

## Devicix Engagement Process

Devicix follows a simple but very effective process for helping our clients understand the timeline and costs associated with executing a development effort or project. The outcome from this process alone adds significant value to our clients because it creates a detailed plan that forms the basis for the client’s project plan required as part of the design controls in medical device development.

The project proposal is a key document that we create to identify and communicate the expected scope and duration of a project. To truly understand the effort involved and the client needs, we follow a process outlined below. A set of initial meetings give us the opportunity to meet with our clients to gain an understanding of their needs, and their product or technology. We then create a detailed project plan. A “bottoms-up” schedule and cost assessment provide the detail necessary to truly understand the product development effort, requirements, deliverables and uncertainties. This project schedule also has other benefits to our clients. It provides them the detail and transparency to better understand the effort involved, and becomes the basis for the formal project plan that is created as part of the design controls required for the development of a medical device. The final proposal includes this schedule and descriptions of the outlined work tasks. Work plans range from specific tasks needed to solve a production or field issue, to the tasks needed to take an idea from a napkin sketch through the market release, including all the required regulatory, mechanical, electrical and software verification and validation efforts.

