

ASHLEIGH E. MCNABOE

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EDUCATION

GEORGIA INSTITUTE OF TECHNOLOGY | Atlanta, GA

May 2019

College of Engineering – Bachelor of Science in Biomedical Engineering

- **Minor – Health, Medicine, and Society**
- Georgia Tech Lorraine – Study Abroad Spring 2017
- Biomedical Engineering Innovator Scholarship
- Georgia Tech Yellow Jacket Marching Band, Alpha Phi Omega National Service Fraternity Member

EXPERIENCE

SENIOR SYSTEMS DQA ENGINEER – BOSTON SCIENTIFIC | Marlborough, MA

October 2021 – present

- Systems Design Quality Assurance (DQA) Engineer and IEC 60601 global subject matter expert (SME)
- Corporate process owner for IEC 60601 Standard Operating Procedure (SOP) and Work Instruction (WI)
- Lead of the corporate-wide IEC 60601 Community of Practice (CoP) and Technical Advisory Group (TAG) across Boston Scientific divisions to facilitate best practices and continuous improvement efforts
- Establishing corporate best practices for IEC 60601 by developing global QMS procedures, Work Instructions, tools, templates, standards-specific assessments, and guidance for R&D, quality, labeling, and regulatory
- Supporting divisional new product development programs and acquisitions as an IEC 60601 SME, technical reviewer, and approver of DHF documents and design reviews to ensure holistic conformance throughout lifecycle process and sustaining
- Regularly conduct training activities with project teams on IEC 60601 and standard-based assessments
- Lead of Boston Scientific reliability processes, including Knowledge Sharing Documents (KSDs) and Work Instructions (WIs)

SENIOR PRODUCT SAFETY ENGINEER – STRYKER INSTRUMENTS | Portage, MI

June 2021 – October 2021

- Subject matter expert and internal consultant for electrical design to meet the IEC 60601 series of standards (IEC 60601-1, IEC 60601-1-2, IEC 60601-2-2), IEC 62366, IEC 62304, ISO 14971, and ISO 13485 to ensure global compliance requirements are met on new and existing products undergoing changes
- Develop conformance strategies for launching in global markets and for EU MDR initiative
- Conduct testing and develop test plans for IEC 60601 series of standards, including IEC 60601-1, IEC 60601-1-2, IEC 60601-2-2, IEC 61000-4-2, and AIM 7351731, on products and evaluate the results for development and official certification.
- Officially qualified under National Certified Bodies Satellite Testing programs to perform certification testing on medical electrical equipment for IEC 60601-1 and IEC 60601-2-2 as a test engineer
- Collaborate cross-functionally to regularly provide input for accompanying documents, labels, electrical prints, and engineering notebooks to ensure conformance to specific product safety standards on a holistic level
- Collaborate with external testing facilities to conduct certification testing on medical electrical equipment and serve as a direct interface between Stryker and Nationally Recognized Testing Laboratories during audits.

PRODUCT SAFETY ENGINEER – STRYKER INSTRUMENTS | Portage, MI

June 2019 – June 2021

BIOMEDICAL ENGINEERING INTERN – STRYKER ORTHOPAEDICS | Mahwah, NJ

May 2018 – August 2018

- Member of the project management team supporting New Product Development Process (NPDP) Joint Replacement Programs.
- Created an Execution Timeline and a separate regulatory 510(k) and EU MDR critical path timeline for the Cases and Trays portion of a Knee Replacement Program for internal team members and outside vendors.

GEORGIA TECH UNDERGRADUATE FACILITATOR | Atlanta, GA

August 2018 – May 2019

GEORGIA TECH MICROCONTROLLER TEACHING ASSISTANT | Atlanta, GA

January 2019 – May 2019

EXTERNAL COMMITTEES

IEC TC62/SC62A WG 42 – Electrical Hazards US Expert

IEC TC62/SC62A/PT62A-1 Essential Performance Fault Safety Committee Member

AAMI – ES Electrical Safety Committee Primary Voting Member

SKILLS

STANDARDS: IEC 60601 series of standards, ISO 14971, ISO 13485, IEC 60825-1, IEC 62304, FCC part 15/18

PROGRAMMING/SOFTWARE: MATLAB, SolidWorks, AutoCAD, HTML/CSS, LTSpice, ANSYS 19.1, Computational Fluid Dynamics, NI LabVIEW, Microcontrollers, Arduino, Machine Learning Programming, Printed Circuit Board Creation

MACHINING: 3D printing, Laser cutting, Lathe, GD&T

LABORATORY: X-ray analysis, CCK-8 Assay, Aseptic Cell culturing technique, Annexin V Assay