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Projects Portfolio

1. **GMP System:** Establishing a quality system in accordance with the FDA's GMP/QSR, implementing the system, and training the employees on its use and maintenance – at various medical device and pharmaceutical companies.

2. **GMP/QSR/ISO Documents, Training and Audits:** For various medical device and in-vitro diagnostic operations.

3. **Internal Audits:** Establishing audit schedules, conducting the audits, and following up on the resultant corrective actions – at various medical device companies.

4. **Design Controls:** SOPs and employee training related to design control activities in the R&D departments.

5. **ISO/GMP/QSR Training:** Classes for employees from various disciplines in medical device and diagnostic industry.

6. **Process Validation:** Remediation strategy development and execution in response to the FDA's 483 and Warning Letter findings. Development of PV methodologies, training and implementation.

7. **Process Validation:** Development of corporate policy and procedures on process validation, and monitoring of their adaption and effectiveness at multiple global manufacturing sites.

8. **Process Validation:** Development and commercialization of InfoPV10i, a web app for process and test method validation.

9. **Software Validation:** On various software-driven medical devices and software-based quality system tools.

10. **Software Systems for QSR:** Development, training and implementation of various software tools for QSR compliance – InfoMed (complaints), InfoCAPA (non-conformance and CAPA), InfoAudit (internal and supplier audits), InfoTrain (employee training), InfoSQA (software development life cycle), InfoPV (process and test method validations).

11. **Temporary Pacing Catheters:** Qualification testing and 510(k) submission for FDA approval.

12. **Enteral Nutrition Catheters:** Qualification testing and 510(k) submission for FDA approval.

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13. **Automated Infusion Pump:** Failure mode analysis and software QA/Validation. 510(k) submission for FDA approval.

14. **Microwave Sterilizer for Peritoneal Dialysis:** Reliability study, Bellcore modeling.

15. **Ultrasound Blood Flow Monitor:** 510(k) submission for FDA approval. Software QA/Validation.

16. **Central Venous Catheters:** Qualification testing, statistical analysis and 510(k) submission for FDA approval.

17. **Left Ventricular Assist Device:** Nationwide market survey of cardiac surgeons on features and feasibility.

18. **Left Heart Pump:** Focus study with cardiologists, and cardiac surgeons, design and development of prototypes, laboratory and animal studies.

19. **Angiography Guidewires:** Qualification and simulation studies.

20. **Neural Pulse Generator Prosthesis:** Reliability study and software QA/validation.

21. **Cyto Analyzer:** Software QA/validation.

22. **Intra Aortic Balloon Pump:** Market study, design requirements and qualification tests. GMP system implementation. Simulation circulatory model design and qualification.

23. **Microwave Blood Warmer:** Electronics reliability study, Bellcore Modeling and failure mode analysis.

24. **Heparinized Coating for Vascular Catheters:** Formulation development and process validation.

25. **Vascular Catheters:** Material selection, process development and validation (custom blending/extrusion), and qualification testing.

26. **Orthopedic Model:** Knee Prosthesis to determine typical force applied during orthopedic surgery.

27. **Ophthalmic Instruments:** 510(k) and IDE submissions for FDA approval. Failure mode analysis and software QA/Validation.

28. **Blood Gas Monitors:** GMP audits for design control and customer complaints, design, implementation and training on software QA.

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29. **Urological Devices:** Accelerated aging and qualification testing.

30. **Patient Restraints:** 510(k) submission for FDA approval. Mechanical testing.

31. **Steam Sterilizers:** Failure mode analysis and software QA/Validation. 510(k) submission for FDA approval.

32. **Blood Bank Software:** SDLC model, software QA policy and procedures, 510(k) Submission and HIPAA compliance.

33. **Ultrasound Imaging System:** 510(k) submission for FDA approval. Software validation.

34. **Nerve Conduction Velocity Measurement Device:** 510(k) submission for FDA approval. Software validation.

35. **Genomic Cancer Detection System:** 510(k) submission for FDA approval. Software validation and HIPAA compliance.

36. **Remote Patient Monitoring System:** Smart phone and Cloud-based technology. HIPAA and EU Privacy compliance.