

# Timothy R. Smith

East Bethel, MN 55005

(336) 508-0630  
timsmith0777@gmail.com

**Objective** Obtain the position Validation Specialist in the Medical Device Industry

**Education** **North Carolina A&T State University**  
2001 to 2004 Bachelor of Science in Electrical Engineering, Graduated with Honors: Cum Laude, May 2004  
Coursework includes:  
Wireless Communications Embedded Systems  
Power Electronics Linear Systems and Control Theory

**Experience**  
1995 to Present **Federal Regulatory Experience with the FDA, Department of the Air Force, Department of Defense, Department of the Army**

2014 to present **Boston Scientific (Formerly American Medical Systems): Minnetonka, MN**  
*Senior Remediation Consultant*

- Lead effort to define scope of project that will significantly improve product design specifications that will directly feed into a successful Process Validation OQ/PQ as required by the FDA
- Lead effort to define project schedule that will significantly improve product design specifications
- Lead Effort to complete a project that will document every dimensional change on AMS 700 IPP Design Specifications as required for Remediation to ensure a successful OQ/PQ in Process Validation
- Lead effort to complete FEA Model Confirmations. FEA Models are used to challenge product conditions that will be used to understand dimensional limits of product design specifications
- Lead effort to complete a series of Design of Experiments using the FEA Models to develop Transfer Functions,
- Leading effort to define product design specifications tolerances by using Monte Carlo Simulations along with the Transfer Functions.
- Senior Key Contributor that Completed Deliverables to meet FDA Milestones on time
- Lead Contributor on Improving Equipment lifecycle through continuous improvement activities
- Lead activities to help standardize equipment lifecycle activities
- Lead continuous improvement effort to eliminate wasted IQ activities on identical off the shelf equipment

2006 to 2014 **Boston Scientific: Maple Grove, MN**  
*Project Manager - Direct Employee.*

- Equipment Engineering Project Lead, responsible for leading teams that maintain existing and develop new manufacturing systems for Operations (Manufacturing and Production), and both the PD and R&D Groups
- Equipment Engineering Project Lead with an average of 30 projects and 3 to 5 resources assigned per project
- Experience with Lean manufacturing techniques, value stream mapping, and continuous improvement methodologies
- Estimate and Prepare project budgets and control expenditures to stay within spending limits.
- Continuously collaborates, cross functionally, with engineers and department managers to aide in selecting and scheduling resources for projects, both Operations support and new equipment builds
- Equipment Engineering Project Lead, leading projects to support Lean Business Principles
- Equipment Engineering Project Lead, leading projects that map the value stream and identify ways to reduce the overall timeline of new equipment development.

*Previously Systems Validation Engineer*

- Lead the Validation Effort to Qualify Manufacturing Lines ahead of schedule, under budget for new product release in which I was assigned 4 validation resources
- Responsible for managing up to 15 resources at one time while responsible for qualifying a new manufacturing line
- Key Support of efforts that helped reduce the cost of validation by \$1 Million for a new manufacturing line
- Key Support of efforts that helped reduce the time of validation by three months for a new manufacturing line
- Participated in the development of Boston Scientific's new corporate Software Development Life Cycle
- Exceptionally knowledgeable in Boston Scientific's SDLC and Validation of Automated Systems in Manufacturing
- Supported many CAPA's helping improve in the way BSC does business
- Working very well cross-functionally easing the resolution of technical and organizational issues.
- Over \$3 Million in Value Improvement Projects in 2009 and 2010 alone.
- Fluent in software development, scripting, many programming languages and database validation
- Working in an FDA regulated environment.

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- Successfully works under extreme high stress situations in order to maintain the manufacturing operations.
- Working in a procedurally controlled environment.
- Working in a manufacturing environment and/or clean room.
- Project and Validation lead for many Boston Scientific new product development projects.
- Responsible for developing requisitions for contractors to work on projects.
- Assisted in the development of consistency efforts.
- Authoring and execution of standard validation protocols compliant to FDA and corporate policy

2005 to 2006

## **Guidant Corporation / Boston Scientific: Saint Paul, MN**

*Consultant: Software Verification and Validation Engineer*

- Software and Test development and maintenance of design verification testing.
- Development and maintenance of protocols used in design verification testing
- Insignia Software Maintenance Release.
- Improved the process of summarizing weekly regressions, enabling engineers to quickly determine which areas of the test suite needed the most improvement

2004 to 2005

## **Medtronic Gastroenterology and Urology: Minneapolis, MN**

*Consultant: Systems Engineer*

- Developed a measurement algorithm, which enabled Medtronic to utilize longevity and rated capacity features in their new user interface for a handheld physician programmer used in InterStim therapy
- Eliminated measurement failures for Neurostimulators with an upgrade to the ATS functional test
- Responsible for validating portions of a new user interface for a handheld programmer used for InterStim therapy
- Automated portions of a test procedure to validate the user interface for the InterStim II physician programmer
- Developed and implemented several hybrid level tests to verify the InterStim II software requirements
- Analyzed programmer reports from 1000 patients. This data will be critical in the design and implementation of future InterStim Therapy Implantables
- Developed an application and GUI in VBA that significantly improved the ease of navigation for users analyzing telemetry data
- Coordinated the completion of electrical design verification and validation testing for InterStim II
- Developed and performed electrical characterization for the InterStim II Neurostimulator
- Developed and implemented a test that will characterize the electrical performance of the InterStim battery at end of service, providing valuable input for longevity predictions

Summer 2004

## **Center for Power Electronics Systems: Virginia Polytechnic Institute and State University**

- Graduate Research Assistant
- Designed and fabricated an 18-pulse, 3 phase autotransformer

2003 to 2004

## **Geophysics Research Team: North Carolina A&T State University**

- Designed and implemented a prototype which was used to model the earth's resistivity

2000 to 2001

## **Kellogg Brown and Root / Halliburton**

*Fire Fighter, Hazardous Materials Technician, and Emergency Medical Technician*

- *Crew Chief:* Responsible for the lives of three firefighters and a \$350,000 vehicle.
- *Fire Alarm Communicator:* An Imperative communication link with the incident commander to coordinate emergency response of the fire department.

1995 to 2000

## **United States Air Force**

*Fire Fighter, Hazardous Materials Technician, and Emergency Medical Technician*

- *Crew Chief:* Responsible for the lives of three firefighters and a \$350,000 vehicle.
- *Fire Alarm Communicator:* An Imperative communication link with the incident commander to coordinate emergency response of the fire department.

1992 to 1995

## **Realtor: Real Estate Sales Professional, Phoenix, AZ**

- Developed and Coordinated a Telemarketing group responsible for increasing sales by 40%
- Accumulative Reals Estate sales in the range of 3 Million Dollars
- As a Seller's agent, average days on market of homes was 90 days

## **Ongoing Education**

- Strong Desire to Complete a Master degree in Business Administration
- Project Management Professional (PMP) Certification Training
- Problem Solving for Practitioners

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## Skills

### BSC Awards

- Process Improvement for Practitioners Mod 1 and 2 (BSC's equivalent to **Six Sigma Green Belt**)  
C/C++, Assembly, VBA, PVCS, Windchill, Visio, MATLAB, PSpice, Saber, CVS, Labview
- 2012 CRV Values Nominee
- 2012 CRV Heart of a Leader Nominee
- 2011 CRV Values Nominee – Recognized out of 9,000 individuals as a person with Core Values
- Quality Ambassador Awards – Recognized by the Quality-Ops Group 4 times for quality above all
- SQE Quality Awards– Also recognized by the Software Quality Group 3 times for appreciation

### Military Awards

- Academic Achievement
- Honorable Discharge
- Good Conduct Medal
- Military Achievement Medal