

# Gordon J. Skiba

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## SUMMARY

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Conscientious, innovative, and enthusiastic engineer/manager with superb technical, project management, and problem-solving skills. Extensive experience in GMP/ISO compliance and traceability audits. Proven leadership and organizational skills, with unique ability to thrive both independently and as part of a team.

## TECHNICAL EXPERIENCE

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Jan. 2011 – Oct. 2011                      **Steriluent, Inc.**                      Minneapolis, MN

*Quality Manager (Jan. 2011 – Oct. 2011)*

- Quality Manager, and Management Representative for Hydrogen Peroxide (H<sub>2</sub>O<sub>2</sub>) Sterilizer manufacturer located in NE Minneapolis.
- Responsible for creating our Standard Operating Procedures, Quality Manual and Policies and associated forms/records to ensure compliance to ISO 13485 and the FDA's CFR 820 Regulations.
- Reviewed and approved all QSR/Product related Test Plans and Reports, Process Validations, Gage Studies, Process Capability, Installation, Operational and Production Qualification Validations.
- Responsible for the reviewal, dispositioning of CAPA and NCMR's.
- Conducted Employee Training on QSR, FDA, ISO requirements and SOP updates.
- Directed activities related to Documentation, implemented paperless documentation system and assured all external standards were updated and applicable for our applications.
- Worked with Regulatory Affairs to document all MDD, CMDD and FDA activities relevant to complaint handling, vigilance reporting, MDR's, 510(k) submissions, recall, field service corrections, technical files and other relevant regulatory documentation requirements.

Nov. 2009 – Aug. 2010                      **Creganna Tactx Medical**                      Plymouth, MN

*Quality Engineer (Nov. 2009 – Aug. 2010)*

- Quality Engineer responsible for Customer (Guidant, Boston Scientific, Bard Access Systems, Spire Medical Systems and Stryker) products (hemodialysis catheters, esophageal/ureteral kits, defibrillator sheaths and assorted catheter components) and Manufacturing support for each customer's projects.
- Initiation of Engineering Change Orders and associated documentation (Device Master Records, Product Specifications, Component Drawings) for new, and existing customer product updates.
- Generate and facilitate the creation of Test Plans and Reports, conducting Process Validations, including Gage Studies, Process Capability and Operational and Production Quality Validations.
- Responsible for the reviewal, dispositioning and corrective action for non-conforming materials.
- Conducted Employee Training on process updates.

Aug. 2008 – Jan. 2009                      **Via Biomedical, Inc.**                      Maple Grove, MN

*Quality Engineer II (Aug. 2008 – Jan. 2009)*

- Quality liaison performing Product Design Assurance for customers Stent on a Wire (SoaW) project.
- Created Test Plans, Report forms and Test Fixtures based upon the requirements of; ISO 10555-X, ISO 11070, ISO 11135-1, ISO 25539-X, and various ASTM standards and FDA Guidance documents.
- Developed Sterilization Protocols for product validation, including scheduling various laboratory testing (LAL, Bio, Residual and BI) and related sterilization activities.
- Responsible for ISO Class 7 Cleanroom Validation and Certification activities.
- Conducted Critical Supplier Audits in accordance with ISO 9001/13458 system requirements.

Feb. 1993 – Jul. 2008                      **Nonin Medical, Inc.**                      Plymouth, MN

*Product Development Engineer (Mar. 2004 – Jul. 2008)*

- Served as Process Improvement Manager and Technical Lead, providing leadership and expertise in sensors, cables, components, and other accessories.
- Led project teams for thermometry, EMC product testing, DC light level testing, EU and China RoHS compliance, and product updates for water ingress, disposable sensor redesign, etc.
- Created internal setup and test procedures for EMC compliance, reflecting IEC 60601-1 requirements.
- Established and verified EMC compliance test systems; created product-specific test plans and reports.

Developed technical training materials and conducted training for engineering staff on a variety of complex standards (GMP/MDD/IEC requirements, 61000-4-x standards on testing/measurement techniques, ISO 9919 - pulse oximetry requirements, RoHS, disposable sensor designs, etc.).

Feb. 1993 – Mar. 2004                      **Nonin Medical, Inc.**                      Plymouth, MN

*Supplier Quality Engineer (Feb. 1993 – Mar. 2004)*

- Supervised technical staff in Inspection, Metrology, and Manufacturing QA Engineering.
- Analyzed and implemented CAPAs relating to product returns and manufacturing discrepancies.
- Served as QA lead for Supplier Optimization Team — responsible for consolidating and benchmarking Nonin's supply base.
- Served as QA liaison for both domestic and international manufacturing and vendor sites — responsible for managing audits, reviewing processes and procedures, and issuing corrective actions.
- Led Nonin's Material Review Board (MRB), Quality Improvement, and First Article Inspection teams.
- Served as QA representative and technical expert on Nonin's new product development teams.
- Established First Article Inspection protocols and vendor certifications.

May 1991 – May 1992                      **G.V. Medical Inc.**                      Minneapolis, MN

*Senior QA Technician*

- Generated and reviewed technical documents pertaining to device (Balloon & Laser Angioplasty Catheters) fabrication and inspection methods.
- Investigated and analyzed returned product.
- Designed and developed test fixtures and inspection protocols for both in-process and final product.
- Skilled in optical comparators, toolmaker microscopes, tensile testers, and various measurement tools.

## **EDUCATION, TRAINING, AND CERTIFICATES**

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*Technology and Job-Specific*

- MoreStream University: Lean Six Sigma Black Belt
- University of Minnesota: Geometric Dimensioning and Tolerancing (I, II, III)
- University of Wisconsin: Adhesive Bonding Technology; Designing Plastic Parts for Injection Molding
- Hennepin Technical College: Electro-Mechanical Technology – graduate; AutoCAD I, Programming Logic, Computer Basic I and II (proficient in PC-based Microsoft software)
- Century College: Advanced Precision Measurement; Destructive and Non-Destructive Testing; Design of Experiments; Algebra; Statistics; Sample Inspection; Statistical Quality Control Charts

*Project and People Management*

- University of St. Thomas: Project Management Certification Series; Supply Chain Quality Management Certificate Series
- University of Wisconsin: Six Sigma – Green Belt
- Dale Carnegie and Associates: Dale Carnegie Course
- Century College: Education and Training Techniques; Industrial Safety; QC Philosophy