

Project Management Services

Tailored to your process & preferences

Product Life Cycle Management

§820.30 Design Controls

PMBOK[®] Methodologies

Full Submission Support

Planning, review, or outsourcing

Monte Carlo Risk Analysis

Project, Primavera[®], Suretrak[®] based

PMP[®] certified staff

...Turn for details



Project Management Services

- **Compatible with §820.30 and PMBOK[®] guidelines**
- **Fully integrated with other SoftwareCPR services**
- **Planning, review, or outsourcing**

We will work with you to plan your medical device project design and development plan and processes, either prospectively or retrospectively. We will help prepare an integrated project plan in accordance with your current product design and development processes, or we will jointly develop new or updated processes based on your particular circumstances, applicable standards, and our years of experience. Upon plan approval by your stakeholders, we can help implement, control, release, and close-out your project, using industry standard methodologies.

Our approach is risk-based, emphasizing risk management planning and mitigation early in the project to help prevent or reduce costly changes during the development cycle. Our clients range from large corporations to small start-up companies. We can work with your staff, your contractors, or provide full support.

Our staff has years of experience managing medical and high tech hardware / software products. Robert West, SoftwareCPR[®]'s resident Project Management Professional, (PMP[®]), has led medical device project teams for Johnson & Johnson and Baxter Healthcare from feasibility stage through global launch and product support, including 510(k) submissions. He has helped develop proprietary project management software for a leading computer developer and then implemented and trained their key project teams in project management tools and methods.

Submission Support – Our project management methodology will support your required regulatory submittals (510(k), PMA, and IDE) by providing for the earliest possible submittal, consistent with meeting the full requirements of submission and §820.30 design controls.

Monte Carlo Risk Analysis – We can help you obtain realistic schedules that will not disappoint your stakeholders. Your current CPM scheduling techniques typically result in a schedule with a less than 5% chance of being met. Monte Carlo risk simulation, applied to your current project schedule, offers a real-life schedule that accounts for known project risks and constraints, and provides you with probabilistic completion dates that are tough but real. Simulation can also model the impact of redesign due to design reviews or test failures, the possible delays due to regulatory re-submission, and even the little understood but very real probability of additional delays imposed when a project schedule is revised to reduce duration (crashing).

Front end Planning – Our staff can help facilitate your project's initial planning, so critical to the project's success. Our staff will assist your team to establish plans for your project's scope, deliverables, schedule, budget, resources, risks, communications, staffing, and change control. The end result is an integrated project plan which will serve as a roadmap for your project leader and team, including subcontractors.

Recovery Planning – We can help review your current project status and documentation and assist you in formulating a recovery plan to put the project back on its feet, and provide you with a detailed, revised plan to completion. As needed, we can assist you in implementing the plan.

Project Management Tools – We are experienced in Project, Primavera[®], and Suretrak[®], along with Risk+ and Monte Carlo software for risk-based project scheduling. Our staff has provided training in project management software and methodologies and can work with your team to provide customized training.