LION DESIGN CONSULTING, INC.

Capabilities and Services

619-683-2462 cgriswold@lion-dc.com www.lion-dc.com

Capabilities and Serivces

01
Design

02
Manufacturing

03
Quality

Corporation to Corporation contract help to companies that need tasks done.
Mechanical Design, Manufacturing or Quality done in a timely, professional manner.
The work gets done, you to take the credit.
A Purchase Order, and Consulting Agreement is all it could take.

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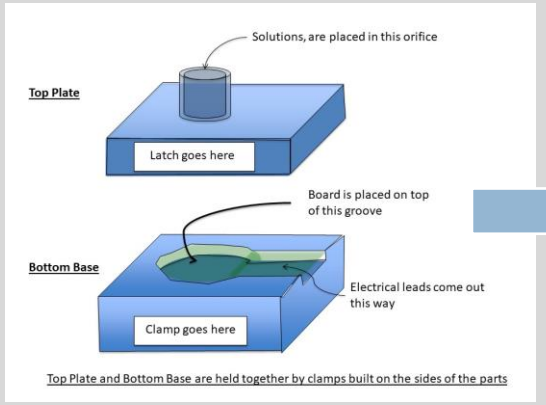
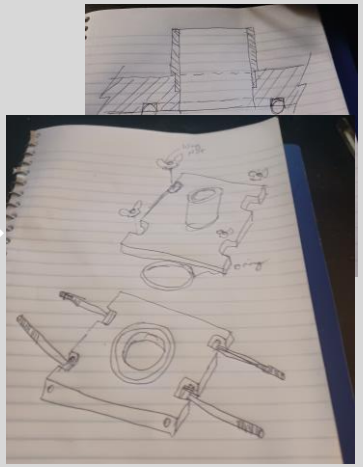
01 Design

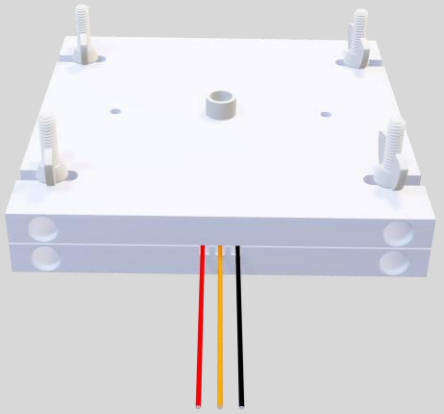
Customer Concept



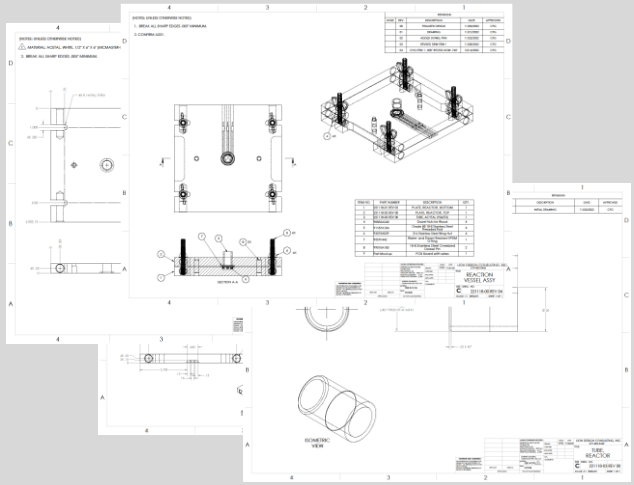
Design Concepts



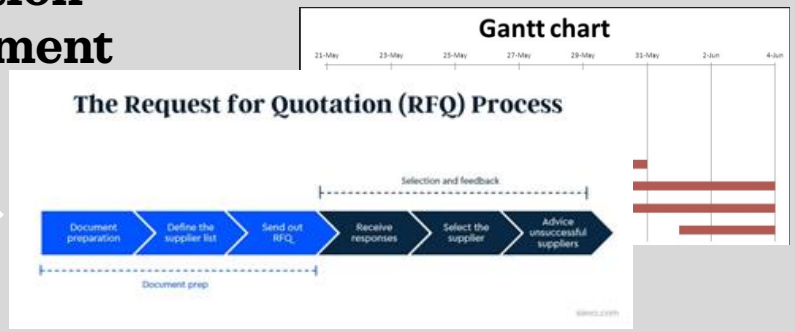
Design Models



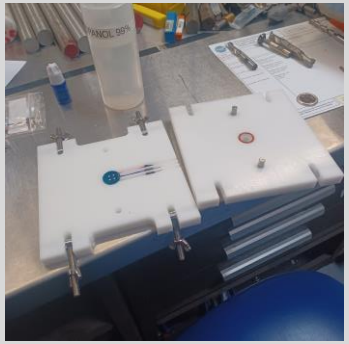
Design Documentation

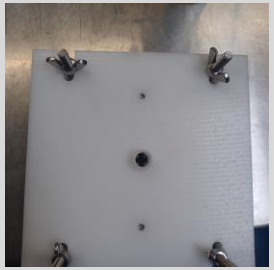


Fabrication management



Inspection, Assembly, Testing





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01 Design

-Product Design
-Injection molded parts
-Fixtures, labware, tooling
-Customized Automation Equipment
-Prints/Control Documentation
-3D printing/CNC Fabrication
-Independent Design Review

-Material Selection and Testing
-Customized Sterilization Trays
-Packaging
-Manufacturing/Sustaining Engineering
-Computer-Aided Design (CAD) Modeling
-Models/Mockups/Prototypes

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02 Manufacturing

-Vendor Specification/Approval
-Quality Control and Assurance
-Manufacturing Equipment Maintenance
-Lean Manufacturing Implementation
-Supply Chain Management
-Industrial Automation and Robotics Integration
-Sustainability Practices
-Process Engineering and Optimization
-Product Lifecycle Management
-Project Management
-Continuous Improvement Initiatives
-Ergonomics and Safety
-Regulatory Compliance

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02 Quality

-Supplier Audits
-Technical File update
-External Documents update
-Design Verification and Validation
-Corrective & Preventative Actions (CAPA)
-Quality Training and Development
-Quality Documentation and Reporting
-Customer Feedback Analysis
-Independent Internal Audit
-FDA, ISO13485/MDR Reconciliation
-UDI assigning, marking and registering
-Root Cause Analysis
-Product Testing and Validation
-Inspection and Metrology
-Risk Management

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03 Quality

ISO9001/ISO13485/FDA/FAA/MDR/Mil-Std……..Did you know?

•Suppliers, and Regulations, should be formally “management reviewed” every year.

•If a change occurs to an FDA regulated product, or manufacturing process, it requires Verification and Validation documentation prior to production.

•Design Control reviews require at least one Independent Reviewer.

•Legacy CE marked products, or ISO 13485 certified companies, are required to update their Quality Systems and Technical files to recently revised standards.

•May 26th, 2020 the European MDD (Medical Device Directives) has been replaced with the MDR (Medical Device Regulations). “Essential Requirements” have been replaced with “Safety and Performance Requirements”. Reconciliation is probably necessary.

•In April 2019, the FDA updated their Code of Federal Regulations Title 21. Any company that falls under these regulations should download the new standards, and reconcile their Quality System to comply with the changes.

•Post September 24th, 2022, a Universal Device Identifier (UDI) is required for all but legacy Class I devices. The barcode and number should appear on the Labeling, Instructions for Use and the product itself (if reused). It must be registered with the FDA under the company’s name.

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