer (07/97 to 12/98)
- Managed projects that reduced the cost of the product through lean manufacturing and process improvements. Saved $900,000 in one year.
- Improved the mold for the T1 packaging tray to resolve the lid removal problem.
- Performed shipping test and tray validation after the mold modification.
- Managed to cost reduce the T1 package and saved $500,000 in 1999.
- Performed IQ, PQ for the new tray sealer validation.
- Performed shipping test for the new T1 package per ASTM standard.
- Delivered 100% of 1999 projects on or before time and on or under budget.
- Installed, validated and released production equipment, tools and fixtures.
- Reconfigured line layout, increasing production rate from 228 cath. /week to 7000 cath. /month.
- Employed tools to ensure and improve reliability of both design and process such as DOE, Gage R&R, Statistical Process Control (SPC), process capability, run charts, process validation.
- Provided engineering and technical support of the ThermaChoice products introduced into both the domestic and international markets.
- Manage all issues with the T1 handle prototype injection mold.
- Procured and managed outside vendors and suppliers' audits as required
- Worked in compliance with quality systems, including design control and document control, in coordination with the Quality Assurance and Clinical functions. Provided support to resolve product complaints and/or safety issues
- Performed failure analysis on all product returns and implemented the necessary CAPA for product and processes.
- Performed all internal audits for the QA Department.
- Managed the cable contract manufacturing for the controller cable in San Jose.

Perkin-Elmer Applied Biosystems (Foster City, Ca) **Apr. 1996 - Jul. 1997**
Developer of analytical diagnostic equipment for the biotech industry.
Mechanical Engineer
- Managed to save over a million dollars in process and design improvements.
- Supported the 310 Genetic Analyzer day-to-day activities and improved assembly processes and procedures.
- Changed the design of the closure mechanism of the system doors, which resulted in more reliable latch and $300 cost savings per unit.
- Analyzed optic assembly and implemented improvements, which increased yield.

Abbott Laboratories (Mountain View, Ca) **May 1986 – Nov. 1995**
Developer of the Oximetry system for the blood oxygen saturation monitoring
Member of the Technical Staff
- Interfaced with R&D to support the new catheter products introduction.
- Performed design and process improvements validation.
- Performed IQ, PQ for all new equipment and processes validations.
- Performed software and hardware validations
- Implemented advanced manufacturing technologies and automation for production processes.
- Employed tools to ensure and improve reliability of both design and process such as DOE, Gage R&R, process capability, Yield charts, process validation and lean manufacturing.
- Performed failure analysis on all product returns and implemented the necessary CAPA for product and processes.

- Used Statistical Process Control (SPC) to analyze the Op-Mod III assembly, identified design problems and implemented improvements which increased yield from 75% to 95% and decreased Op-Mod product returns by 1.5%.
- Developed and validated processes to rework and save all of Op-Mod returns and new build failures.
- Managed all issues with the injection molded Op-mod case and coupler.
- Performed all ISO internal audits for all the departments.
- Member of a 30-people cross-functional team that helped Abbott in getting their ISO 9001 certification.

Adept Technology (Mountain View, Ca) **Dec. 1984 – Dec. 1985**
The leader in the Robotic arm industry
Manufacturing Engineering Consultant

- Provided technical direction to facilitate the integration process of robotic technology.
- Managed all production daily activities.
- Write all process and assembly instruction.
- Increased production from 7 robots a month to 35 robots a month through process improvements and lean manufacturing.

EDUCATION:
Helwan University
B.S., Mechanical Engineering

CERTIFICATIONS & TRAINING:

- Project Management
- Basic Language
- Industrial Bar-Coding
- SolidWorks 2017
- ISO 9000 Auditor Training
- Microsoft Word, Excel & PowerPoint
- Six Sigma Lean Manufacturing
- Minitab 2016

Programmable Controllers
FDA Regulations
Quest
Front Line Leadership
AutoCAD Release 13 & 14
Six Sigma Green Belt
Six Sigma Master Black Belt Certificate

Hany Selim

- San Jose, CA, USA
- San Francisco, CA, USA

Contact Information

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- 4084206646 (Preferred)

Work History

Total Work Experience: 37 years

- **project manager | calibra medical, inc.**
  Jan 01, 2015 - No End Date
- **sr. manufacturing engineer | airxpanders, inc.**
  Jan 01, 2015 - Jan 01, 2015
- **senior manufacturing engineer | teleflex medical**
  Jan 01, 2012 - Jan 01, 2015
- **engineering consultant | manufacturing | medtronic**
  Jan 01, 2011 - Jan 01, 2012
- **engineering manager | insound medical**
  Jan 01, 2010 - Jan 01, 2011
- **director of manufacturing | insound medical**
  Jan 01, 2001 - Jan 01, 2002
- **mechanical enginer | life technologies**
  Jan 01, 1996 - Jan 01, 1997

- **staff process engineer | abbott**
  Jan 01, 1985 - Jan 01, 1995

- **manufacturing engineering consultant | adept technology**
  Jan 01, 1984 - Jan 01, 1985

Education

- **bachelor's degree**, No Dates Provided | helwan university cairo

Skills

- **design of experiments** | 15yrs | 2020
- **engineering management** | 15yrs | 2020
- **iso 13485** | 15yrs | 2020
- **manufacturing** | 15yrs | 2020
- **medical devices** | 15yrs | 2020
- **3d printing** | 15yrs | 2020
- **5s** | 15yrs | 2020
- **conceptual design** | 15yrs | 2020
- **construction management** | 15yrs | 2020
- **continuous improvement** | 15yrs | 2020
- **control system** | 15yrs | 2020
- **cost reduction** | 15yrs | 2020
- **design engineering** | 15yrs | 2020
- **document review** | 15yrs | 2020
- **documentation** | 15yrs | 2020
- **drawing** | 15yrs | 2020
- **engineering design** | 15yrs | 2020
- **failure analysis** | 15yrs | 2020
- **injection molding** | 15yrs | 2020
- **materials science** | 15yrs | 2020
- **capital expenditures** | 15yrs | 2020
- **control engineering** | 15yrs | 2020
- **cross-functional team** | 15yrs | 2020
- **departmental management** | 15yrs | 2020
- **design controls** | 15yrs | 2020
- **design for manufacturability** | 15yrs | 2020
- **design review** | 15yrs | 2020
- **lean six sigma** | 15yrs | 2020

- **electromechanics** | 15yrs | 2019
- **foundry** | 15yrs | 2018
- **ehs** | 15yrs | 2016
- **project management** | 30yrs | 2014
- **budgeting** | 30yrs | 2014
- **microsoft excel** | 30yrs | 2014
- **microsoft powerpoint** | 30yrs | 2014
- **microsoft word** | 30yrs | 2014
- **packaging** | 30yrs | 2014
- **quality control** | 30yrs | 2014
- **basic** | 30yrs | 2014
- **six sigma** | 14yrs | 2014
- **autocad** | 12yrs | 2014
- **san** | 2014
- **management** | 30yrs | 2009
- **negotiation** | 30yrs | 2009
- **purchasing** | 30yrs | 2009
- **3d** | 30yrs | 2009
- **mechanical** | 30yrs | 2009
- **solidworks** | 14yrs | 2009
- **acoustics** | 14yrs | 2008
- **process engineering** | 30yrs | 2004
- **spc** | 30yrs | 1995
- **iso** | 20yrs | 1995
- **gd&t** | 15yrs | 0
- **engineering** | 0
- **calibration** | 0
- **capa** | 0
- **cross-functional team leadership** | 0
- **design for manufacturing** | 0
- **fda** | 0
- **lean manufacturing** | 0
- **machining** | 0
- **manufacturing engineering** | 0
- **manufacturing operations** | 0
- **manufacturing operations management** | 0
- **mechanical engineering** | 0
- **process improvement** | 0
- **product development** | 0
- **project engineering** | 0
- **quality assurance** | 0
- **r&d** | 0
- **systems engineering** | 0
- **v&v** | 0
- **validation** | 0

- **design**
- **lean**
- **testing**

Work Preferences

- Likely to Switch: Possibly
- Willing to Relocate: Yes
- Travel Preference: Prefers No Travel
- Work Authorization:
    - US
- Work Documents:
    - US Citizenship
- Desired Salary: 125000+ (USD)
- Security Clearance: No
- Third Party: No
- Employment Type:
    - Full-time

Profile Sources

- Facebook: http://www.facebook.com/hany.selim.1481
- Linkedin: http://www.linkedin.com/in/hanyselim
- Twitter: https://twitter.com/hselim2
- Dice: https://www.dice.com/employer/talent/profile/c074290c1b66784c7f41c8cc295cbf340cc16e0b