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 Engineering Services for infrequent, or surge, demands in skilled labor.
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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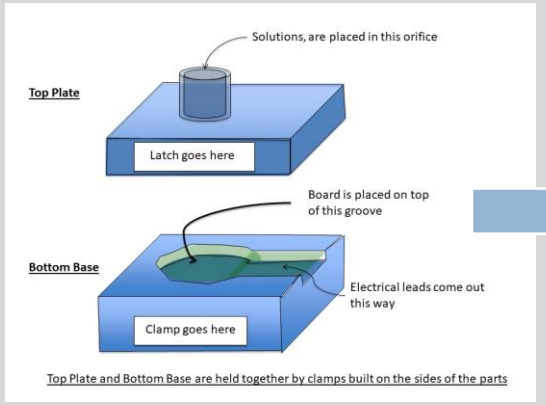
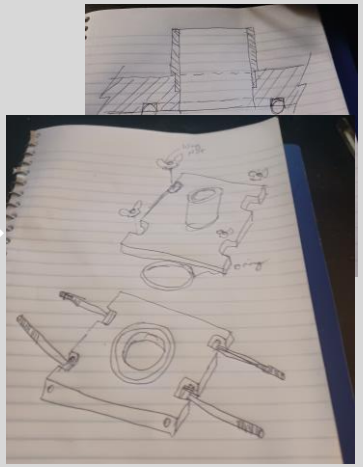
01 Design

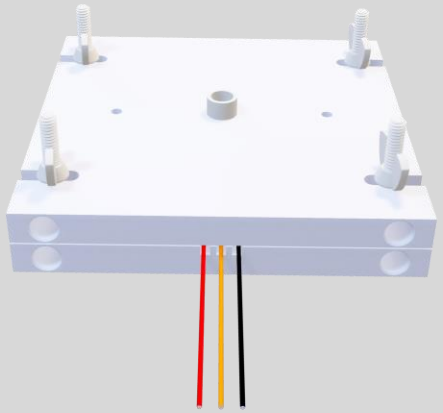
Customer Concept



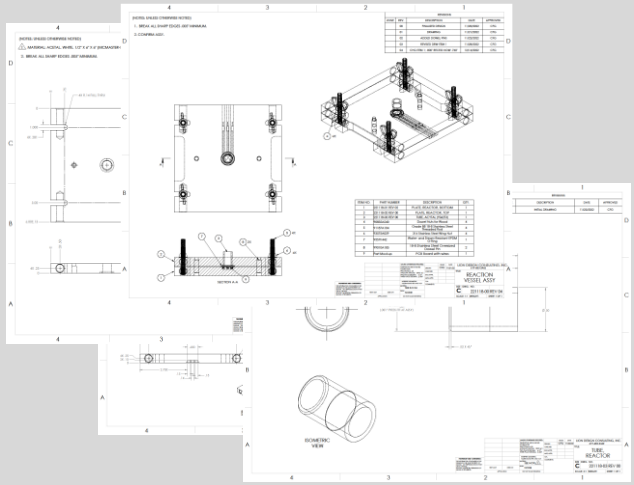
Design Concepts



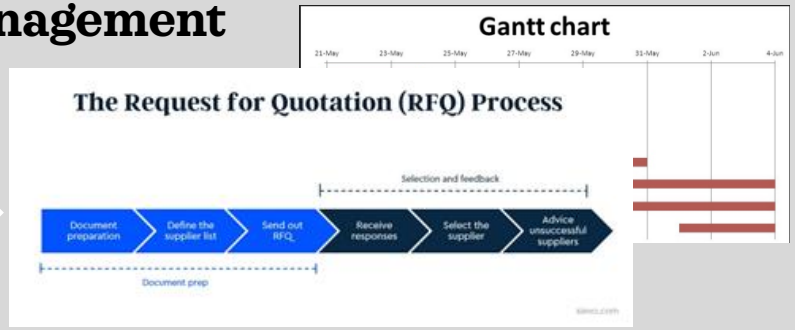
Design Models



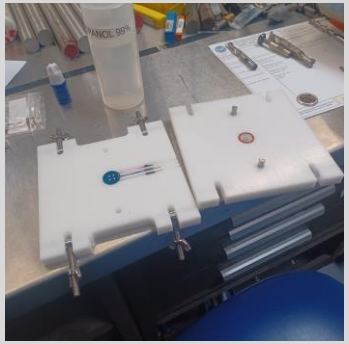
Design Documention

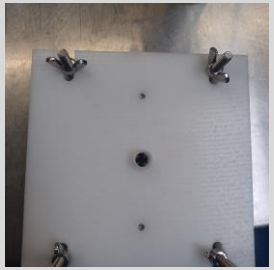


Fabrication management



Inspection, Assembly, Testing





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01 Design

Possible Outsourced Tasks- Machine Shops/Fabricators

- Reverse Engineering of prototypes, or sketches, into documented acceptance criteria.
- Creation of 3D(.STL, .IGES, .SLD), or 2D (.DXF) files for Digital manufacturing.
- Creation of GDT documentation for analog manufacturing.
- Project estimating and managing.
- Consulting on material, sourcing, heat treatment, fits and tolerances.

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01 Design

Possible Outsourced Tasks- General

- Product Design
- Dimension and Tolerance Analysis
- Customized Sterilization Trays
- Customized Packaging
- Manufacturing/Sustaining Engineering
- Computer-Aided Design (CAD) Modeling
- Models/Mockups/Prototypes
- Material Selection and Testing
- Injection molded parts
- Fixtures, labware, tooling
- Customized Automation Equipment
- Prints/Control Documentation
- 3D printing/CNC Fabrication
- Independent Design Review

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02 Manufacturing

Possible Outsourced Tasks

- Supplier Determination
- Risk Analysis
- Product Lifecycle Management
- Manufacturing Equipment Maintenance
- Lean Manufacturing Implementation
- Supply Chain Management
- Industrial Automation Robotics Integration
- Sustainability Practices
- Process Engineering/Optimization
- Quality Control
- Statistical Process Control
- Project Management
- Continuous Improvement Initiatives
- Ergonomics and Safety
- Regulatory Compliance

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03 Quality

Possible Outsourced Tasks

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

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03 Quality

ISO9001/ISO13485/FDA/FAA/MDR Did you know?

•Regulatory requirements incorporate both law and accepted Good Practices in management, business and industry.

•Suppliers and Quality Systems should be formally reviewed by management every year.

•If a significant change occurs to a regulated product, or manufacturing process, Verification and Validation requires documented approval prior to commercial use.

•Design Control reviews require at least one Independent Reviewer (outside the company, or department)

•Legacy products, in regulated industries, should update their Quality Systems and Technical files to most 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”.

•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, the FDA requires 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).

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