SOFTWARECPR

# DAVID MANALAN

## EXPERIENCE

- 40+ years of process development, quality systems, and regulatory affairs experience in the FDA regulated products sector
- Design, creation and implementation of product and process documentation systems for ISO and for FDA compliant quality systems at 10 different companies.
- FDA GMP certification audits pursuant to consent decrees for 3 different companies.
- Preparation of Pre-Market Notifications (510-K) for dialyzer reprocessing units, orthopedic devices, filtration devices, and blood processing devices.
- Creation and submission of Drug/Device Master Files for chiral drug substance, for bioseparation hollow fiber devices, and for sterilizing grade filter cartridges.
- Creation and filing of phase I IND for a periodontal disease product using New Molecular Entity.
- Creation and delivery of "FDA Regulations" and "Process Validation" courses for ASQ's Boston Sector.
- Developing hardware and software for filtration data acquisition device used in optimizing process systems.
- Management of and response to FDA inspection findings for 4 companies.

## CREDENTIALS

- Fellow, American Society for QA
- Board Member of New England Discussion Group, ASQ Biomedical Division, Program Chair, past editor of Biomedical Division newsletter - BioFeedback, Region 1 Councilor ASQ FD&C Division
- ASQ Certified Biomedical Quality Auditor, ASQ Certified Quality Auditor, ASQ Certified Software Quality Engineer, RAB Quality Systems Auditor (ISO 9000)
- Member AAMI, contributor to CAPA task force
- Massachusetts Department of Environmental Protection, Toxic Use Reduction Planner
- Co-author of original work for HIMA Standard on sterilizing filters.
- Massachusetts Quality Award, Trained Examiner
- Past Director, Quality Assurance and Regulatory Affairs, SEPRACOR Inc.
- 20 years R&D, QA, Regulatory Affairs, and Corporate Planning experience at Millipore Corporation
- BS in Chemical Engineering, M.I. T., Cambridge MA, 1965
- Biomedical Engineering Certificate, Northeastern University, Boston, MA, 1968