Quality Engineer, Equipment Validations

• Quality Management System (QMS) team member, Subordinate to QMS Manager
• Develop validations for equipment and software per ISO 13485 / FDA 21 CFR part 820
• Generate and review documents such as: drawings, SOPs, equipment and software validation protocols and reports
• May perform or lead QMS or Design Assurance activities (e.g., document control, audits, nonconforming product, ECO)

Required Experience & Skills:
• At least 3 years of experience in validation activities in the medical device field
• Quality Management System experience
• Familiar with QMS investigation tools (fishbone, 5 whys, etc.)
• Proficient in English and technical writing
• Highly developed understanding of technical equipment
• Willingness to travel abroad up to twice a year

Education:
• B.Sc. in Mechanical / Electrical / Biomedical Engineering

CV to: michal@insighthr.co.il