

Medical Device- Director V&V

Location: IL-Caesarea

In this role, you will...

- ◆ Lead HW V&V teams, for testing dental scanner system.
- ◆ Lead Clinical Validation team for validating new clinical features presented to the doctors.
- ◆ Lead Continuous Reliability team, leading all reliability and aging tests for the system
- ◆ Manage V&V contractors, for leading various short-term V&V activities.
- ◆ Work with external labs (Carmel, SII, Aminolab) - performing regulatory & environmental tests.

In this role, you need...

Bachelor's degree in Systems Engineering, Mechanical Engineering, Electrical Engineering, Biomedical Engineering or related field.

- ◆ Professional experience (at least 10 years) leading or supporting product Verification and Validation teams.
- ◆ At least 8 years of proven experience with management large groups, min. 30 people.
- ◆ Experience from multi-disciplinary companies, preferred medical device industry.
- ◆ Working knowledge of regulatory standards applicable to design of medical devices, including FDA QSR 21 CFR 820, ISO 13845, ISO 14971 and IEC 60601.
- ◆ Proficiency with statistical techniques including familiarity with Gage R&R, Reliability, analysis of variance (ANOVA) and design of experiment (DOE) methodologies highly desired.
- ◆ Strong project management skills, ability to build detailed plan.
- ◆ Strong technical skills- capability of taking requirements to detailed spec, assisting the team to define the detailed tests.
- ◆ Experience working with Medical QA QMS, having design controls expertise.
- ◆ Experience solving problems, provides detailed insight and constructive criticism in complex situations, and foresees problems along with potential solutions.
- ◆ Experience with implementing tests through a structured, phase-gated product development process.
- ◆ Experience with designing best practices, including design for reliability and testability, expertise in common risk management techniques

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