



88 Stiles Road
Salem, NH 03079 USA
Tel: 603-890-3311
Fax: 603-890-3322

email: info@makromed.com
Visit us at: www.makromed.com

Projects Portfolio

- 1. Documentum (Documentation Management Software):** Software validation and Part 11 assessment.
- 2. SAP QM Module (Incoming Inspection, Non-conformance):** Part 11 gap analysis, compliance strategy and implementation, and software validation.
- 3. InfoMed & InfoCAPA (QS Software - complaint handling, CAPA):** Part 11 assessment, software validation and risk analysis.
- 4. ClearQuest (Software bug tracking and version control):** Part 11 gap analysis, compliance strategy and implementation, and software validation.
- 5. RamanSoft (Spectrometry data analysis):** Part 11 gap analysis, compliance strategy and implementation, risk analysis and software validation.
- 6. Quality System:** Establishing a quality system in accordance with the FDA's QSR and/or ISO 13485:2003, implementing the system, and training the employees on its use and maintenance – at various medical device companies.
- 7. GMP/QSR/ISO 9001/13485 Documents, Training and Audits:** For various medical device and in-vitro diagnostic operations.
- 8. Design Controls/SDLC:** SOPs and employee training related to design control and software development life cycle activities in the R&D departments.
- 9. Internal Audits:** Establishing audit schedules, conducting the audits, and following up on the resultant corrective actions – at various medical device companies.
- 10. Blood Bank Software:** SDLC model, software QA policy and procedures, employee training and 510(k) submission.
- 11. Automated Infusion Pump:** Failure mode analysis and software QA/Validation. 510(k) submission for FDA approval.
- 12. Microwave Sterilizer for Peritoneal Dialysis:** Reliability study, Bellcore modeling.
- 13. Ultrasound Blood Flow Monitor:** 510(k) submission for FDA approval. Software QA/Validation.
- 14. Neural Pulse Generator Prosthesis:** Reliability study and software QA/validation.
- 15. Cyto Analyzer:** Software QA/validation.
- 16. Microwave Blood Warmer:** Electronics reliability study, Bellcore Modeling and failure mode analysis.
- 17. Orthopedic Model:** Knee Prosthesis to determine typical force applied during orthopedic surgery.
- 18. Ophthalmic Instruments:** 510(k) and IDE submissions for FDA approval. Failure mode analysis and software QA/Validation.



45 Stiles Road
Salem, NH 03079 USA
Tel: 603-890-3311
Fax: 603-890-3322

email: info@makromed.com
Visit us at: www.makromed.com

19. **Blood Gas Monitors:** QSR audits for design control and customer complaints, design, implementation and training on software QA.
20. **Urological Devices:** Accelerated aging and qualification testing.
21. **Steam Sterilizers:** Failure mode analysis and software QA/Validation. 510(k) submission for FDA approval.