



**Tanima Ghosh**

QMB-Qualiverse

Senior Executive

Ms. Tanima Ghosh has over 30 years of experience in medical devices, combination drug-device systems, digital health, and AI/ML-enabled SaMD. Tanima develops, leads, implements, and manages global Regulatory Affairs, Quality Assurance, and Clinical Study initiatives. She brings her executive RA/QA leadership, agile R&D, and operational expertise to manage the entire product life cycle of complex hardware, software, platforms, and systems used for measurement, detection, diagnosis, triage, and treatment of various diseases and cancers. She has accelerated global market clearances and authorisations and has helped re-engineer, navigate, and simplify new product introduction processes. She has developed, qualified, and commercialised innovations including combination drug-device theranostic systems for nuclear medicine; computer-assisted surgical robots; cardiac PET imaging; MRI-based body composition analysis; radioisotope infusion sets; SaMD/SiMD plus novel AI/ML-enabled devices; telemedicine/telehealth remote patient monitoring platforms; and paediatric expert systems using AI models.

Ms. Ghosh is a graduate from McGill University (Physics) with two National Science and Engineering Research Council of Canada (NSERC) Industrial Research Fellowship Awards. She is a McGill-certified Agile Scrum master, a certified ISO-13485 lead auditor, and she has completed the Executive Development Program from Queen's School of Business. With numerous technical contributions to advance emerging hardware & software through patents & global regulatory submissions, Tanima has helped companies grow organically and through acquisitions as part of their SLT, IPO and M&A integration teams.