CICERO BIOINSTRUMENTATION

Cicero Bioinstrumentation's engineering staff can provide professional design services for your product development needs. We provide design outputs that comply with medical regulatory compliances ranging from FDA, to CE and JIST.

Our requirements gathering, V&V planning and risk management procedures ensure quick and reliable product testing and release into the market.

Consequently, think about Cicero Bioinstrumentation the next time your R&D and product development teams need to outsource device development services.

For more information on Cicero Bioinstrumentation please contact:

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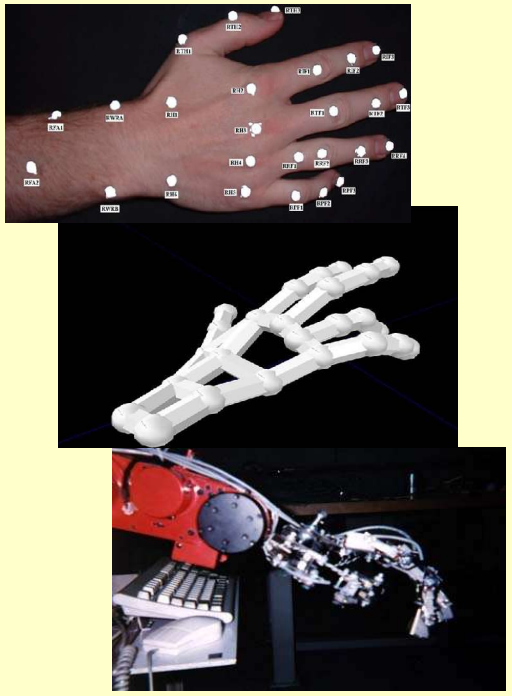
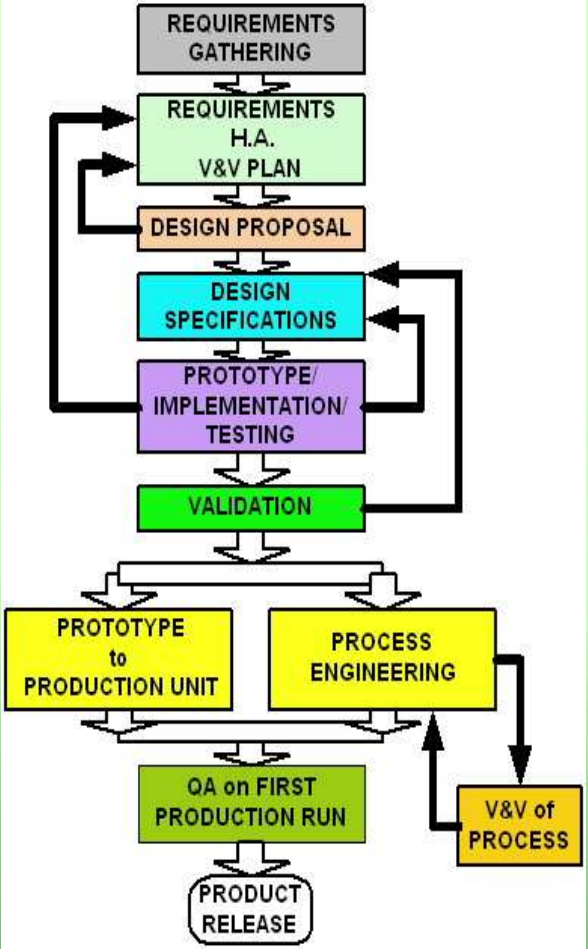


Custom Engineering for the Medical Device World

Cicero Bioinstrumentation has experience in the entire range of device design activities, from early concept requirements gathering through design-for-manufacture and quality control system design. Our experience working within regulatory environments means we can provide process-controlled solutions for diagnostic and therapeutic

DESIGN PROCESS

Every design project at Cicero Bioinstrumentation follows a design process created to ensure the final product meets customer requirements, with the design controls in place to meet any regulatory compliance requirements.



DESIGN OUTCOMES

Cicero Bioinstrumentation's approach to any design project is to ensure that the final outcome provides the following,

- **Requirements Gathering**
- **Hazard Analysis**
- **User Requirements**
- **Functional Requirements**
- **Validation Planning**
- **Design Specifications**
- **FMEAs**
- **Verification Planning**
- **Test Development and Test Documentation**
- **Unit Testing**
- **Integration Testing**
- **System and Acceptance Testing**

Cicero Bioinstrumentation uses strict documentation control guidelines

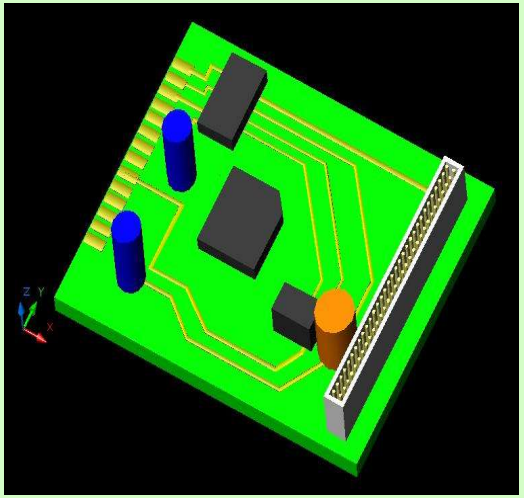
These guidelines assist in the management of prerelease and post release documentation to ensure regulatory compliance. Control guidelines includes revision, version, and part numbering schemes for component, subassembly, and assembly management.

PROTOTYPE TO PRODUCTION

The engineering staff at Cicero Bioinstrumentation can provide the manufacturing engineering solutions for a product during the product development stage, as well as providing design-for-manufacture services for products that have completed their prototype designs. We can also provide the process engineering required for the manufacturing of the production unit

DESIGN TOOLS

The engineering staff at Cicero Bioinstrumentation uses several CAD packages to produce 2-D drawings and 3-D CAD models as well as schematic capture software such for electrical designs and the production of PCBs. All drawings are manged by our document control system.



TESTING & PROTOTYPING

Often before the design process can be completed it is necessary to build prototypes for testing and test fixture development, ans well as preliminary production/process/work cell design and for proof of concept. Cicero Bioinstrumentation can produce mechanical, electromechanical, electronic, and plastic prototypes to enhance the overall design process, or to provide working prototypes for demonstrations such as trade shows and expositions.