Rome Student Branch IEEE

IEEE Sensors Council ITALY CHAPTER

Measurements and Biomedical Instrumentation Lab

Seminario

Engineering approach Story of adaptability

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Abstract

A career in engineering can unfold into unexpected paths and suddenly turn into a dreamed opportunity. A comparison between a family-owned business where an engineer is a handyman problem-solver and a corporate company where an engineer is a micro gear within an infinitely bigger system will be illustrated. A quality engineer for medical devices manufacturer is a professional that links the profit driven part of the business and the one trying to be in compliance with the regulatory agencies. The Six Sigma approach is central in this role to improve quality through reducing variation for every process; the reasons will be explained. The 21 Code of Federal Regulation (CFR) part 820 introduces a set of regulations from Food and Drug Administration (FDA) for the good manufacturing practice (GMP) requirements. An overview of the quality system and its applications will be presented. In US, medical devices manufacturers must comply with these rules with regards to their quality system and the quality engineer is the figure to enforce all GMP policies and procedures. The requirements are intended to ensure that medical devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act. A quality engineer is a key expert on complaint processing using electro-mechanic knowledge and statistical analysis; control of inspection, measuring, and test equipment including handling, preservation, and storage of equipment so that its accuracy and good condition for use are maintained; calibration to ensure precision and accuracy limits are met; risk assessment applied in any quality related activity just to cite a few. The main tasks of a quality engineer will be introduced. The final aim is to find the optimal tradeoff for the company between boosting the profit and being fully in compliance with regulations. The presentation will provide useful tool to better understand where a quality engineer fits among the needs and expectations of companies, hospital personnel, and regulatory agencies. As for each career, some personal lessons will be drawn.

Biography

Lorenzo Dinia received his M.Sc. in Biomedical Engineering in Rome, earning a 4.0 GPA. In 2014, he received a second M.Sc. in Industrial Engineering from the NYU Tandon School of Engineering. In February 2019, he completed a Ph.D. program in Mathematical Models for Engineering, Electromagnetics and Nanosciences, majoring in Electromagnetics, at Sapienza University of Rome. In October 2018, he also won the "Marabelli prize". The primary topic of his research is the fiber Bragg grating sensor and its applications, mainly related to the conservation of the original condition of artworks and biomedical applications. His research activities focus on finite element analysis, fiber Bragg grating, guiding structures, theoretical scattering models, optical propagation, sensors, biomedical applications, and cultural-heritage applications. He has three years of experience as a medical equipment maintenance Manager at two major hospitals in Rome. He was responsible for coordinating the work of a team of technicians performing corrective and preventive maintenance and quality inspections. During his professional career, he held different engineering roles in the USA, as Process Technical Engineer at a manufacturing company in Brooklyn, as a Field Service Engineer at a packaging company in New Jersey, and, currently, he is working as a Quality Engineer at a company manufacturing medical devices.

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