QUALITY MANUAL

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INTRODUCTION

Mission Statement
To improve and enhance the quality of health of the user through innovative assistive technologies.

Policies
On customers: We will have utmost respect for our customers, their needs, and their privacy while balancing the customers' best interest based on the opinion of our professionals. Our goal will be to attain satisfaction of all parties involved in the company.

On leadership: At all levels of the company there will be leadership to promote and encourage the vision and mission of the company. This will be achieved by establishing a set of core values for the company, maintaining the quality management system, and conducting internal reviews.

On people: We will listen and value the opinions and ideas of employees, investors, and other company supporters to further the goals of the company and the interests of the customers. We will establish our company as an equal opportunity company and seek the knowledge and experience of all members of the organization.

On processes and systems: We will approach each situation with due process according to the process needed. We will not cut any corners when it comes to problem solving because we know the importance of developing ideas and solutions in the specified way.

On continual improvement: The various departments in our company will continually be evaluated for improvement by both their peers and their colleges. The environment in which our employees work would be one where they will be held accountable for any shortcomings with the focus on self-improvement more so than peer discipline within reason.

On Quality: We will always hold the quality of our products in the highest regard in order to promote effectiveness, safety, and customer satisfaction. Our commitment to quality will be reflected in our material selection, manufacture processes, talent acquisition, and customer service.

On decisions: Decisions will be made after consulting others within their department. The department leader will ultimately be responsible for the product, but a system will be put in place to encourage certain employees to build up ideas to further the company.

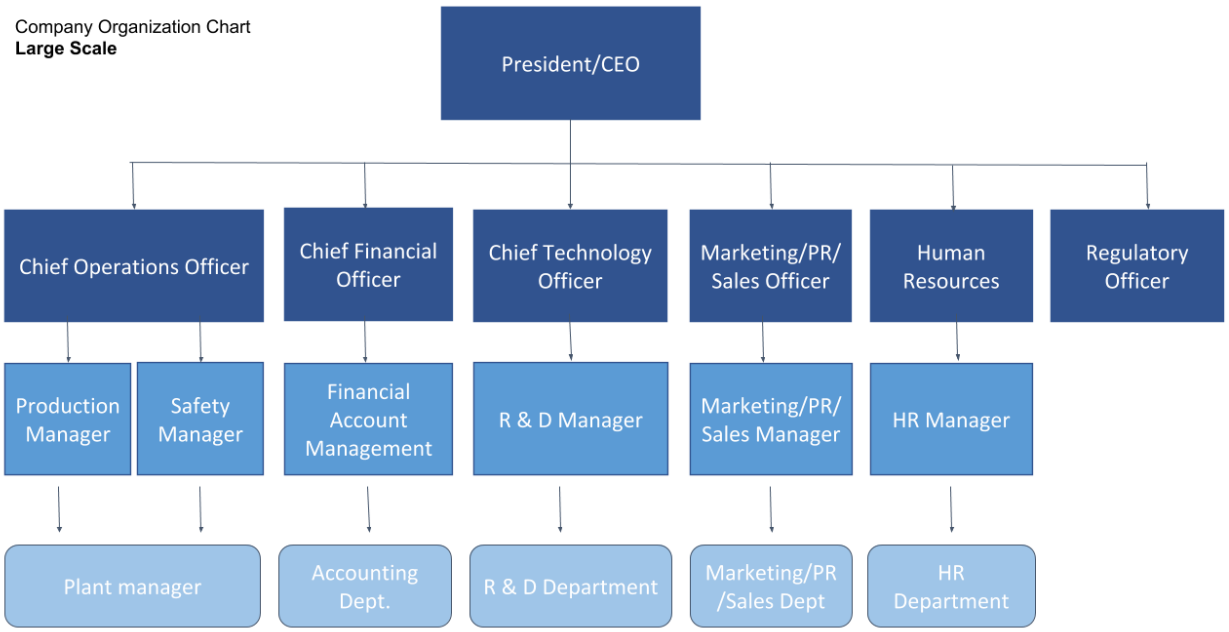
On supplier relationships: We will always exhibit honesty and fair treatment in business deals conducted with suppliers. This includes, but is not limited to, expeditious delivery of all payments, documentation of all deals, safe keeping of all confidential information, and general operation that is mindful of the company's and supplier's best interests.

On profits: We will conduct business such that the interests of our customers, business partners, stockholders, and employees are balanced in regard to the earning of and disbursement of profits.

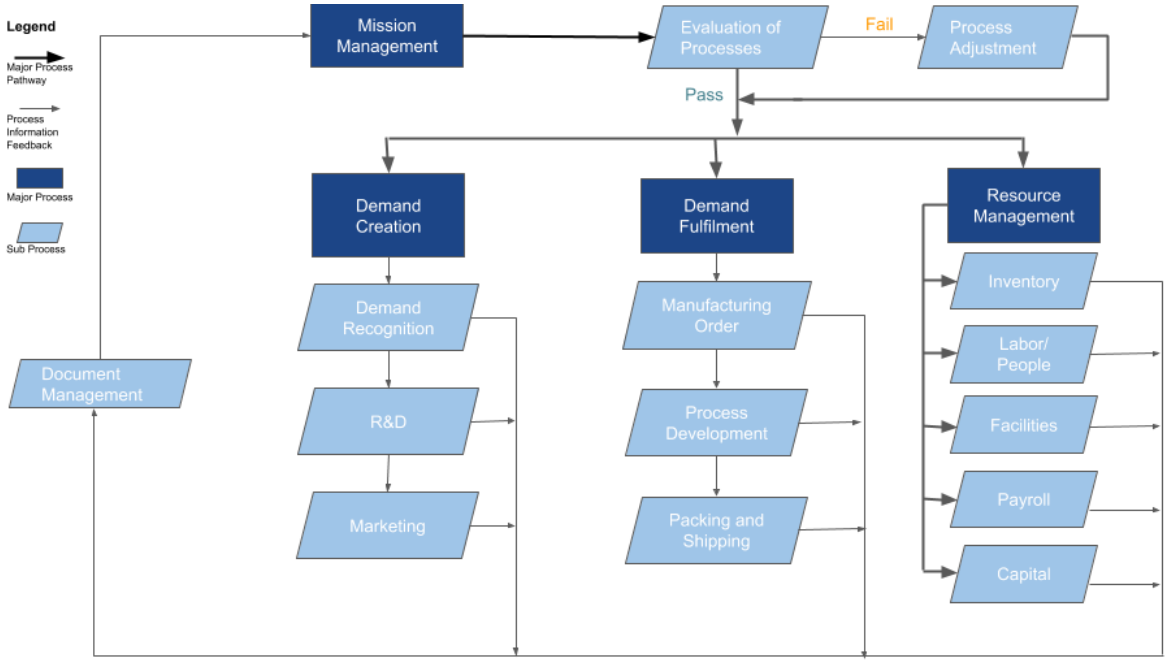
On the environment, health and safety: We will conduct all operations with consideration and utmost respect for the current and continued well-being of the environment in which it operates.

COMPANY PROCESSES

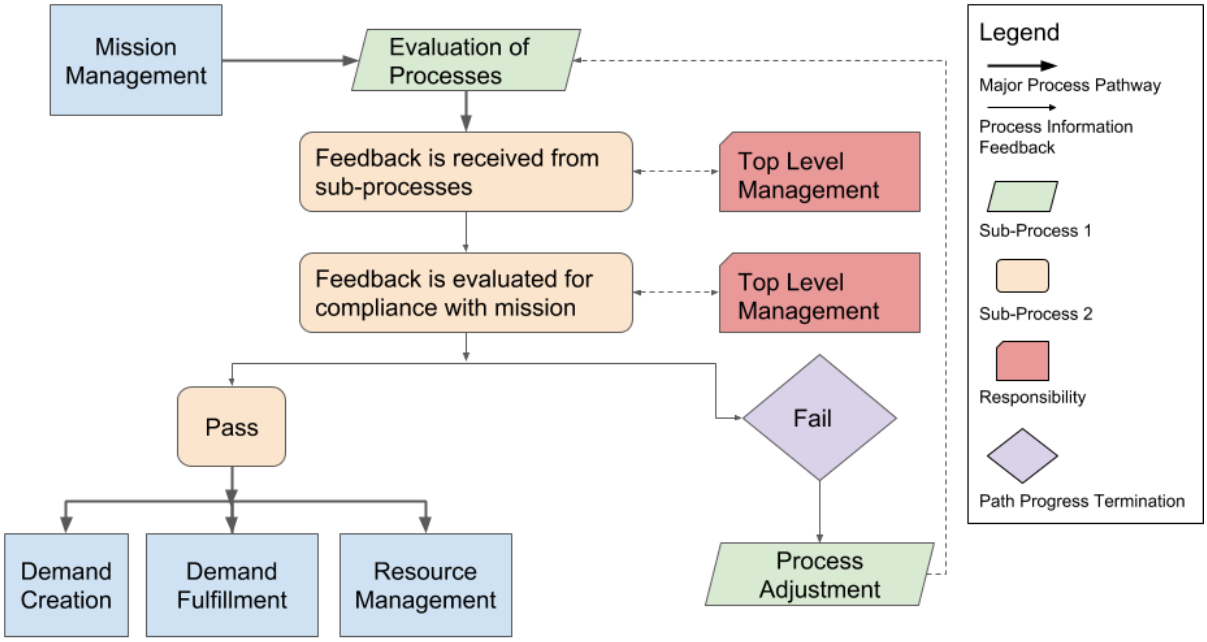
PERSONNEL/ENTITY STRUCTURE CHART



MISSION MANAGEMENT



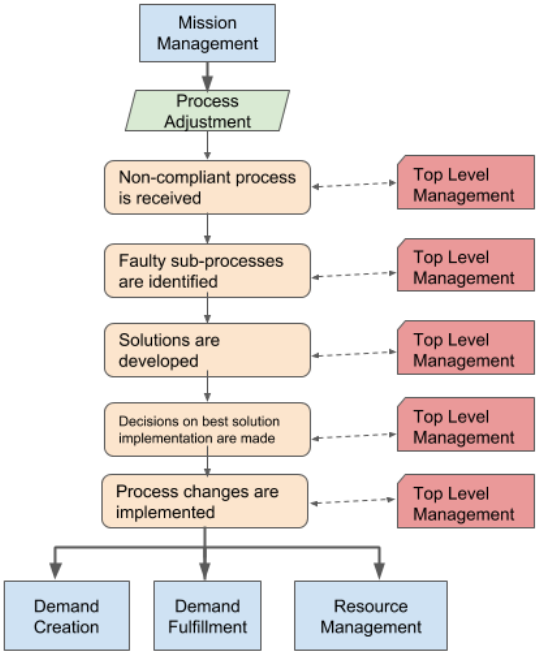
EVALUATION OF PROCESSES



Process Objectives

- Processes should be evaluated on a monthly basis to ensure effectiveness and success of the processes and to ensure that the mission is being upheld.
- The review process should last no longer than one week before being approved and sent on to other major processes or being adjusted and reevaluated.

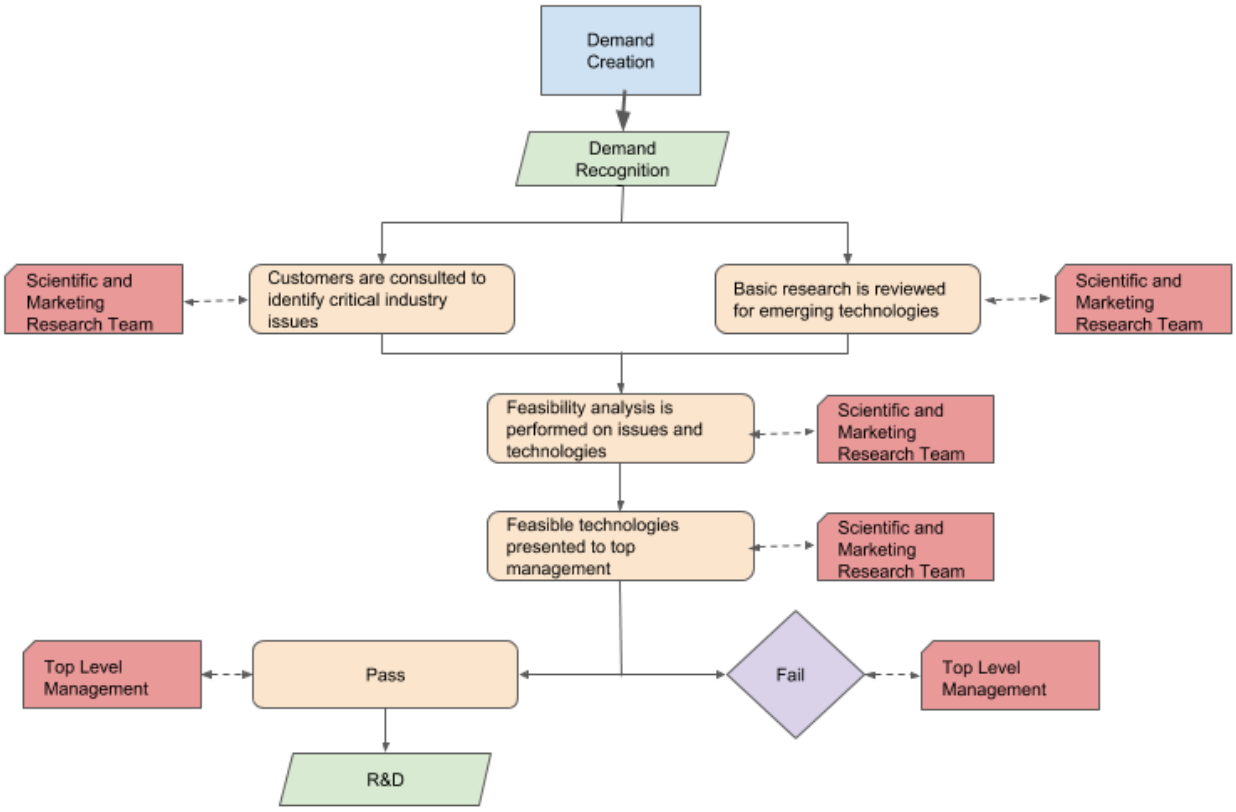
PROCESS ADJUSTMENT



Process Objectives

- Address and improve faulty and ineffective processes. Faulty processes should be identified within one week of the notice of non-compliant processes.
- Within two weeks after the faulty sub-processes are identified, a solution should be approved and implemented.

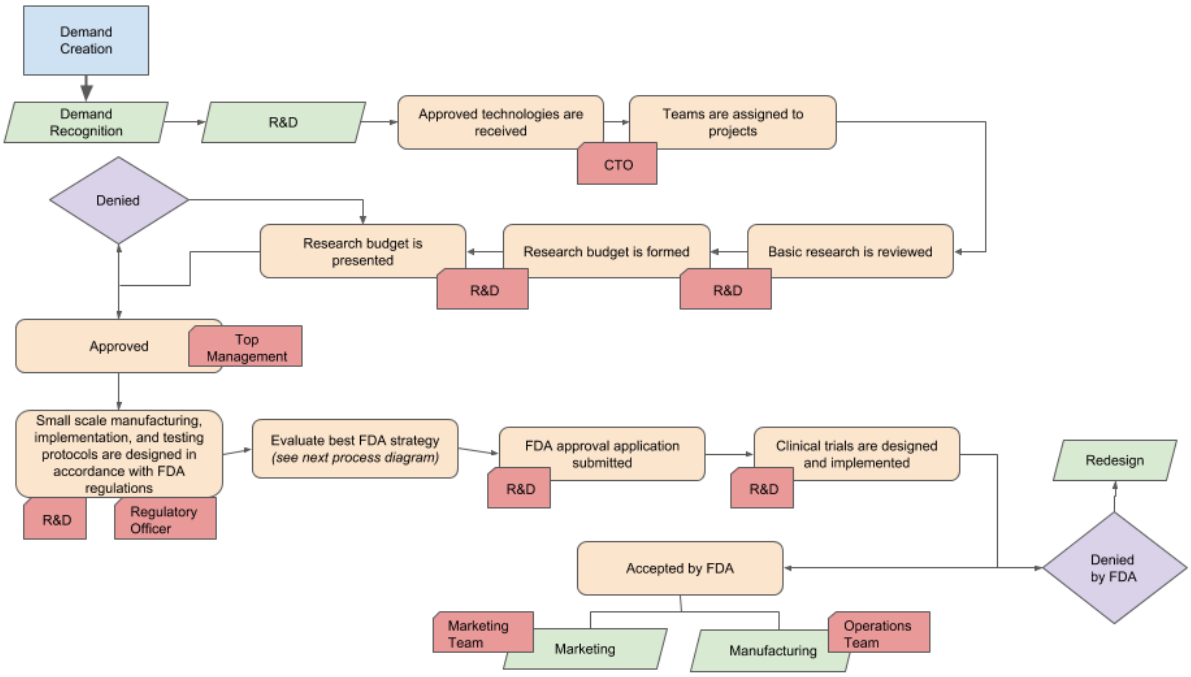
DEMAND RECOGNITION



Process Objectives

- Maintain mission management through customer discovery and research. Research should be conducted continually by R&D, with a formal report on emerging technologies at least once a month.

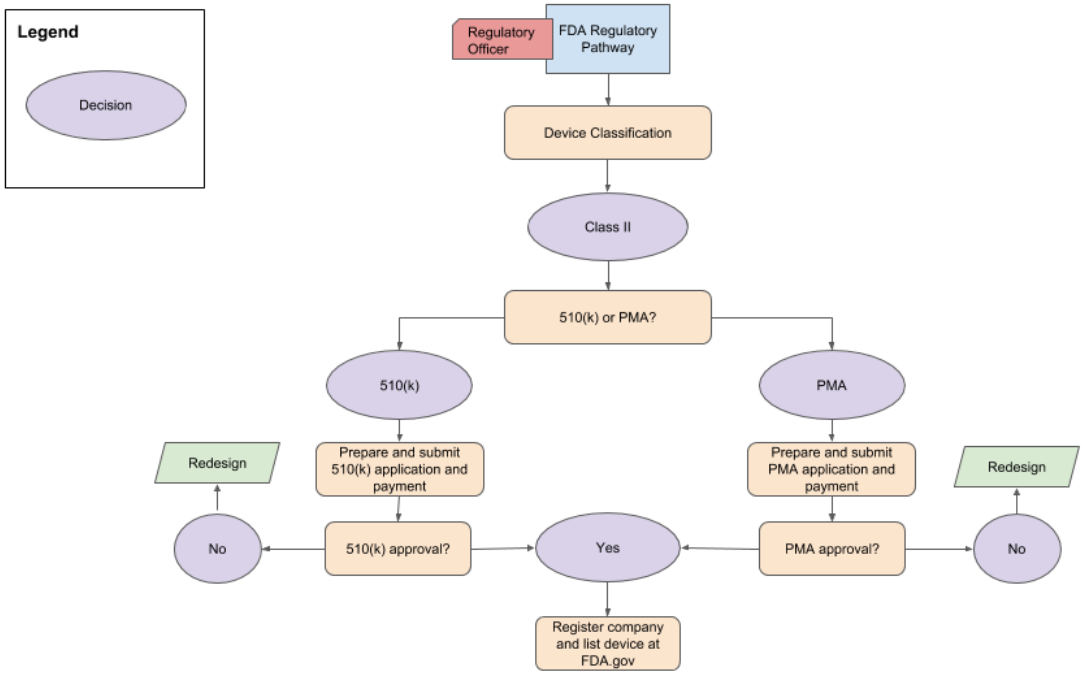
FDA REGULATORY PROCESS



Process Objectives

- Promote company mission by meeting standards of current technology.
- Research budget should be set within 2 months.
- Projects should adhere to set research budget.
- The FDA approval process should not be longer than 3 years.

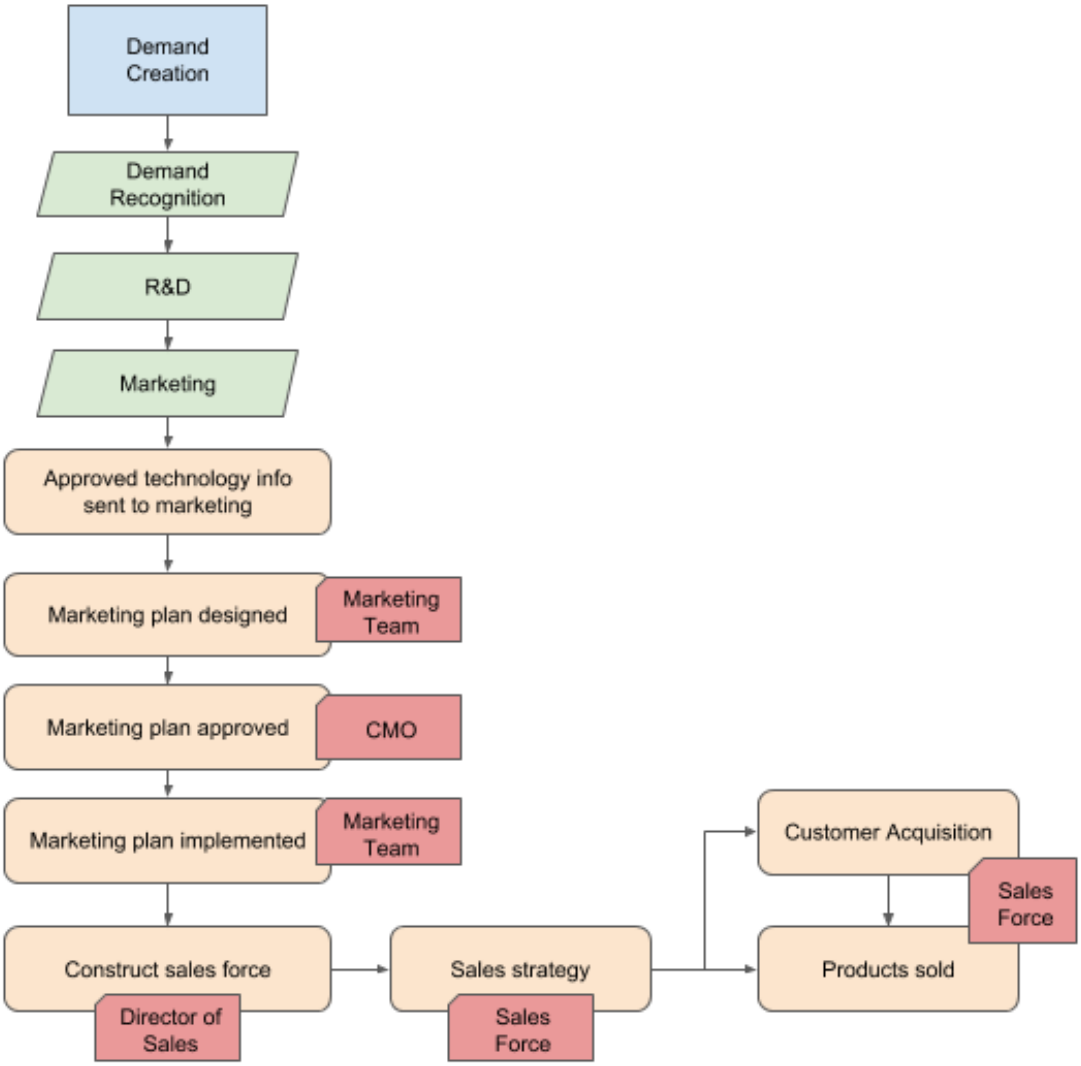
EVALUATION OF FDA STRATEGY



Process Objectives

- Decide which FDA process will be appropriate for the device.

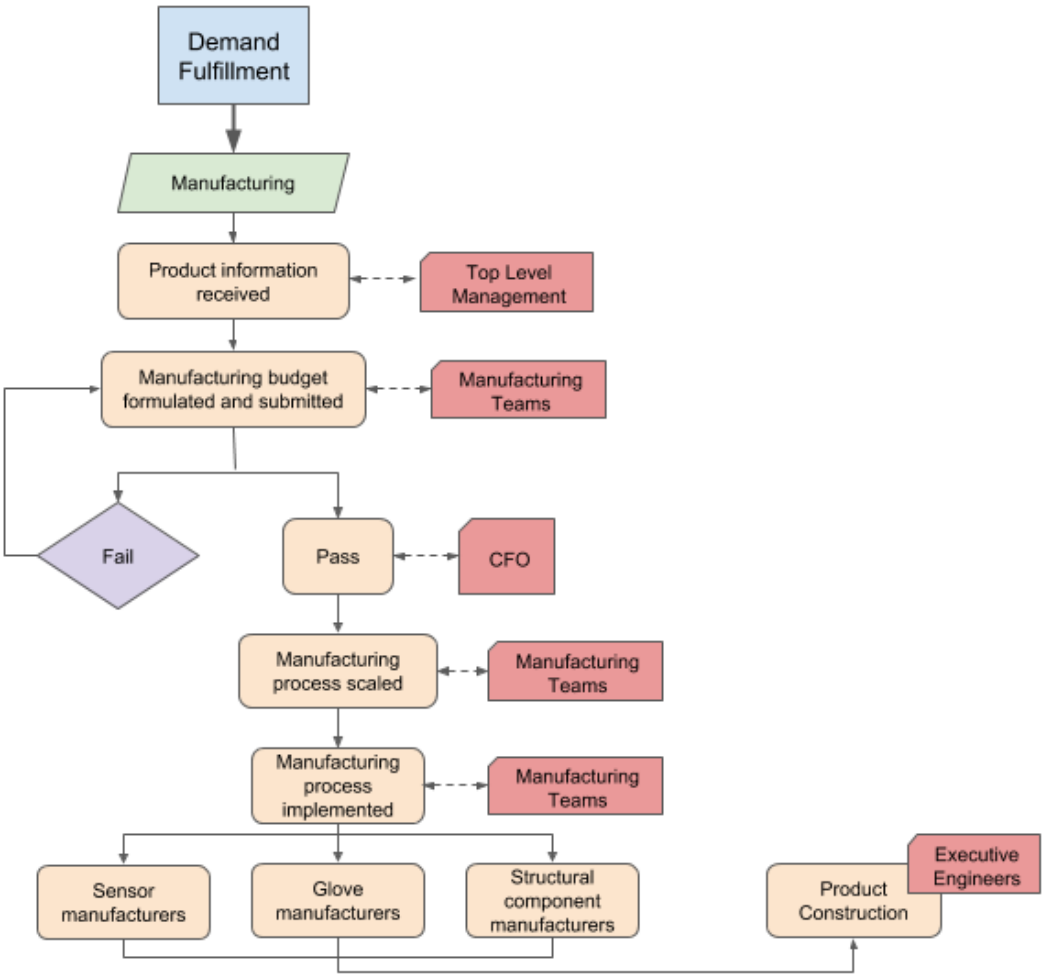
MARKETING PLAN



Process Objectives

- Marketing plan should adhere to budget allotted for marketing.
- Marketing plan should take no more than one month to complete.
- Sales strategy should take no more than one month to complete.
- Company mission should be a cornerstone to the sales strategy.

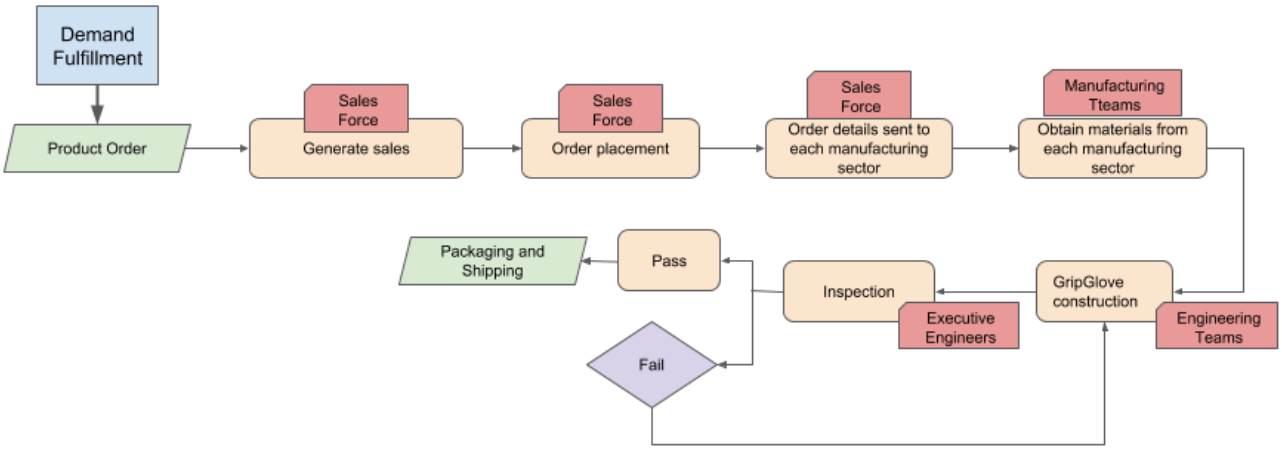
MANUFACTURING PROCESS



Process Objectives

- Manufacturing should adhere to budget set for the department.
- Manufacturing development and scaling should not take more than three months.
- Teams should complete training within one month from time of process implementation.

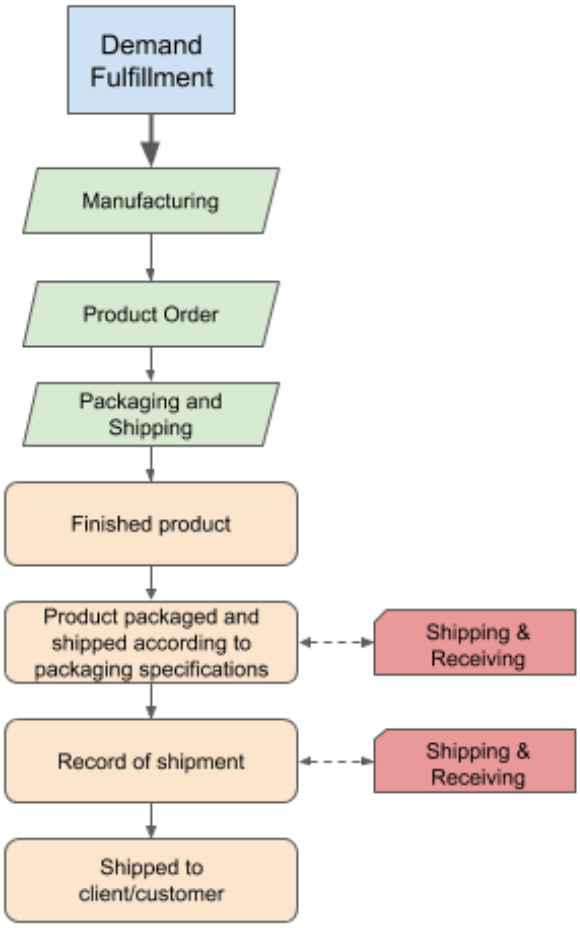
PRODUCT ORDER FULFILLMENT



Process Objectives

- From time of order placement, order should be processed in 3 weeks or less, due to the customization of the product.
- Construction of final product after component manufacturing stages should not take more than 5 days, including testing and inspection.
- Product should not fail more than two times before determining the product or its components to be faulty.

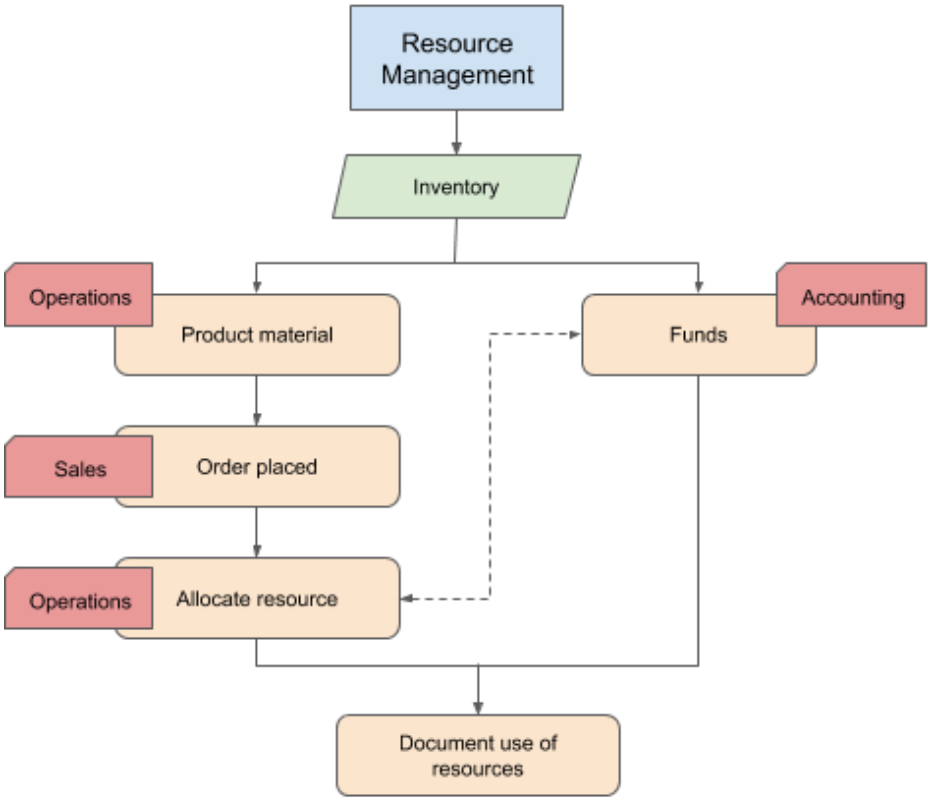
PACKAGING AND SHIPPING



Process Objectives

- Product should be packed and shipped within 24 hours of passing inspection.

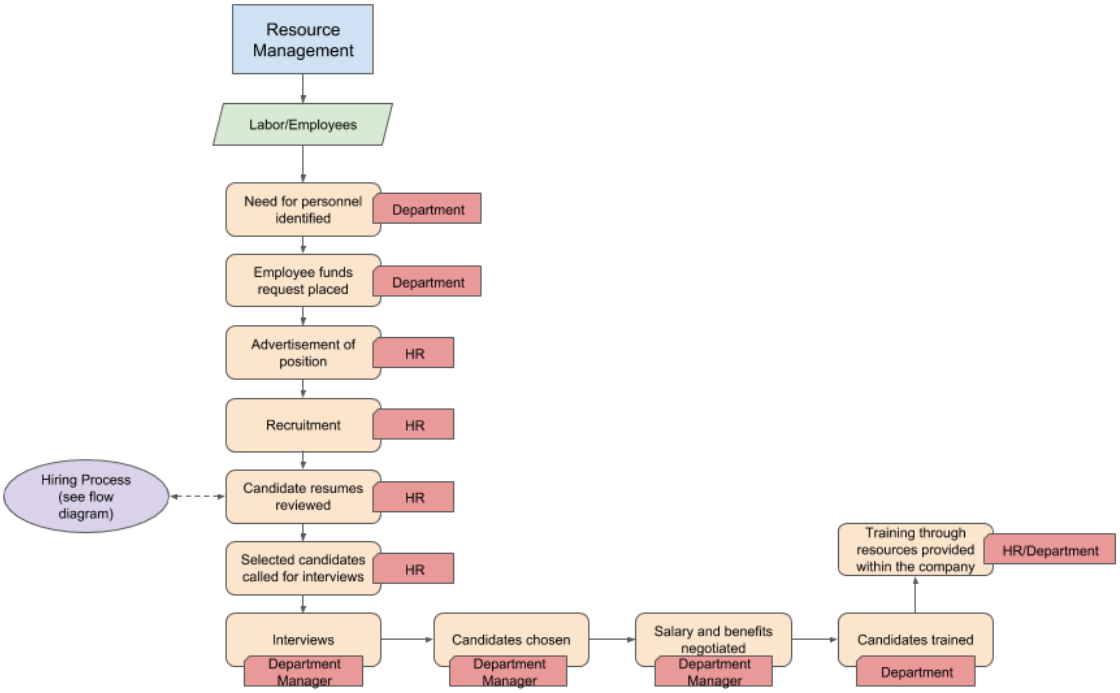
INVENTORY PROCESS



Process Objectives

- Resources should be allocated within 24 hours of order placement.
- As resources are used, they should be documented and inventoried within 24 hours.

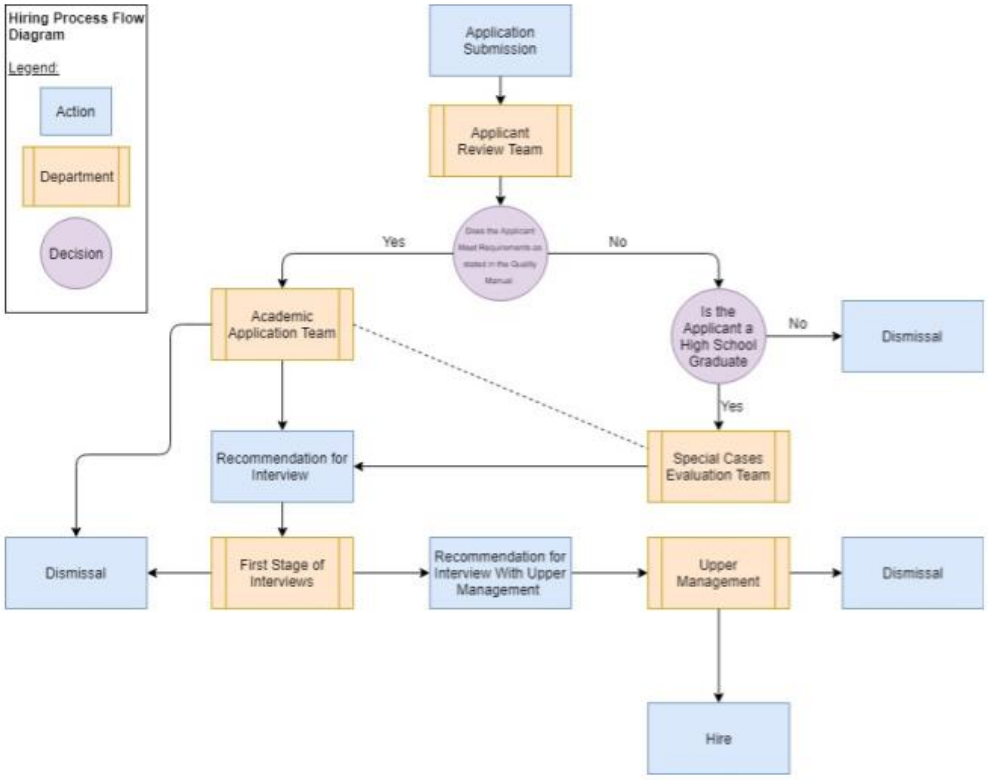
HIRING PROCESS



Process Objectives

- Hire qualified individuals who will uphold company mission
- Offer competitive benefits and salaries

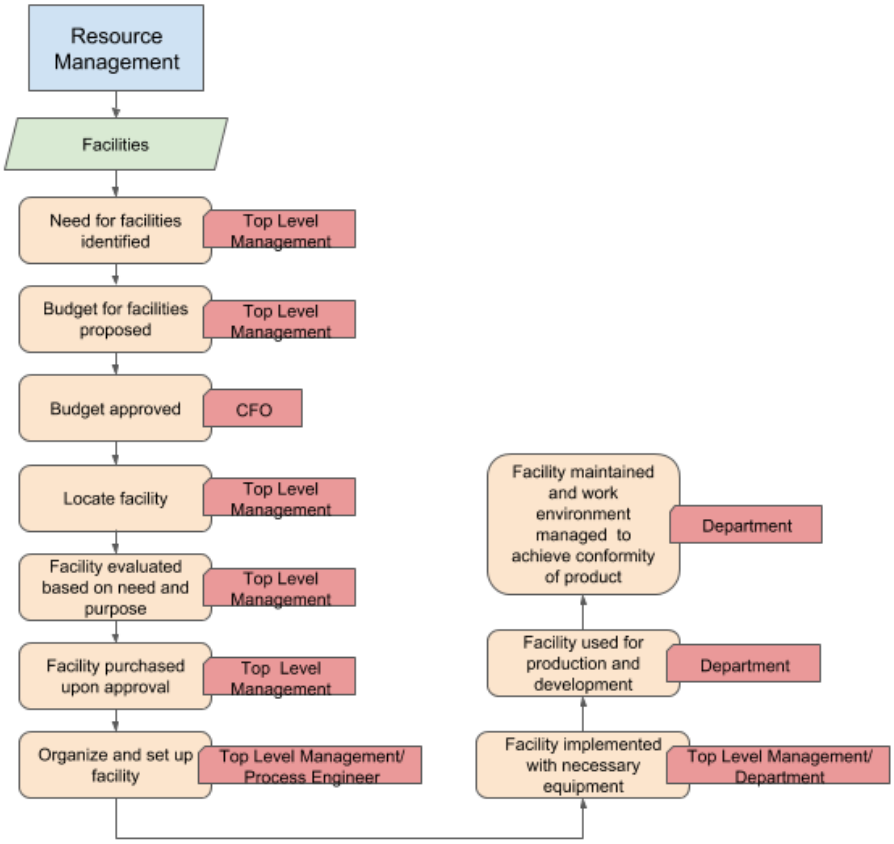
HIRING PROCESS, CONTINUED



Process Objectives

- Provide opportunities for qualified individuals who may not have extensive education.

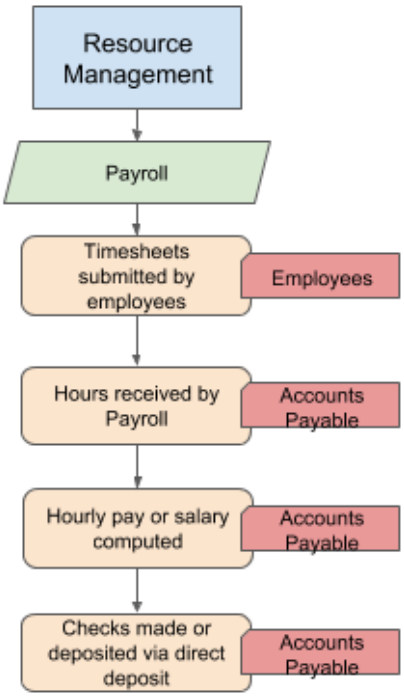
FACILITIES MANAGEMENT



Process Objectives

- Facilities should be appropriate for their intended uses and meet department needs according to their purpose.
- Facilities should be properly set up and organized so that workflow is most efficient.
- Facilities and work environment should be maintained and managed so that product conformity is achieved.

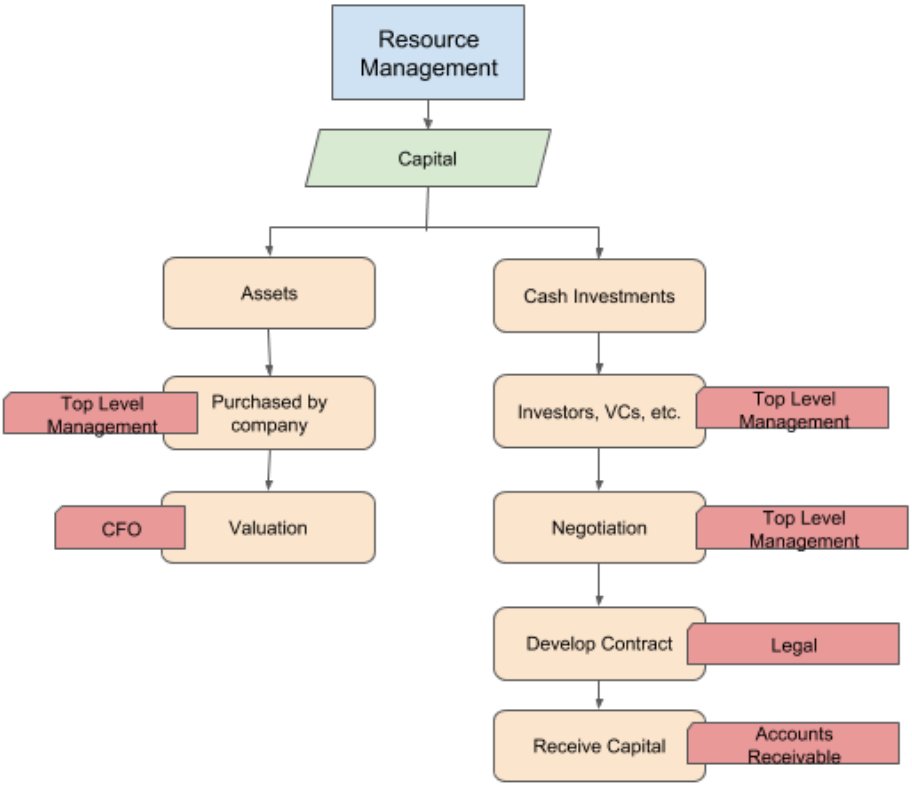
PAYROLL MANAGEMENT



Process Objectives

- Employees should be paid on time and according to amounts stated in employee contracts.

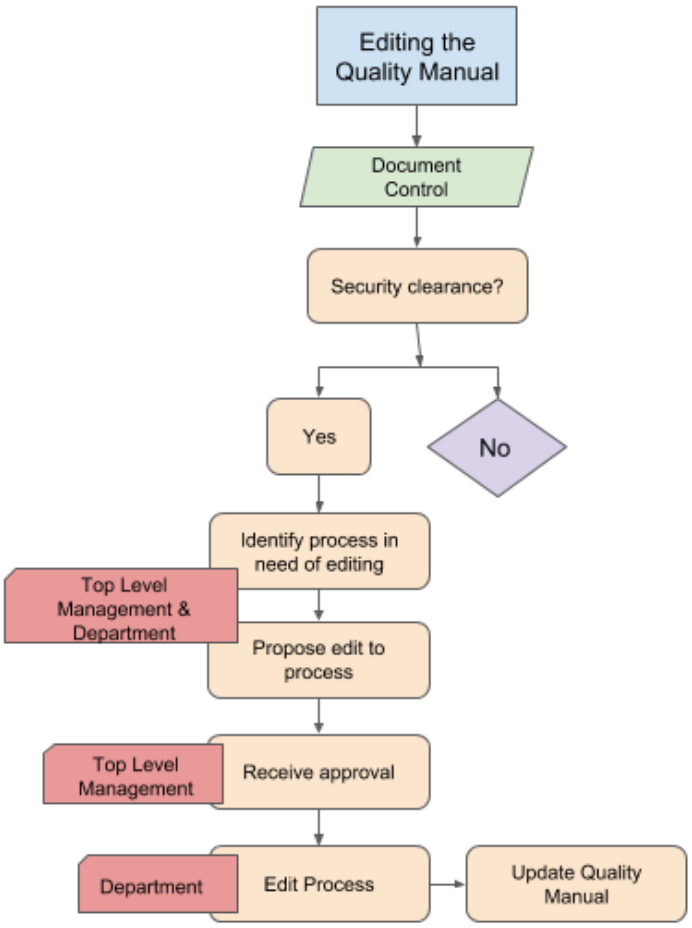
INVESTMENT MANAGEMENT



Process Objectives

- Capital should be accounted for in terms of cash investments and other assets.
- Executives should be in agreement in negotiations of investment and who the stakeholders in the company will be.

EDITING PROCESS

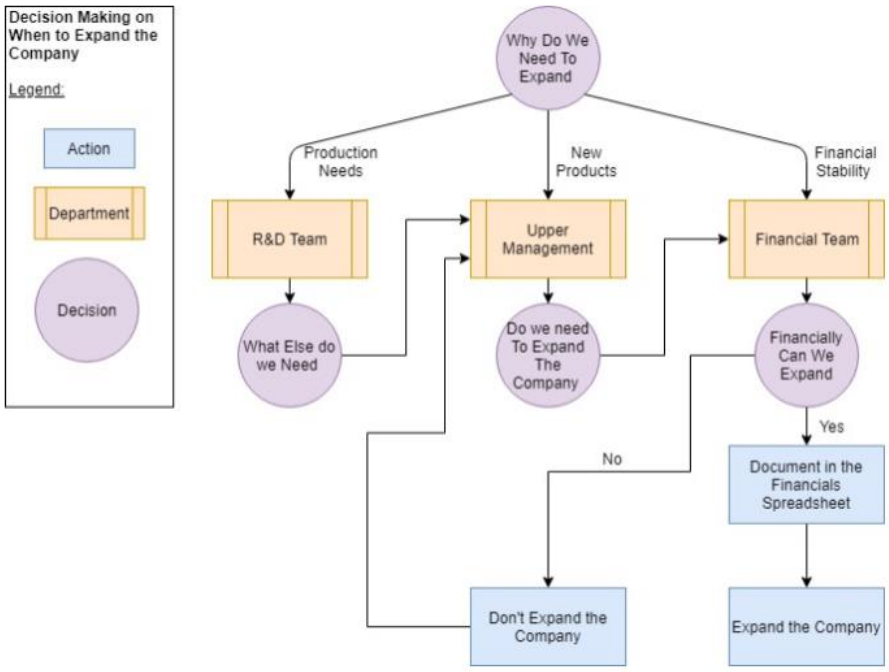


Process Objectives

- Maintain an updated quality manual as processes are edited.
- Edits are controlled.

ADDITIONAL PROCESSES

COMPANY EXPANSION

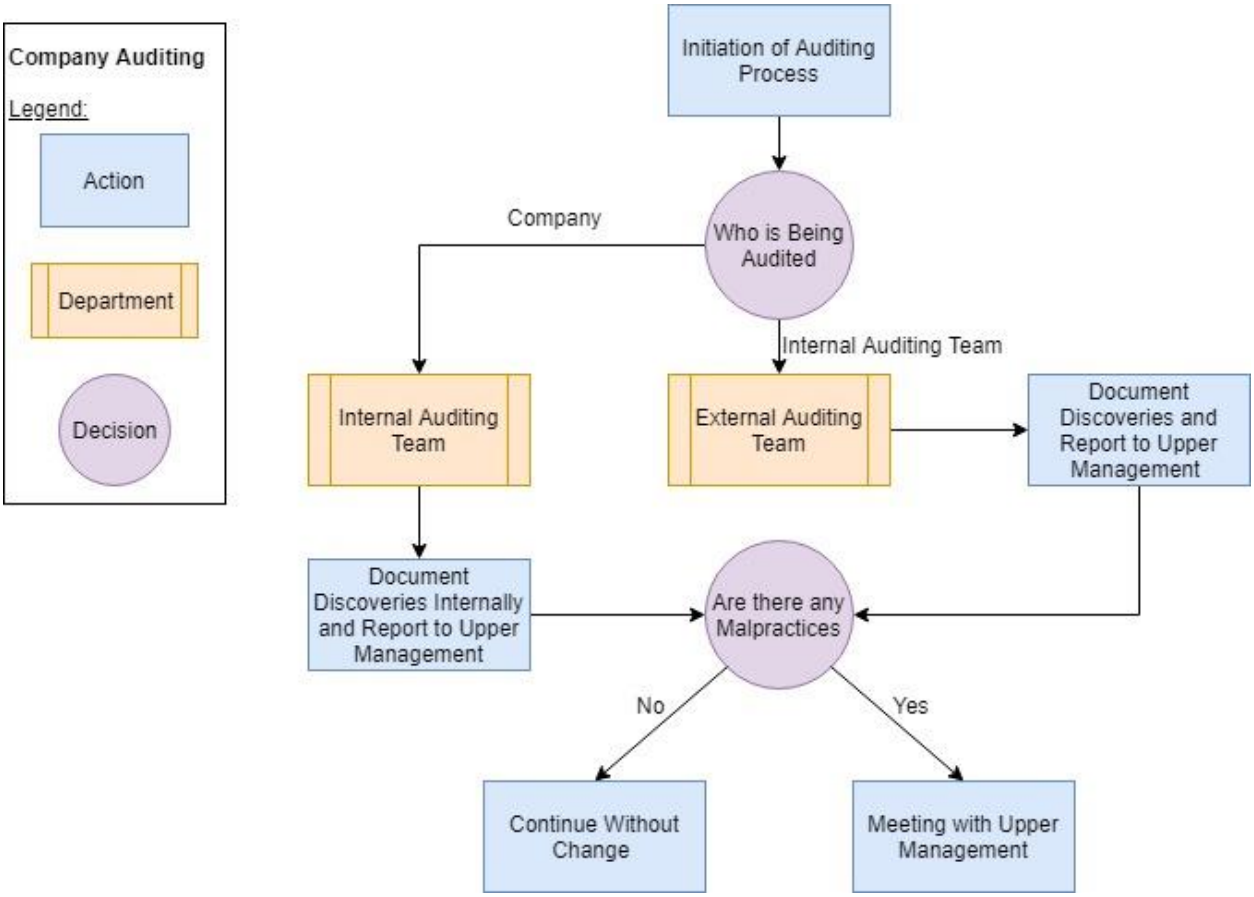


Process Objectives

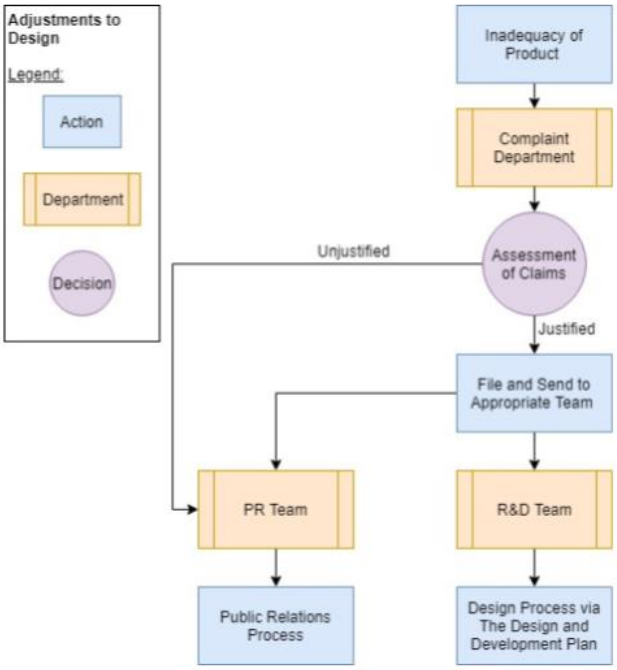
- Awareness of sense of need and ability to expand and grow the company.

COMPANY AUDITING PROCESS

The company performs companywide audits once every quarter. These audits will focus on each specific department intermittently to ease the load of the auditors as well as to ensure the best results. These company process will be done largely by internal auditing teams to ensure that any malpractices can and will by caught and dealt with quickly and within the company before it becomes a larger issue. Any and all audits will be documented and any malpractices that are found will be presented to upper management. The company will also choose to hire an external auditing team to overlook the internal team to ensure there are no malpractices. In the event of any findings involving any member of the upper management, a meeting will occur with the rest of the party and decisions will be made to ensure the best course of action.



DESIGN CONTROLS



Process Objectives

- Address customer dissatisfaction, improving design as necessary.

Address complaints within one week of being received.

DESIGN PLAN

Inputs

The Research and Development team will be responsible for delivering a list of customer needs and performance specifications that is in agreeance with both the Voice of Customer and the System Requirement Specifications.

Design and Development Overview

- **Stage 1:** 6 months beginning January 2019, $150,000
    - Market research and product development
    - Create prototypes from preliminary designs
    - Research glove materials and find distributors/sources for materials
    - Consult neural prosthetic researchers
    - Outputs: approved design, specified component materials
- **Stage 2:** 6 months beginning June 2019, $300,000
    - Finalize design and build functional prototype
    - Testing of functional prototype according to Testing Specifications
        - Must meet functional requirements, including safety and reliability
    - Redesign device as necessary
    - Outputs: functional prototype, testing data
- **Stage 3:** 12 months beginning January 2020, $500,000
    - Design clinical trials
    - Begin candidate search for clinical trials
    - Submit application for FDA approval
    - IRB consent forms and approval
    - Monitor clinical trials
    - Gain medical device approval from FDA
    - Outputs: clinical trial data, FDA approval

Voice of Customer (VOC)
The stakeholders presented in the document include our customers (device users), our company/employees, our distributors, our investors.

Characteristic 1 - Increase independence
For many paraplegic individuals or individuals who have nerve damage that affects their ability to move and use their hands, one of the most important losses is not only mobility, but independence. The goal of the product is to increase independence of the user by enabling them to have better grip strength and finger dexterity to perform tasks of daily living.

Characteristic 2 - Function
Due to weakness and loss of muscle strength of the user, the gloves need to provide the ability to grip objects with greater force as necessary as well as improved dexterity, providing more stability in everyday tasks, from using utensils to gripping exercise equipment.

Characteristic 3 - Longevity
Day to day, the power supply to the product must last for a 24-hour period of time. The lifespan of the product must be at least 10 years (2 years without repairs), and therefore must be a durable product.

Characteristic 4 - Cost
The device should be competitively priced, yet also be reasonable so that it is accessible to customers. Depending on the quality and level of the technology used, current similar products on the marked range from about $30 - $300.

Characteristic 5 - Safety
The mechanical function of the gloves and the toxicity of the materials used must be taken into consideration. No function, material, or component of the glove should harm the user.

Code	VOC Findings	Representative(s)
1. *Users*	*The voice of the users was the result of interviews and surveys completed by potential users of the device.*	
a.	Need for a device that will improve hand function, including grip strength and dexterity, allowing the wearer to better perform activities of daily living (ADLs) an regain independence.	R/D
b.	The power supply to the device must last for a 24-hour period of time, and the lifespan of the device must be at least two years without repairs.	R/D
c.	The device must be competitively priced and be	R/D

	covered by insurance.	
2. Company/Employees	*The voice of the company and its employees was found through surveys of employee candidates and will continue to be evaluated by research conducted by Human Resources.*	
a.	Need for a positive, supportive, and encouraging work environment and company culture.	Human Resources Upper Management
b.	Need for available resources to promote employee well-being, productivity, and creativity.	Human Resources Departments
c.	Need for open communication lines between various departments.	Human Resources
3. Distributors	*The voice of our distributors was found through interviews and negotiations with potential distributors of the product.*	
a.	Need for effective lines of communication between company and distributors.	Upper Management
b.	Need for contract of business relationship and schedule of distributions.	Upper Management
4. Investors	*Voices of investors will be learned through stages of the company development process and business development programs.*	
a.	Need for an innovative and functional idea that is backed by a functional mission management system which will keep the company accountable for its actions and processes.	Upper Management
b.	Need for a passionate team that can lead, innovate, and be disruptive in the marketplace.	Upper Management

System Requirements Specifications (SRS)

1.

A. Function Requirements

1. Grip strength: strength should be 30N.
2. Range of motion: each joint should be able to open to angle of 180 degrees and close to 90 degrees.
3. Speed: The glove should be able to go from open to closed or closed to open in less than 3 seconds.

B. Physical Requirements

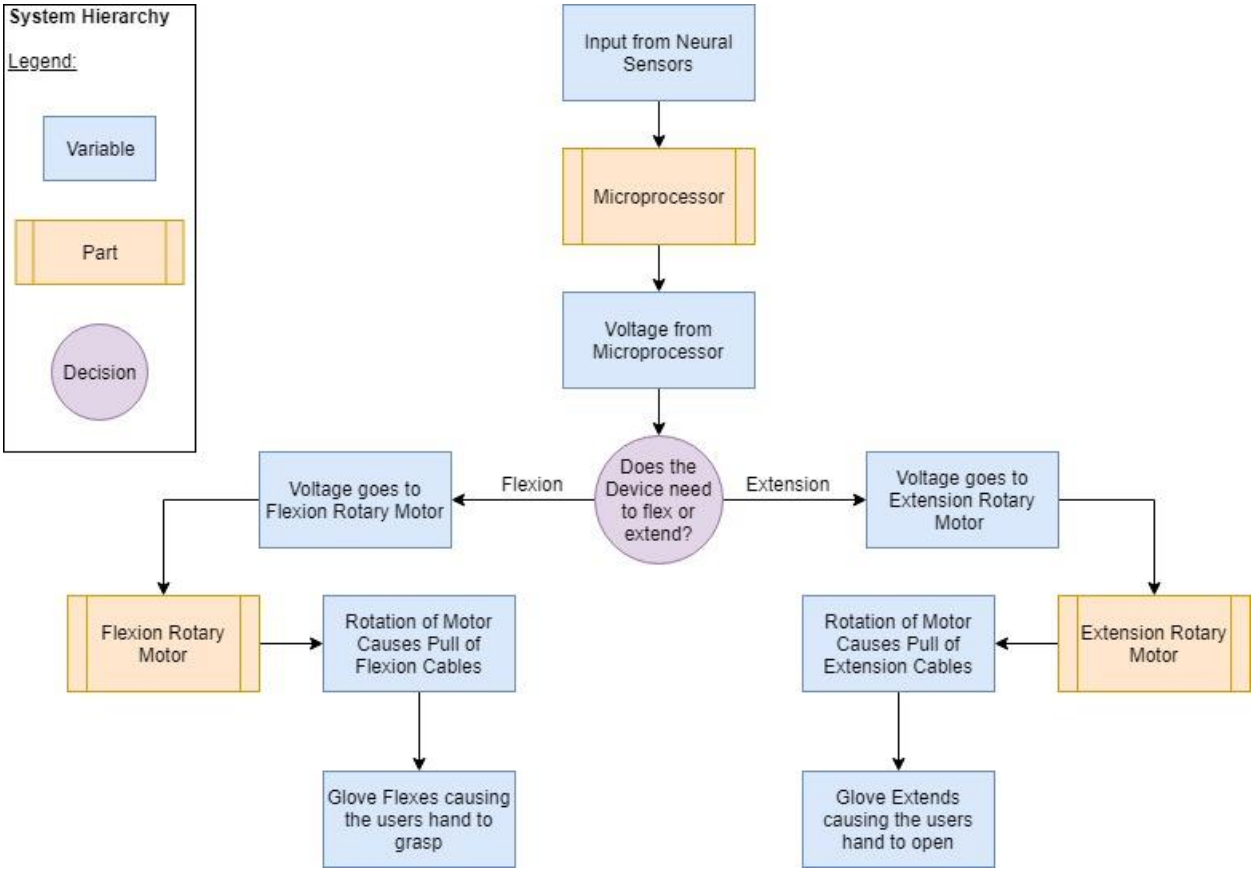
1. Size of customer's hand: device will be within +/- 1/16th of an inch of the customer's hand.
2. Response times: response times will be within 1 second of time signal is received by sensor.
3. Limits of operation
4. ***Safety****:* the product must not endanger the user. Electrical components must be properly insulated.
5. ***Reliability****:* device must a have a reliability score of 0.9 or higher.

C. Interface Requirements

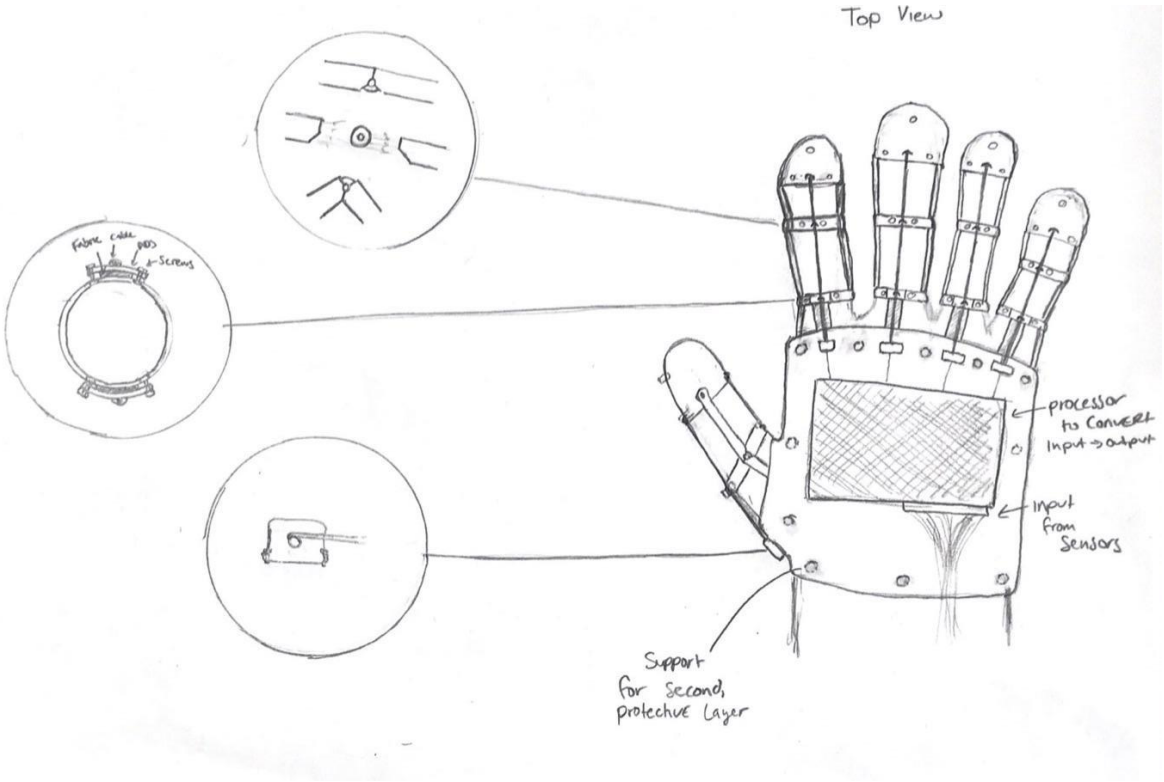
1. Power: Battery that is rechargeable and lasts for at least 24 hours.
2. Resistance: Waterproofing able to be submerged up to 1 meter of depth.
3. Patient interface: No pinching, abrasion, hyperextension, or other harm.

D. System Architecture

See following page.


System Hierarchy
Legend:
Variable
Part
Decision
Input from Neural Sensors
Microprocessor
Voltage from Microprocessor
Does the Device need to flex or extend?
Flexion
Extension
Voltage goes to Flexion Rotary Motor
Voltage goes to Extension Rotary Motor
Flexion Rotary Motor
Rotation of Motor Causes Pull of Flexion Cables
Glove Flexes causing the users hand to grasp
Extension Rotary Motor
Rotation of Motor Causes Pull of Extension Cables
Glove Extends causing the users hand to open

Design Diagram of System Hierarchy



Additional illustrations can be found in the DHF.

E. Software requirements

1. MATLAB coding to take in a range of values from the nervous inputs of the sensors and convert them into values which can be evaluated by motors to move the device.

Testing Specifications

Specification A.1: Grip Strength

The grip strength of the glove should be between 25N and 30N.

Test Protocol A.1:

Equipment:

- Mechanical glove
- Grip force sensor
- Data acquisition device

The grip strength of the glove will be tested by placing the grip sensor in the glove in a rod grip configuration, and the glove will be closed around the grip force sensor until the force reaches a maximum. This process will be repeated 5 times, and the maximum force produced in each test will be recorded and examined to make sure it falls within the acceptable range.

Specification A.2: Range of motion

Each joint of the glove should have a range of motion of between the angles of 90 degrees and 180 degrees. The joints should be unable to move outside that range.

Test Protocol A.2:

Equipment:

- Mechanical Glove
- Angle Sensor
- Data acquisition device

Range of motion testing will be conducted in several environmental extremes. The glove will be cycled through its full range of motion at temperatures of 0, 75, and 120 degrees Fahrenheit, and while fully submerged in 75-degree water. The angle of each joint will be recorded and analyzed to determine if the range was exceeded.

Specification A.3:

The glove must remain safe and operational when being operated while submerged in up to 1m of water.

Testing Protocol A.3:

Equipment:

- Mechanical glove
- Water container
- Electrical sensor
- Data acquisition device

The waterproof testing will be conducted by submerging the glove to a depth of 1 meter, and all of the joints will be operated through their entire range of motion 5 times. Throughout the testing, the environment will be tested to determine if there is any electrical energy being discharged from the glove.

The results of the test will be recorded and a qualitative assessment of the operation of the glove will be made after the submerged testing is complete to ensure that the glove is still fully operational.

Specification A.4:
The glove will cycle from open to closed or from closed to open in between 2 and 3 seconds.

Testing Protocol A.4:
Equipment:

- Mechanical glove
- Angle sensor
- Data acquisition device

The opening and closing period testing will be conducted by measuring the angle over time of the joints during 5 glove openings and 5 glove closings. The amount of time needed for the glove to move from one state to the other in each test will be averaged to ensure that it is within the acceptable range of 2-3 seconds. The results of the test will be recorded and filed appropriately.

Verification and Validation Test Protocols can be found in the DHF.

Stage 1 Detailed Plan

Milestones:

Conduct Market Research

- Inputs
    - Research technology
    - Consultation from somebody with knowledge of the target market
    - Sufficient sample
- Outputs
    - Analysis of collected data
    - Market competition, product differentiation, and product interest information
    - Viability of business/product idea
- Design Activities
    - Market research
    - Data analysis
    - Viability study

Contact Neural Prosthetic Researchers

- Inputs
    - Ability to contact the appropriate researchers
    - List of information that needs to be collected from professionals
- Outputs
    - Information about the feasibility, and necessary components for neural prosthetic technology
- Design Activities
    - Concept Development
    - Research

Create Internal Contracts

- Inputs
    - Corporate lawyer
    - Team members
- Outputs
    - Equity stakes for team members
    - Business license
    - Business contracts between owners
- Design Activities
    - Contract writing
    - Equity distribution
    - Business licensing

Product Modeling

- Inputs
    - CAD software
    - Drawing equipment
    - Product specifications

- Outputs
    - Digital 3D model
    - Drawings and blueprints of design
    - Description of how the design meets the specifications
- Design Activities
    - Digital Modeling
    - Blueprinting creation
    - Specification fulfillment

Determine Materials to Be Used

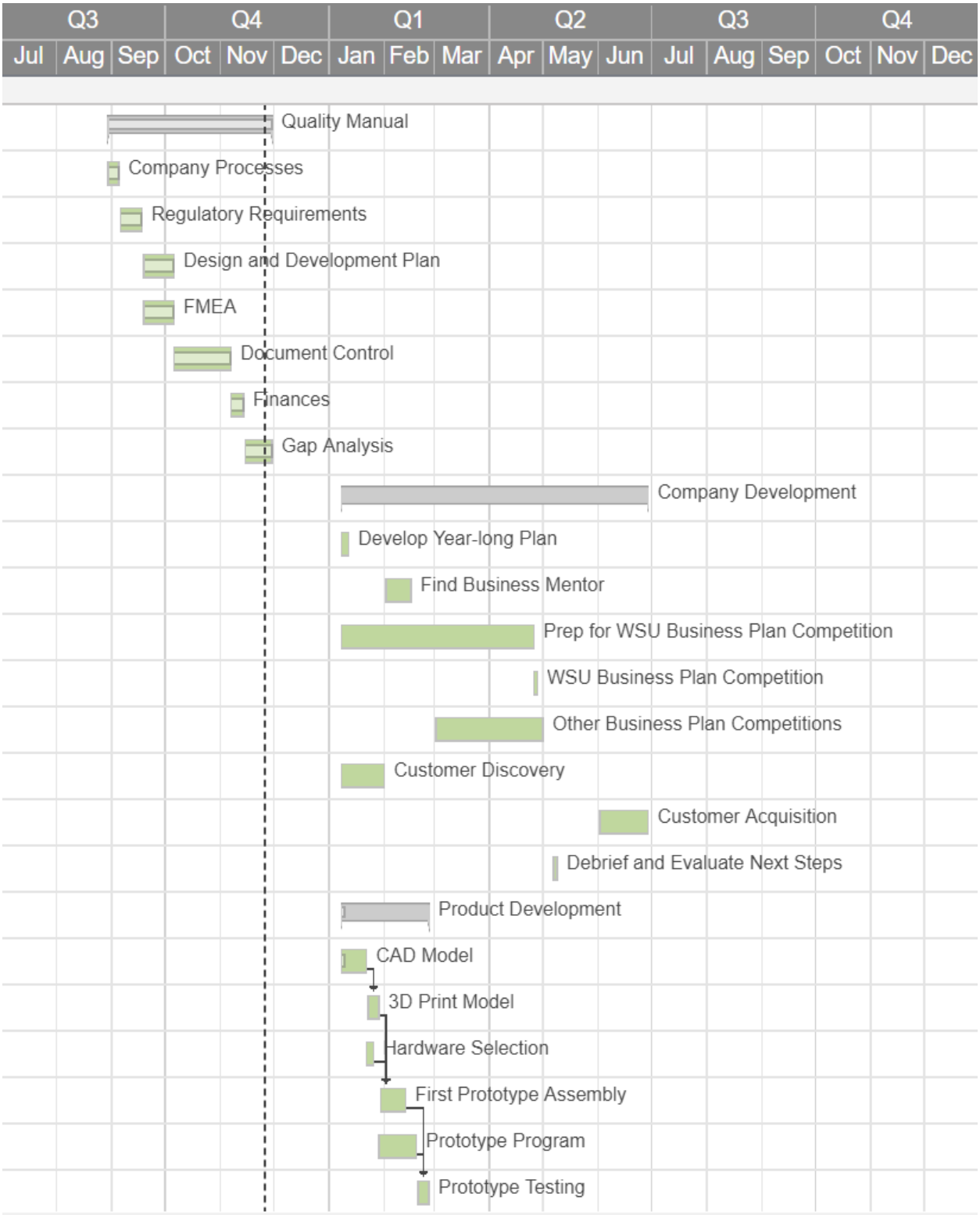
- Inputs
    - List of properties that each component's material needs to exhibit
    - Consultation from somebody in the material science field
- Outputs
    - List of viable materials for each component of the glove
    - Per unit cost of the viable materials
    - Final decision on materials for the first prototype
- Design Activities
    - Material research
    - Material testing

Create Prototype

- Inputs
    - Glove model and designs
    - Materials/parts
    - 3D printer
    - Electrical system production equipment
- Outputs
    - Prototype Grip Glove
    - Prototype control system/program
- Design Activities
    - Product assembly
    - Electronic/program testing
    - Mechanical testing

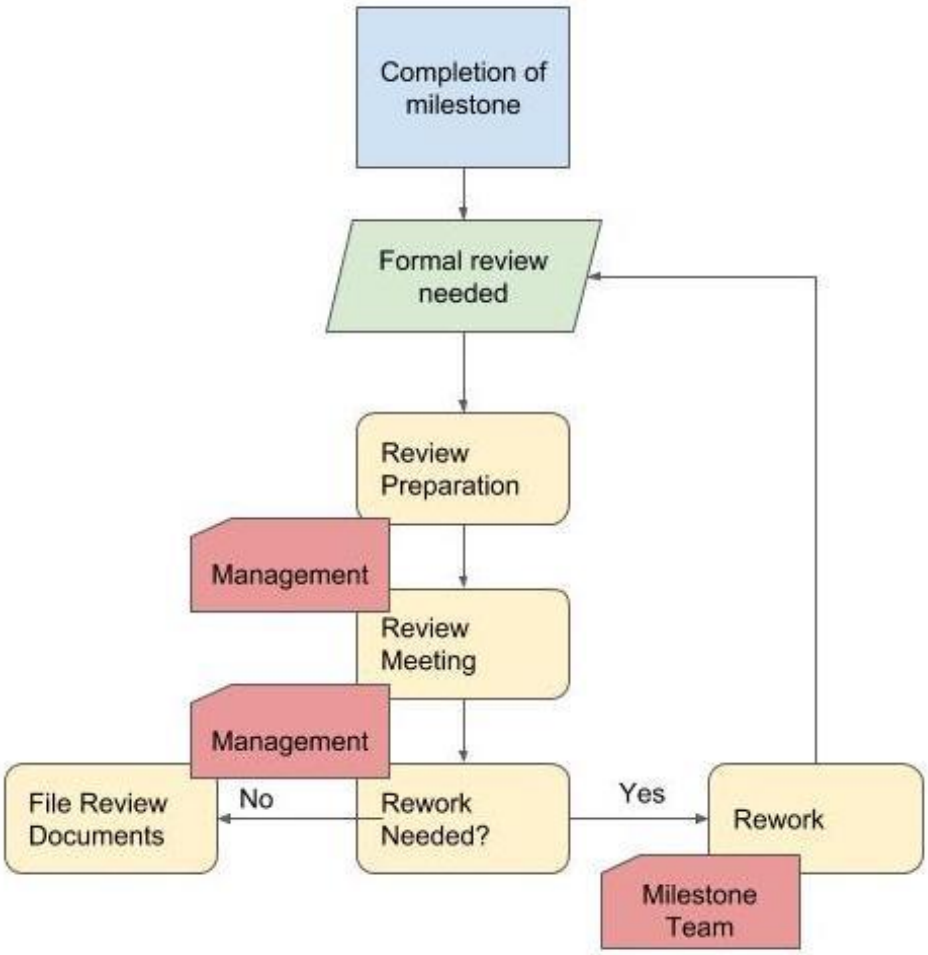
Gantt Chart

Task Name	Start Date	End Date	Duration	Predecessors	% Complete	Status
Quality Manual	**08/29/18**	**11/29/18**	**67d**		**100%**	**In Progress**
Company Processes	08/29/18	09/04/18	5d		100%	Completed
Regulatory Requirements	09/05/18	09/17/18	9d		100%	Completed
Design and Development Plan	09/18/18	10/05/18	14d		100%	Completed
FMEA	09/18/18	10/05/18	14d		100%	Completed
Document Control	10/05/18	11/06/18	23d		100%	Completed
Finances	11/06/18	11/13/18	6d		100%	Completed
Gap Analysis	11/14/18	11/29/18	12d		100%	In Progress
Company Development	**01/07/19**	**06/28/19**	**125d**		**0%**	**In Progress**
Develop Year-long Plan	01/07/19	01/11/19	5d		0%	Not Started
Find Business Mentor	02/01/19	02/15/19	11d		0%	Not Started
Prep for WSU Business Plan Competition	01/07/19	04/25/19	79d		0%	Not Started
WSU Business Plan Competition	04/25/19	04/26/19	2d		0%	Not Started
Other Business Plan Competitions	03/01/19	04/30/19	43d		0%	Not Started
Customer Discovery	01/07/19	01/31/19	19d		0%	Not Started
Customer Acquisition	06/01/19	06/28/19	21d		0%	Not Started
Debrief and Evaluate Next Steps	05/06/19	05/06/19	1d		0%	Not Started
Product Development	**01/07/19**	**02/25/19**	**36d**		**1%**	In Progress
CAD Model	01/07/19	01/21/19	11d		5%	In Progress
3D Print Model	01/22/19	01/28/19	5d	21	0%	Not Started
Hardware Selection	01/21/19	01/25/19	5d		0%	Not Started
First Prototype Assembly	01/29/19	02/12/19	11d	23, 22	0%	Not Started
Prototype Program	01/28/19	02/18/19	16d		0%	Not Started
Prototype Testing	02/19/19	02/25/19	5d	24, 25	0%	Not Started


Q3
Q4
Q1
Q2
Q3
Q4
Jul
Aug
Sep
Oct
Nov
Dec
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
Quality Manual
Company Processes
Regulatory Requirements
Design and Development Plan
FMEA
Document Control
Finances
Gap Analysis
Company Development
Develop Year-long Plan
Find Business Mentor
Prep for WSU Business Plan Competition
WSU Business Plan Competition
Other Business Plan Competitions
Customer Discovery
Customer Acquisition
Debrief and Evaluate Next Steps
Product Development
CAD Model
3D Print Model
Hardware Selection
First Prototype Assembly
Prototype Program
Prototype Testing

Formal Review Protocol

There will be a formal review of the progress at the completion of each milestone listed in this detailed plan. The review will be conducted by management, and will consist of reviews for any discrepancies, defects, or inaccuracies in the completion of the milestone.



CONTROL OF DESIGN DOCUMENTS

As required by the Quality Management System regulations, a system and protocol must be created to control the requirement, approval, revision, availability, storage, and control of documents for the organization.

Required Documents

Upper Management

- Mission Statement
    - Policies
- Company-wide memos
- Contracts
    - With employees, suppliers, clinical trials, etc.

Research and Development

- Technical records
    - Design History File, Device Master Record, Device History Record, and Technical Documentation File
    - Device labeling
- Reports
    - Development plans
    - White papers
    - Test results
    - Personnel/facilities records
- Intellectual Property
    - Patents, trademarks, copyrights
- Interdepartmental memos from R/D management
- Equipment

Accounting

- Order processing
    - Incoming orders
    - Order fulfillment/invoices
    - Supplier transactions
- Inventory
    - Weekly report
- Payroll receipts

Production

- Equipment
    - Manuals, maintenance
- Reports

- Quality inspection
- Errors in production
- Testing summaries

Approval of Documents

Upon generation, documents must be approved before being indexed and stored. All department managers have the authority to approve documents produced in their respective departments. Documents pertaining to upper management, including white papers, must receive initials of approval or receipt from upper level management.

This excludes documents that require committee approval.

Review and Revision of Documents

As outlined in the company processes, certain documents require official review to gain approval, including strategic research plans, development plans, and policy generation. At the conclusion of the committee meetings, all members present must vote to approve the document.

A revision of a current document requires the removal of the old document and marking it as obsolete for record keeping. Upon generation of a revised copy of a document, the new document must still receive the same approval attention as the original.

Maintaining accurate and comprehensive technical documentation files will be prioritized per QMS regulations. When revision occur for technical documents, they must be added/removed from the DMR, DHF, DHR, and TDF as necessary.

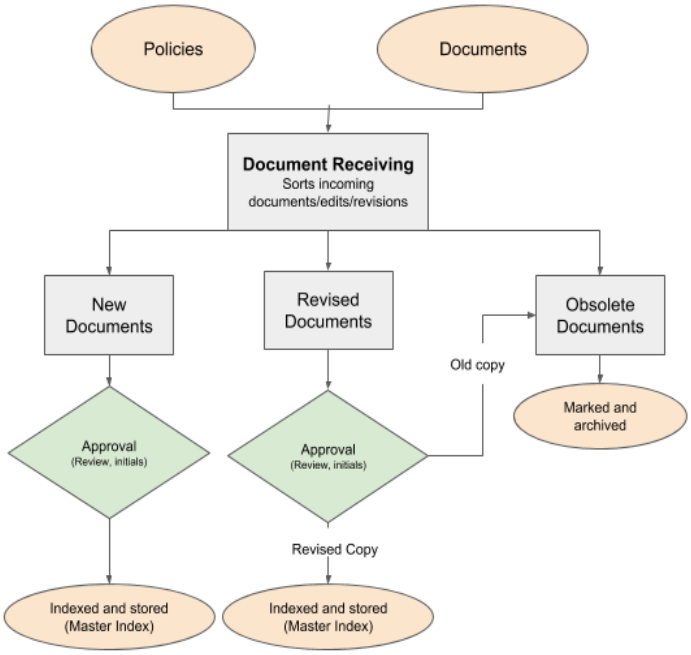
Availability of Documents

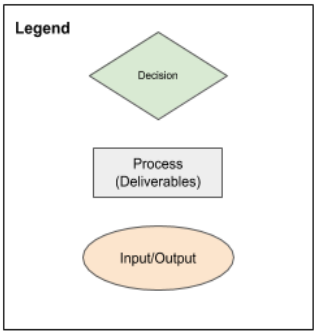
Each document will be associated with a minimum clearance level required for viewing. This level is assigned at the time of generation and approved by the authority initialing the document.

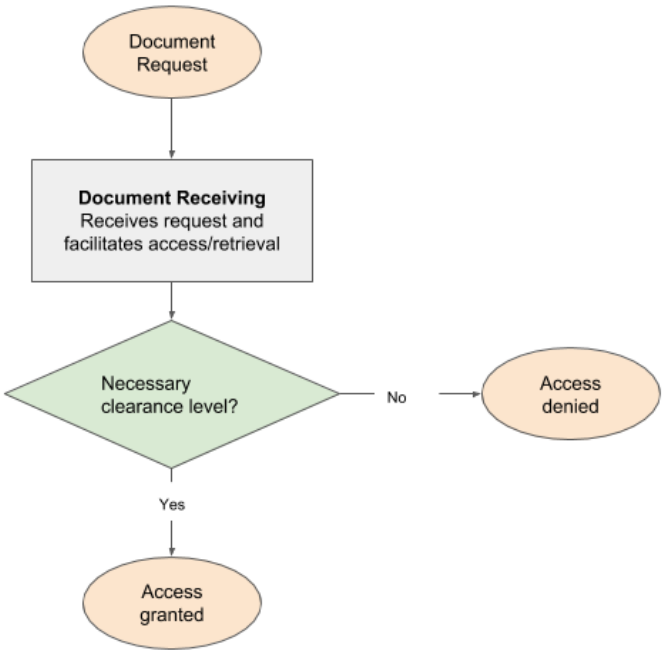
Control of Obsolete Documents

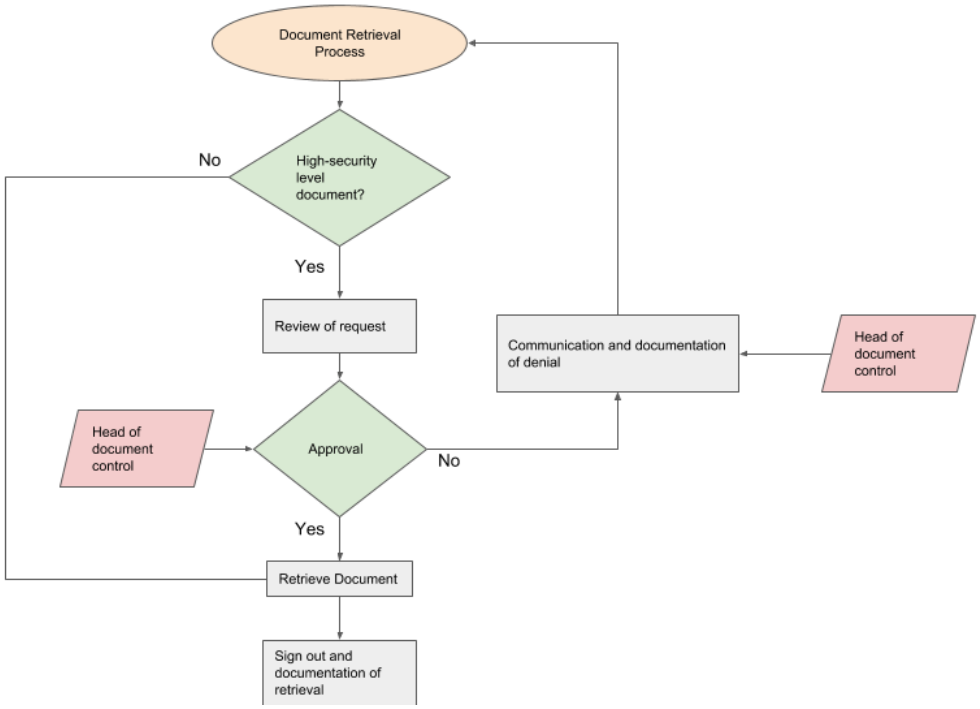
Documents marked as obsolete will be retained in the master record for seven years, unless otherwise noted.

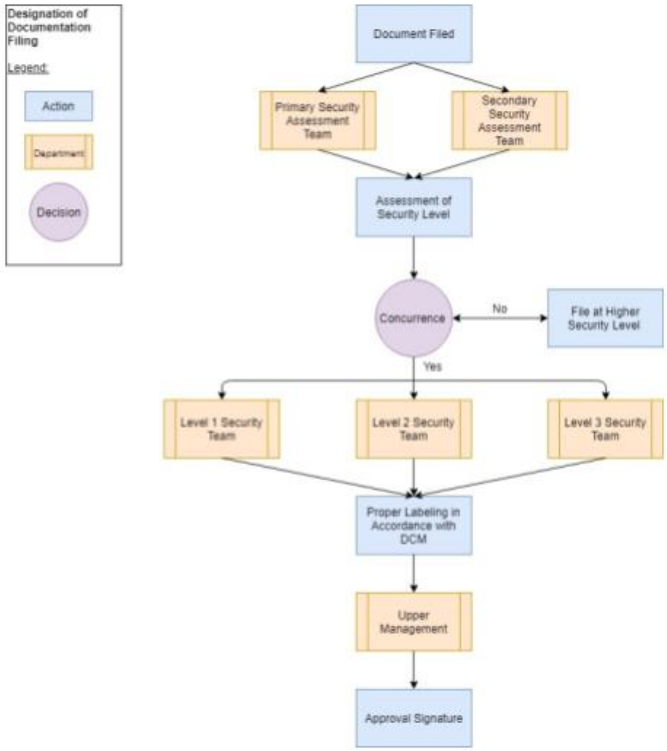
Document Control Processes








Document Retrieval Process
High-security level document?
No
Yes
Review of request
Communication and documentation of denial
Head of document control
Head of document control
Approval
No
Yes
Retrieve Document
Sign out and documentation of retrieval


Designation of Documentation Filing
Legend:
Action
Department
Decision
Document Filed
Primary Security Assessment Team
Secondary Security Assessment Team
Assessment of Security Level
Concurrence
No
File at Higher Security Level
Yes
Level 1 Security Team
Level 2 Security Team
Level 3 Security Team
Proper Labeling in Accordance with DCM
Upper Management
Approval Signature

Document Control Master Index

Index #	Title	Type	Date Generated	Initials	Date of Approval	Storage Location	Security Level
1	Component Stress Testing	Memo	11/28/18	KP	11/28/18	DHF	1
2	Design Review Minutes	Mintues	3/2/19	CT	3/2/19	DHF	1
3	Verication Testing Protocol	Technical Document	10/15/18	CT	10/20/18	DHF	2
4	Validation Testing Protocol	Technical Document	10/15/18	CT	10/20/18	DHF	2
5	Engineering Journal Entry	Journal Entry	2/15/19	CT	2/19/19	DHF	1
6	Production Process Specifications	Technical Document	10/10/18	AC	10/15/18	DMR	2
7	Software Specifications	Technical Document	10/21/18	KP	10/23/18	DMR	2
8	Packaging Specifications	Technical Document	10/13/18	KP	10/17/18	DMR	2
9	Production Record	Production Data	3/31/18	AC	4/1/18	DHR	1
10	FMEA	Technical Document	11/15/18	AC	11/17/18	DHR	2
11	Product Description	Technical Document	11/5/18	KP	11/5/18	TDF	1
12	Design Plans	Technical Document	10/5/18	KP	10/5/18	DHF	2
13	Design Description	Technical Document	11/4/18	KP	11/4/18	TDF	1
14	Instructions for Use	Technical Document	11/4/18	KP	11/4/18	TDF	1
15	Grip Material for Gloves	Memo	12/8/18	KP	12/8/18	DHF	1
16	Design Plan	Drawing	10/10/18	AC	10/1018	DHF	2
17	Acceptance Criteria	Technical Document	10/12/18	AC	10/13/18	DMR	2
18	Supplier Qualification	Production Process	11/12/18	AC	11/10/18	DHF	1
19	Impacts of Design Process	Company Process	11/12/18	AC	11/10/18	IDP	1
20	Labeling of GripGlove	Technical Document	11/2/18	CT	11/10/18	DMR	1

**Clearance level: 1 - All employees; 2 - R/D, Production employees; 3 - R/D, Production management*

Design History File (DHF)

This is the compilation of all the records that describe the history of the design of the finished device.

An official DHF includes the following types of files:

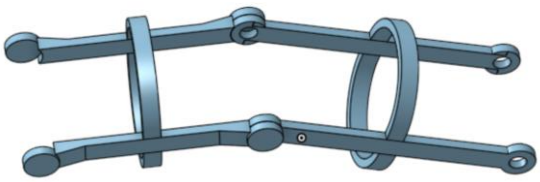
- Design plans
- Review minutes
- Sketches, Drawings, Photos
- Procedures
- Engineers notebooks or journals
- Component qualification information
- Verifications
- Validations
- Protocols for verification and validation

This example DHF includes the following sample documents:

- Memo
- Design Review Minutes
- Procedure for filing a document in the database
- Supplier Qualification
- Verification Testing Protocol
- Validation Testing Protocol
- Design Plans
- Sketches, Drawings, Photos
- Procedures

Design Plans

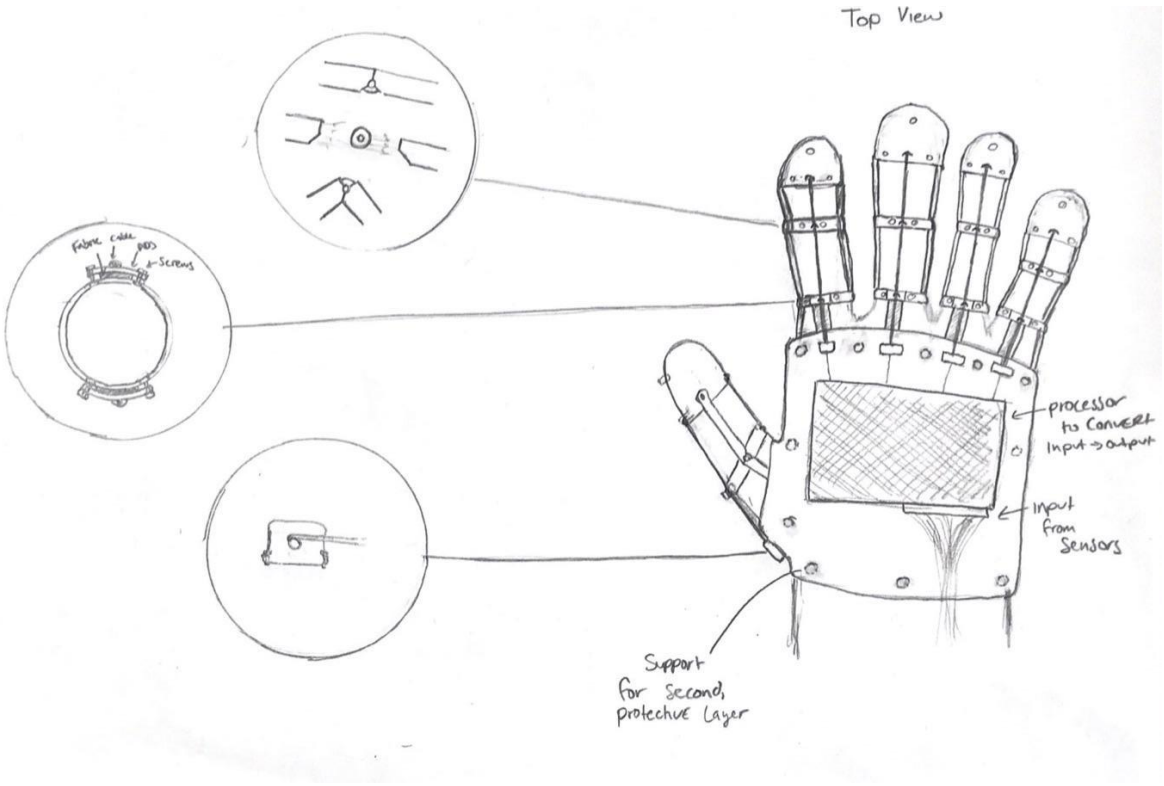
Preliminary Joint Mechanism

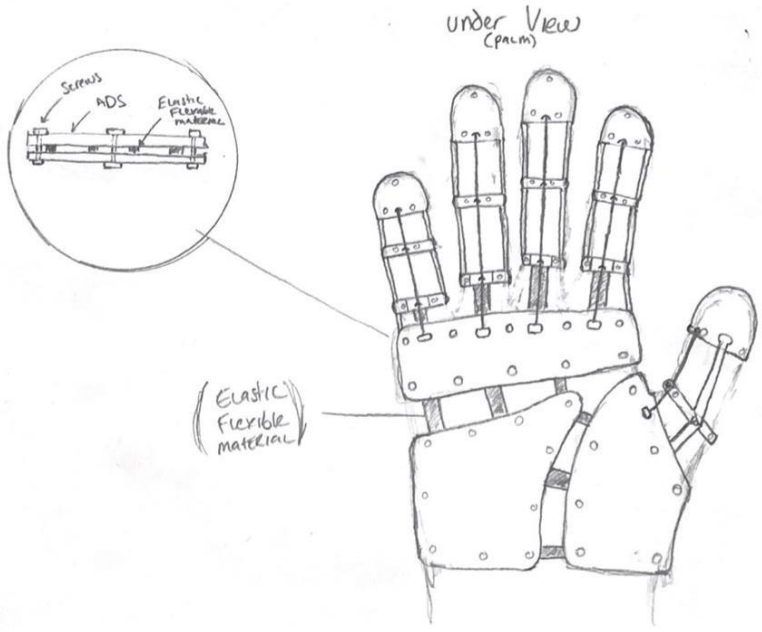


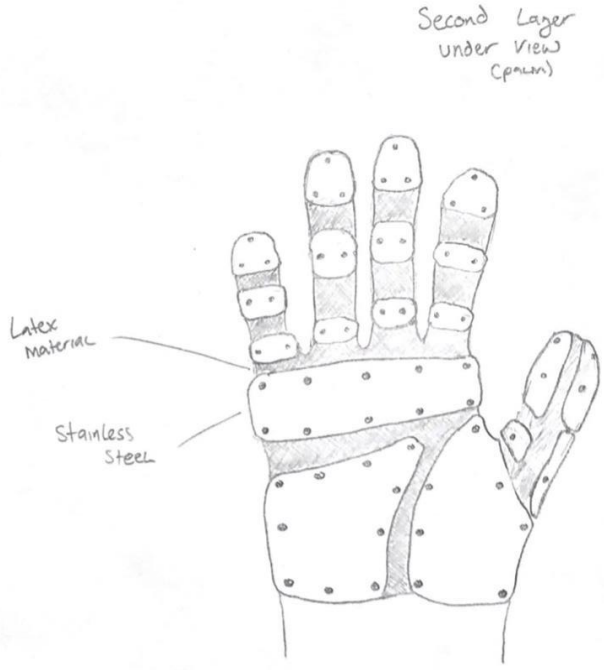
The design of the carpal framework has a built in joint to allow for the movement of the fingers

Device Specifications

Preliminary, First Layer Design Drawings:

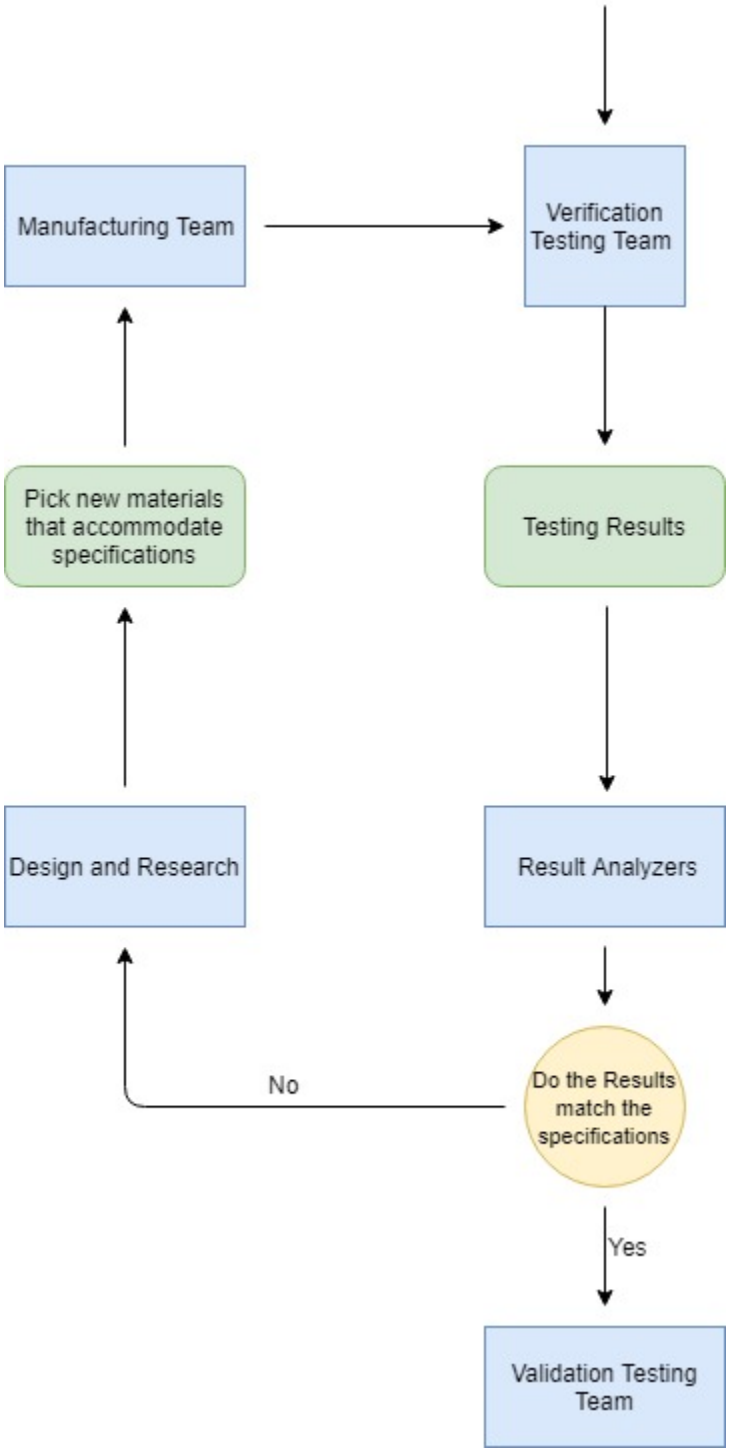



under View
(palm)
Screws
ADS
Elastic Flexible material
(Elastic Flexible material)


Second Layer
under View
(palm)
Latex material
Stainless Steel

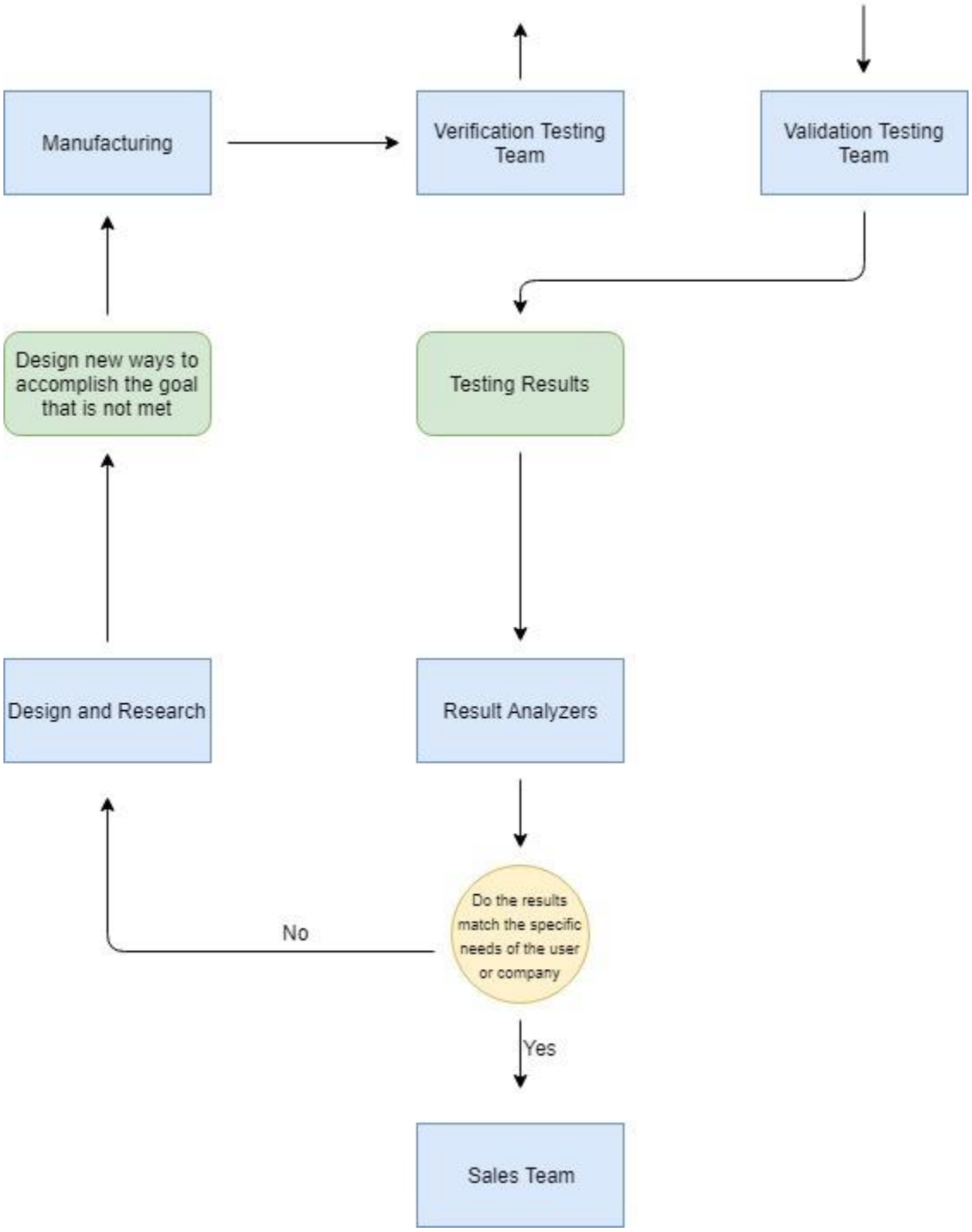
Verification Testing Protocol

- The verification protocol consists of meeting the goals stated in the FMEA below. The verification protocol purely consists of meeting the specification goals stated beforehand in the DDP.
- The verification protocol process can be located at the end of the DHF document.



Validation Testing Protocol

- The validation testing consists of meeting the goals and needs of both the consumer and the company as to the performance and completion of goals presented. The goals and needs of the consumer and company are constantly evolving as the company grows.
- The validation protocol process can be located at the end of the DHF document.



Supplier Qualifications

After the design and testing processes are completed, a list of potential suppliers is created. The suppliers are then evaluated on the quality of their product, their competitive pricing, their specialty in the specific material production, their history in the field and their flexibility with changes in the design. The requirements for the supplier to be considered is that the supply must operate in a legal manner and must abide by all the ISO 9001 qualifications specified below.

Memo

To: Alan Coe, Chandler Teigen

From: Kaitlin Pankratz

Date: 11/28/18

Subject: Component Stress Testing

The stiff "brace" components that make up each segment of each finger on the glove will need to undergo stress testing to determine failure points. We can design a test protocol using the Instron to test the stress and strength properties of our prototypes. We can also use this protocol to test other materials in order to find the most appropriate material for our glove design.

Kaitlin Pankratz

Memo

To: Alan Coe, Chandler Teigen

From: Kaitlin Pankratz

Date: 12/8/18

Subject: Gripping Material for Gloves

The following materials were listed as common materials used for the palms of work gloves, so we should consider these as options for the fingertips and other appropriate parts of our glove to increase the gripping property of the glove.

- Standard nitrile (also called flat nitrile)
- Foam nitrile.
- Micropore nitrile.
- Latex.
- Polyvinyl Chloride (PVC)
- Polyurethane.
- Neoprene.

https://www.superiorglove.com/blog/guide-for-palm-coated-work-gloves

Kaitlin

Design Review Minutes

March 2, 2019
Location: 305 NE Spokane St., Pullman, WA, 99163
Time: 10:00am - 12:00pm

Present:
Alan Coe
Kaitlin Pankratz
Chandler Teigen
Susan Lahey
Floyd Mayweather
Johannes Michelopolis
Edward Witten
Neil deGrasse Tyson

Meeting Chairman: Alan Coe

Meeting called to order at 10:02am. Minutes from February 2nd meeting approved.

Agenda:

Item 1: Introduction

Progress reports from R/D committee, Financial Committee, and Marketing Committee, Sales Committee.

Item 2: Testing procedures performed

Discussed series of tests used for evaluation of current design of the GripGlove. Evaluated testing procedures and determined that they were adequate.

Item 3: Testing results

Discussed results of tests. Need to make adjustments to grip force and release timing. Motion was made for the R/D team to work on the grip force and release timing of the GripGlove, and report back next meeting.

Item 4: Closing remarks

Alan asked if there was any new business, old business, or further discussion. Seeing no further discussion:

Meeting adjourned at 11:55 am

Engineering Journal Entry
Chandler Teigen
2/15/19

DRSQ-1214 9V motor was tested for power consumption, efficiency, dynamic response and torque. The motor fell within the desired range for power consumption, and efficiency, but did not produce torque values that are consistent with the needs of the current design. I sent an email to the manufacturer asking for product suggestions that would retain the desired qualities of the DSRQ-1214 while meeting at least the minimum specifications needed for dynamic response and torque production.

Design Master Record (DMR)

These are the records that specify the finished device, including standard operating procedures and revisions.

An official DMR includes the following documents:

- Device specifications: drawings, material specifications, models.
- Production process specifications, production equipment specs, methods, procedures, production environment specifications.
- Quality assurance procedure and specifications, acceptance criteria, testing equipment specifications.
- Packaging and labeling specifications, methods and processes.
- Usage documents, manuals, installation maintenance, servicing.

This example DMR includes the following sample documents:

- Modeling document: drawing, model, etc.
- Production process specification
- Acceptance criteria for production process
- Packaging specification

Software (MATLAB Coding)

- Software analyzes the input of the neural activity from the brain and produces a voltage to powers the rotational movement of the motors.
- The software has a proportional output to the given input so that a higher neural activity will result in the motors rotating more quickly.
- The software manipulates the motors to either extend or contract the user's carpals.

Production Process Specifications

- The production of the gloves is divided into four essential processes. The production includes the manufacturing of the rotational motor, the cables to clench and release the carpals, the rings and the supporting framework that will be fit to the user to secure the carpals, and the glove which is placed over the user's hand.
    - The production of the rotational motors has a stainless-steel housing to protect the more fragile interior from heat, water and corrosion. On the inside of the motor there is a microprocessor to convert the neural signals of the sensors to an acceptable voltage output which is sent to the rotational component of the motor.
    - The production of the cable is made by the weaving of stainless steel microfibers. This material was chosen for its high durability and resistance to corrosion.
    - The rings are produced using a 3D printer which uses Acrylonitrile Butadiene Styrene. This material is used due to its high durability, heat resistivity and its low cost. The part is 3D printed to insure an easy way to mass manufacture with high customization properties.
    - The gloves are produced with nylon fabrics which will be loosely fit to the 3D printed framework to provide stability to the product and provide the user with comfort against frictional stresses.

Acceptance Criteria

- After production of the device, it will be sent to the quality control division to be put through a rigorous inspection before being shipping to the customer. After the inspection of the device is complete, the Quality Assurance Manager will sign off that the inspection was passed, and the device will be marked for distribution.

- Inspection Criteria:
    - The device will be checked for material defects, or other potentially harmful physical problems.
    - The device is functioning within the design specifications.
    - The device is ready for packaging and distribution from a cleanliness and presentation standpoint.
    - The separate pieces of the device are securely attached in the intended fashion.

Packaging Specifications

- Packaging is made of two distinct materials to both guard from physical damage and moving of the product which provides a means for delivery and storage.
    - The outer layer is made of high carbonated steel to provide protections from dropping, fire and water damage.
    - The inner layer is composed of polyethylene which will surround the product to insure rigidity through transit.
- Packaged product must be labeled with the appropriate information
    - Name of company and location
    - Recipient information
    - Product name followed by identification number
    - Instruction on how to handle
- Multiple products will ship together
- All processed packages must be documented

Device History Record (DHR)

This is the production record for a specific device and must be traceable to a DMR that describes the build specifications for each specific device.

Production record includes:

- Dates of manufacture
- Quantity
- Quantity released for distribution
- Acceptance records
- Identification labeling for each production run
- Any device ID or control numbers

Production Record

Product	Manufacture Date	Quantity	# Distributed	# Accepted	Serial/Control# of Batch
GripGlove SRH	3/15/19	8	5	5	031-1234
GripGlove MRH	3/23/19	20	15	13	023-4322
GripGlove LRH	3/30/19	12	7	7	942-9582
GripGlove SLH	3/15/19	15	15	12	547-2892
GripGlove MLH	3/24/19	9	8	8	257-3498
GripGlove LLH	3/30/19	24	18	18	248-9033

Technical Documentation File (TDF)

The TDF must be kept for 10 years and contains all the relevant design data that demonstrates that safety requirements were met as formulated in the MDD.

This TDF contains the following records:

- Description of the product
- Design description (drawings, methods of manufacture)
- Results of risk analysis and list of applicable standards and solutions (FMEA)
- Description of the sterile methods used in packaging
- Results of design calculations and modeling
- Results showing it can interface properly to the external environment (biocompatibility)
- Test reports and clinical data
- Labels and instruction for use

This sample TDF includes the following sample documents:

- Product description
- Labeling
- Instructions for use
- FMEA Analysis
- Impact on Design Process

Description of the Product

The device is a glove fitted with segmented braces along the fingers, which mechanically bend when prompted by the user's neural signals, allowing the user to grip objects and achieve finer motor movements than they may be able to perform naturally.

Design Description

The GripGloves have several different components including plastic and stainless steel for the main structural components. These components are connected by elastic material to provide support and flexibility to the gaps between the rigid components. There is an onboard microcontroller that will receive input from the sensors on the forearm and send the output signals to the motors in the glove. The signals control small electric motors which control the extension and flexion of the GripGlove fingers by applying tension to cables attached to the joints of the fingers.

Labeling

The GripGlove product has been designed and manufactured to provide extra grip strength and hand mobility to users who have lessened hand function. The GripGlove can be easily put on and removed whenever grip assistance is needed.

The following warnings must be taken into consideration when using the GripGlove product:

- Use of an incorrect size, orientation, or any other usage beyond what is intended and outlined in the instruction manual could result in injury.
- Grip strength is not guaranteed to be sufficient for activities that are far beyond everyday gripping needs.
- Crushing, perforation, or other physical damage to the battery compartment could result in electric shock, chemical burns or other injury.
- The GripGlove product is not intended to completely replace hand and finger function. Unaided hand usage and physical therapy is recommended in conjunction with use.
- Recommended to seek the advice of a medical professional before use.

Instructions for Use

- The user will put on the gloves as a normal set of gloves and attach the muscle sensors to the locations on the forearm specified in the instruction manual diagram. The gloves are powered by battery and will be controlled by the user's nerve activity in their arms, so they will only need to toggle the power switch and attempt to grip the object for the gloves to begin working.

Potential Failure Mode and Effects Analysis in Design (Robust Design FMEA)

Project Number: 1		**Product Number: 1**			**FMEA Number: 1**										
Project Name: Mechanical Grip Gloves		**Product Name: GripGloves**			**Rev: 0**										
No.	Item/Function	Potential Failure Mode	Potential Effects of Failure	Potential Causes of Failure	SEV	OCC	DET	Class	Current Mitigations	Verification	Recommended Actions	S	L	C	RPN
1	Grip Gloves - Mechanical operation of fingers	Won't close	Device inoperable	manufacturing problem	1	5	10	50	experimental studies	Device Closes Normally	Extensive Testing	1	3	5	15
2		Won't open - faulty release mechanism	Device inoperable	manufacturing problem	8	5	8	320	experimental studies	Device Opens Normally	Manual Release Mechanism	4	3	5	60
3	Appropriate fit for user	Fits too tight	cut-off circulation to hand	Fabrication Errors	5	2	10	100	wear studies	Device Fits Comfortably	Custom Sizing	1	1	2	2
4		Fits too Loose	Device May slip off	Fabrication Errors	3	2	10	60	wear studies	Device Fits Comfortably	Custom Sizing	1	1	2	2
5	Material of glove	Wears too quickly	Shortened life of product	Cheap Material	1	7	3	21	material studies	Device Lasts for Over Two Years	Spend the Money to Buy Adequate Materials	1	5	3	15
6		Material is toxic to surrounding tissues	Harm to user	Improper Research of Material Being Used	9	2	7	126	material studies	Device Does Not Cause the User to show signs of toxicity	Research Toxic Materials and Patients Toxicities	2	2	4	16
7		Does not dissipate heat well	Discomfort to user	Inappropriate material choice	4	7	4	112	material studies	Device dissipates heat and does not cause discomfort to user	Research heat-dissipating or breatheable materials	2	4	3	24
8	Nerve impulse activation	Activation failure	Device inoperable	Calibration to User	1	9	6	54	physioloogy/neurology/electrical/muscle studies	Device Functions Normally	Calibrate Sensitivities	1	5	5	25
9		Over Activation	Device is over active	Calibration to User	5	9	8	360	physioloogy/neurology/electrical/muscle studies	Device Functions Normally	Calibrate Sensitivities	3	6	4	72
10	Grip	Grip strength is not adequate	Device does not work according to intended purpose	Miscalculations	2	6	9	108	experimental studies/ force studies	Grip Strength is Adeqate	Adjustable Strengths	2	3	4	24
11		Grip strength is too strong	Device may harm the user	Miscalculations	9	6	9	486	experimental studies/ force studies	Grip Strength is Adeqate	Adjustable Strengths	4	3	4	48
12	Electrical leak	Stripped Wire	May shock user	Manufacturing/ wear and tear	6	3	9	162	quality control	Voltages at Normal Levels and and No Electrical Shocks	Enclose Electrical Wires Within the Casing	2	2	1	4
13	Movement	Involventary Movement	Device Unreliabilty	Calibration Error	7	7	10	490	experimental studies/ parameter design	Device Functions Normally	Recalibrate the Nerve impulses	2	3	5	30
14		Opens Too Wide	Breaks Fingers	Range of Movement Too Large	10	3	10	300	experimental studies/ parameter design	Device has a Normal Range of Movement	Put in Safegaurds to Mechanically stop Over Extension	4	3	3	36
15		Closes Too Tight	Harms User	Range of Movement Too Large	10	3	9	270	experimental studies/ parameter design	Device has a Normal Range of Movement	Put in Safegaurds to Mechanically stop Over Flexion	4	3	3	36
16		Closes Too Fast	Inability to Control Grip	Speed of Motors Too Quick	8	3	6	144	experimental studies/ parameter design	Device Opens At Correct Speed	Pick Variable Speed Motors	2	3	3	18
17		Closes Too Slow	Inability to Complete Tasks	Speed of Motors Too Slow	2	3	8	48	experimental studies/ parameter design	Device Opens At Correct Speed	Pick Variable Speed Motors	3	3	4	36
18	Battery	Battery Life too Short	Device Becomes Inactive	Cheap Material	1	8	9	72	functional design, components studies/research	Battery Can Last a Full Day of Avtivity	Spend the Money to Buy Adequate Materials	1	5	4	20
19		Battery Overheats	May Harm User	Cheap Material	5	6	10	300	functional design, components studies/research	Battery Does Not Overheat	Spend the Money to Buy Adequate Materials	3	4	4	48
20	Alignment	Mechanical Joints Dont Allign to Physical Joints	Break Fingers	Improper Design	10	4	10	400	experimental studies, functional design	Mechanical Joints Allign Over the Physical Joints	Cutom Sizing	3	3	3	27
21		Overlapping of Fingers	Break Fingers	Improper Design	10	3	10	300	experimental studies, functional design	Fingers Can Open and Close Without Overlapping	Extensive Research and Development	3	3	3	27

Impact on Design Process

When conducting new design processes, the new goals must not impede the goals established beforehand. As the product continues to grow and evolve the designers must always keep the mission statement of the company in mind. In the design process, all ideas must be heard and given due process of evaluation. The design team may grow or shrink dependent on the needs at hand and the performance exhibited by the individual. The design team will always look to progress the product and hold the company's best interests in mind.

LIST OF REGULATIONS

FDA Regulations

Section Name		US Code Section #
U.S.C. SUBCHAPTER III -- Prohibited Acts and Penalties		
Prohibited acts		331
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Penalties		333
Seizure		334
Hearing before report of criminal violation		335
Debarment, temporary denial of approval, and suspension		335a
Civil penalties		335b
Report of minor violations		336
Proceedings in name of United States; provisions to subpoenas		337
Extraterritorial jurisdiction		337a
SUBCHAPTER V		
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Misbranded Drugs and Devices		352
Exemptions and consideration for certain drugs, devices, and biological products		353
Risk evaluation and mitigation strategies		355-1
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ASTM Standards

ASTM Standard #	Title
E102-14	Standard Practice for Verification of Testing Frame and Specimen Alignment Under Tensile and Compressive Axial Force Application
F3127-16	Standard Guide for Validating Cleaning Processes Used During the Manufacture of Medical Devices
F594-09(2015)	Standard Specifications for Stainless Steel Nuts
G190-15	Standard Guide for Developing and Selecting Wear Tests
G98-17	Standard Test Method for Galling Resistance of Materials

ISO 9001 Regulations

Code Index Identifier	Description
ISO 9001	
4.1	The standard requires the organization to implement and maintain a quality management system in accordance with the requirements of ISO 9001. This includes insurance of control of any outsourced processes that affect product conformity with requirements and to identify such control within the QMS.

4.1a	The standard requires the organization to identify the processes needed for the quality management system and their application throughout the organization.
4.1b	The standard requires the organization to determine the sequence and interaction of the identified processes.
4.1c	The standard requires the organization to determine criteria and methods required to ensure the effective operation and control of the identified processes.
4.1e	The standard requires the organization to measure, monitor and analyze the identified processes.
4.1,4.2.1	The standard requires the organization to document a QMS in accordance with the requirements of ISO 9001.
4.2.1b	The standard requires a quality manual to be established and maintained that includes the scope of the QMS, the documented procedures or reference to them and a description of the sequence and interaction of processes included in the QMS.
4.2.1c	The standard requires the management system documentation to include documented procedure required by ISO 9001. These include: Document control, the control of record, conducting audits, non-conformity control, corrective action and preventative action.
4.2.1d	The standard requires management system documentation to include documents required by the organization to ensure the effective planning, operation and control of its processes.
4.2.2	The standard requires the quality manual to include the scope of the QMS including details of justification for any exclusion. The quality manual is to include the documented procedure established for the QMS or reference to them. The quality manual is to include a description of the interaction between the processes of the QMS.
4.2.3	The standard requires documents required by the QMS to be controlled. This includes a documented procedure to be established to define the controls needed.
4.2.3a	The standard requires the documents be approved for adequacy prior to issue.

4.2.3b	The standard requires that documents be reviewed and updated as necessary and re-approved following their review.
4.3.3c	The standard requires that changes to documents and the current revision status of documents to be identified.
4.2.3d	The standard requires that relevant versions of applicable documents are available at points of use.
4.2.3e	The standard requires documents to remain legible and readily identifiable.
4.2.3g	The standard requires the unintended use of obsolete documents to be prevented and a suitable identification to be applied to obsolete documents retained for any purpose.
5.1	Top management must provide evidence of its commitment to the development and implementation of the QMS and continually improving its effectiveness
5.1b	The standard requires that top management establish the quality policy.
5.1c	The standard requires that top management ensure that quality objectives are established.
5.1d	The standard requires that top management conduct management reviews.
5.2b	The standard requires customer requirements to be met with the aim of enhancing customer satisfaction.
5.3c	The standard requires the quality policy to provide a framework for establishing and reviewing quality objectives.
5.4.1	The standard requires that top management ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization.
5.51a	The standard requires that the responsibilities and authority be defined.
6.2.2b	The standard requires the organization to provide training or take other actions to satisfy these needs.
6.2.2c	The standard requires the organization to evaluate the effectiveness of the actions taken.

6.3	The standard requires the organization to determine, provide and maintain the infrastructure needed to achieve conformity to product requirements.
6.4	The standard requires the organization to identify and manage the work environment needed to achieve conformity of product.
7.1	The standard requires the organization to plan and develop the processes required for product realization consistent with the other requirements of the QMS. The product realization planning must be in a form suitable for the organization's method of operations.
7.1a	The standard requires the organization to determine the quality objectives and requirements for the product.
7.1b	The standard requires the organization to determine the need to establish documents specific to the product.
7.1.b-2	The standard requires the organization to provide resources specific to the product.
7.1c	The standard requires the organization to determine the required verification, validation, monitoring, inspection and test activities specific to the product.
7.1c2	The standard requires the organization to determine the criteria for product acceptance.
7.1d	The standard requires the organization to determine the records needed to provide evidence that the realization processes and resulting product meet requirements.
7.2.1a	The standard requires the organization to determine requirements specified by the customer including requirements for delivery and post-delivery activities.
7.2.1b	The standard requires the organization to determine product requirements not specified by the customer but necessary for known intended use.
7.2.1c	The standard requires the organization to determine statutory and regulatory requirements related to the product
7.2.1d	The standard requires the organization to specify additional requirements determined by the organization.

7.2.2b	The standard requires the review to ensure that contract or order requirements differing from those previously expressed are resolved.
7.3.1	The standard requires the organization to control design and development of the product. This includes the requirement to plan design and development of the product. Interfaces between different groups involved in design and development are to be managed to ensure effective communication and clarity of responsibilities. Planning output is to be updated as appropriate as the design and development progresses.
7.3.1a	The standard requires the stages of design and development to be determined.
7.3.1b	The standard requires the review, verification and validation activities appropriate to each design and development stage to be determined.
7.3.1c	The standard requires the responsibilities and authorities for design and development activities to be determined.
7.3.2a	The standard requires design inputs to include functional and performance requirements.
7.3.2b	The standard requires design inputs to include applicable statutory and regulatory requirements.
7.3.3	The standard requires that the outputs of design and development be provided in a form that enables verification against the design and development inputs. Outputs are to be approved prior to release.
7.3.3a	The standard requires that design and development output meet the input requirements.
7.3.3d	The standard requires design and development output to define the characteristics of the product that are essential to its safe and proper use.
7.3.4a and b	The standard requires design reviews to be conducted to evaluate the ability of the results of the design and development to fulfill requirements, identify problems and propose required actions.

7.3.5	The standard requires design and development verification to be performed in accordance with planned arrangements to ensure the output meets the design and development inputs. The results of the verification and any required actions are to be recorded.
7.3.6	The standard requires design and development validation to be performed in accordance with planned arrangements to confirm that resulting product is capable of fulfilling the requirements for the specified application or intended use where known. Validation is to be completed wherever applicable prior to the delivery or implementation of the product. Results of the validation and subsequent follow-up actions are to be recorded.
7.3.7	The standard requires design and development changes to be identified and records maintained. Changes are required to be verified and validated as appropriate before implementation. Changes are required to be reviewed and approved before implementation, including the evaluation of the effect of changes on constituent parts and delivered product.
7.5.1f	The standard requires the implementation of release, delivery, and post-delivery activities.
7.5.3	The standard requires the organization to identify the status of the product with respect to measurement and monitoring requirements.
7.5.3.2	The standard requires the organization to control and record the unique identification of the product, where traceability is a requirement.
7.5.5	The standard requires the organization to preserve conformity of product during internal processing and delivery to the intended destination including identification, handling, packaging, storage and protection.
7.6a	The standard requires the organization to identify the measuring and monitoring devices needed to provide evidence of conformity of product to determined requirements.
7.6b	The standard requires processes to be established to ensure that monitoring and measuring can be carried out and are carried out in a manner consistent with the measuring and monitoring requirements.

7.6c	The standard requires measuring and monitoring device to be calibrated or verified at specified intervals or prior to use, against measurement standards traceable to international or national standards.
7.6.2	The standard requires records of the results of calibration and verification to be maintained.
7.6.3	The standard requires confirmation of the ability of software used for measuring and monitoring of specified requirements to satisfy intended application to be undertaken prior to initial use and reconfirmed as necessary.
8.1	The standard requires the organization to plan and implement the monitoring, measurement, analysis and improvement processes needed to demonstrate conformity of the product including determination of applicable methods such as statistical techniques and the extent of their use.
8.2.1	The standard requires the organization to monitor information relating to customer perception as to whether the organization has met customer requirements and requires the methods of obtaining and using this information to be determined.
8.2.2a	The standard requires the organization to conduct internal audits at planned intervals to determine whether the quality management system conforms to the planned arrangements and to the requirement of this International Standard.
8.2.2b	The standard requires the organization to conduct internal audits at planned intervals to determine whether the quality management system is effectively implemented and maintained.
8.3a	The standard requires the organization when appropriate to deal with nonconforming product by taking action to eliminate the detected nonconformity.
8.4a	The standard requires analysis of data to provide information relating to customer satisfaction.
8.4b	The standard requires analysis of data to provide information relating conformity to product requirements.

8.5.2	The standard requires the organization to take action to eliminate the cause of nonconformities in order to prevent recurrence and requires the actions to be appropriate to the effects of the nonconformities encountered.
8.5.3	The standard requires the organization to determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence and for such actions to be appropriate to the effects of the potential problems.

FINANCIALS

Financial Assumptions

General:

- We will be purchasing a Fusion3 F400-S 3D printer and will be using the information from this for the information below.
- We will not take a payroll from the company until year two where we will begin to take a 50% of the net profit for payroll to employees.
- We could not find a specific lifespan for the 3D printer in which we purchased so we are making the assumption that it will last 3 years until we would need to buy another or else upgrade to a better machine.
- We would need a loan of 20,000 dollars for an initial loan to pay for our overhead with an 8% interest rate.
- In year 2 we will hire one more employee to act as our sales representative.
- We will be using a Myoware Muscle Sensor to measure the muscle activation which will then be our input into our microprocessor to activate the Grip Gloves. The cost of one Muscle sensor will be around 40 dollars
- We estimated that a microprocessor and circuit board will be around 10 dollars to buy.

Specifics:

Salaries and wages:

- The Company will be composed of the three original engineers and will be a side job until the company takes off.

Employee Benefits:

- Since our only employees will be the start-up group we have chosen not to collect benefits until the company takes off.
- In year 2 we will give our sales employee health coverage which is on average 440 dollars a month

Payroll Taxes:

- Since we are putting any profits back into the company for the starting period we will not have a payroll therefore we will not have any payroll taxes.

Professional Services:

- Accounting, law services later on

Marketing and Advertising:

- We will target hospitals, rehabilitation facilities, occupational therapists, and caretakers, who will be in contact with patients. We will also have website development, social media presence and commercials.

Rent:

- Garage workshop space (houses our 3D printer)

Equipment and Material:

- We will buy a high end professional 3D printer upfront in January for 3,500 dollars

- We are assuming that we can buy 10 lbs. of material for 150 dollars. Each product will be composed of a pound of ABS material.
- By Jan 2020 we will buy another 3D printer and in Aug 2020 we will buy a 3rd 3D printer.

Maintenance:

- 3D printer comes with a two-year warranty, so anything needed within this time will be covered by the manufacturer of the printer.
- We will have a 1-year warranty on our product. If the product breaks within that first year, depending on how it breaks, we will either fix the part ourselves or else ship it back to the part manufacture or company that we bought the motors from. If we must ship the product we will take on the shipping costs.
- At year 2 we assume that 2% of the products that were sold will be returned. This number was multiplied by 30 to account for shipping and handling.

Depreciation:

- We made the assumption that at the end of the useful lifespan for the 3D printer we would be able to send it back and get it repaired for 1000 dollars. With this we gave a residual value of the product to be 2,500 dollars with a total lifespan of 3 years.

Insurance:

- Insurance numbers were pulled from average costs to start-up companies.

Utilities:

- The utility numbers were estimated given the assets we have and the cost of utilities we observe now.

Office Supplies:

- Everyday items needed for the company would be an average of 50 dollars a month.

Travel:

- April 2019 travel to UW BPC
- By year 2 we are going to assume that each sales trip will cost the company 1,000 dollars, one sales trip a month.

Postage and Shipping:

- Cost of shipping and handling will be 15 dollars per unit.

Interest on Loans:

- The loan we take out will be a 100,000 dollar loan with an 7% interest rate.

2020

Commission:

- $30,000/year salary for sales force + 5% commission. Assuming one salesperson for Year 2.

Salaries and Wages:

- Starting Year 2, 50% of profit will be devoted to Salaries and Wages, of which $2500 per month be the salespersons base salary. The remainder will be evenly split among the executive employees.

Summary Sheet

At the end of Year 1, the company will have made $14,456.16. Starting Year 2 the company incurs more costs as it grows, including expanding the number of employees and increasing the number of 3D printers to increase production capacity. At the end of Year 2 the company profits $143,978.286. Two years is the lifetime of the product (without any repairs or maintenance). The total cost of the project in Year 2 is $643,081.74, which is the cost of goods sold and total expenses in that year. The lifetime value was calculated to be $255,406.33 using predictions for Year 2. The AROI is calculated at 167.06%, the NPV is $85,744.07 and the IRR is 161.52%.

Overview of Finances

INCOME STATEMENT				CASH FLOW		
		2019				
INCOME				CASH FLOW FROM OPERATING ACTIVITIES		
Gross Sales		75920		Net Income (loss)		14456.16
	(Commissions)	0		Adjustments to reconcile net income		0
	(Returns and Allowances)	2555			Depreciation and Amortization	0
Net Sales		73365		**Net cash provided by operating activities**		14456.16
	(Cost of Goods Sold)	25800				
GROSS PROFIT		47565		CASH FLOW FROM INVESTING ACTIVITIES		
				Property and equipment additions		0
EXPENSES - General and Administrative						
	Salaries and wages	0		**Net cash provided by investing activities**		0
	Employee benefits	0				
	Payroll taxes	0		CASH FLOWS FROM FINANCING ACTIVITIES		
	Professional services	6000			Loan Proceeds	100,000
	Marketing and advertising	3100			Equity Capital Investments	0
	Rent	6000				
	Equipment	3500		**Net cash provided by financing activities**		100,000
	Maintenace	120				
	Depreciation	333.36		NET CASH FLOW		14456.16
	Insurance	1200				
	Utilities	480		Begining Cash Balance		0
	Office supplies	600			Cash receipts	14456.16
	Travel	100			Cash disbursements	0
	Postage and shipping	1230		Ending Cash Balance		14456.16
	Interest on loans(Monthly Payments)	7410.48				
	Other	0				
TOTAL EXPENSES		30073.84				
Net Income before taxes		17491.16				
	Provision for taxes on income	0				
NET PROFIT		17491.16				

CASH FLOW		2019												
		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
CASH FLOW FROM OPERATING ACTIVITIES														
Net Income (loss)		-5535.32	-2035.32	-2035.32	-2135.32	-1502.82	-1070.32	-537.82	542.18	2459.68	5867.18	7784.68	12654.68	14456.16
Adjustments to reconcile net income		0	0	0	0	0	0	0	0	0	0	0	0	0
	Depreciation and Amortization	0	0	0	0	0	0	0	0	0	0	0	0	0
Net cash provided by operating activities		-5535.32	-2035.32	-2035.32	-2135.32	-1502.82	-1070.32	-537.82	542.18	2459.68	5867.18	7784.68	12654.68	14456.16
CASH FLOW FROM INVESTING ACTIVITIES														
Property and equipment additions		0	0	0	0	0	0	0	0	0	0	0	0	0
Net cash provided by investing activities		0	0	0	0	0	0	0	0	0	0	0	0	0
CASH FLOWS FROM FINANCING ACTIVITIES														
	Loan Proceeds	100,000	0	0	0	0	0	0	0	0	0	0	0	100,000
	Equity Capital Investments													0
Net cash provided by financing activities		100,000	0	0	0	0	0	0	0	0	0	0	0	100,000
NET CASH FLOW		-5535.32	-2035.32	-2035.32	-2135.32	-1502.82	-1070.32	-537.82	542.18	2459.68	5867.18	7784.68	12654.68	14456.16
Begining Cash Balance		0	-5535.32	-7570.64	-9605.96	-11741.28	-13244.1	-14314.42	-14852.24	-14310.06	-11850.38	-5983.2	1801.48	0
	Cash receipts	-5535.32	-2035.32	-2035.32	-2135.32	-1502.82	-1070.32	-537.82	542.18	2459.68	5867.18	7784.68	12654.68	14456.16
	Cash disbursements	0	0	0	0	0	0	0	0	0	0	0	0	0
Ending Cash Balance		-5535.32	-7570.64	-9605.96	-11741.28	-13244.1	-14314.42	-14852.24	-14310.06	-11850.38	-5983.2	1801.48	14456.16	14456.16

CASH FLOW		2020												
		Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sep	Oct	Nov	Dec	Total
CASH FLOW FROM OPERATING ACTIVITIES														
Net Income (loss)		1711.78	5181.78	6284.28	7386.78	7356.78	9423.88	11518.88	10223.88	15760.98	17995.98	22298.08	28835.18	143978.26
Adjustments to reconcile net income														
	Depreciation and Amortization													
Net cash provided by operating activities		1711.78	5181.78	6284.28	7386.78	7356.78	9423.88	11518.88	10223.88	15760.98	17995.98	22298.08	28835.18	143978.26
CASH FLOW FROM INVESTING ACTIVITIES														
Property and equipment additions														
Net cash provided by investing activities		0	0	0	0	0	0	0	0	0	0	0	0	0
CASH FLOWS FROM FINANCING ACTIVITIES														
	Loan Proceeds	0	0	0	0	0	0	0	0	0	0	0	0	0
	Equity Capital Investments													
Net cash provided by financing activities		0	0	0	0	0	0	0	0	0	0	0	0	0
NET CASH FLOW		1711.78	5181.78	6284.28	7386.78	7356.78	9423.88	11518.88	10223.88	15760.98	17995.98	22298.08	28835.18	143978.26
Begining Cash Balance		0	1711.78	6893.56	13177.84	20564.62	27921.4	37345.28	48864.16	59088.04	74849.02		92845	121680.18
	Cash receipts	1711.78	5181.78	6284.28	7386.78	7356.78	9423.88	11518.88	10223.88	15760.98	17995.98	22298.08	28835.18	143978.26
	Cash disbursements	0	0	0	0	0	0	0	0	0	0	0	0	0
Ending Cash Balance		1711.78	6893.56	13177.84	20564.62	27921.4	37345.28	48864.16	59088.04	74849.02	92845	22298.08	121680.18	527238.96

INCOME STATEMENT				price	912.5		markup	1.5		Cost per Unit	365			
		2019	Year 1											
INCOME		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total 2019
# of sales		0	0	0	0	1	2	3	5	10	15	20	30	86
Gross Sales (dollars)		0	0	0	0	912.5	1825	2737.5	4562.5	9125	13687.5	18250	27375	78475
	(Commissions)	0	0	0	0	0	0	0	0	0	0	0	0	0
	(Returns and Allowances [estimated 3.5% Returns])	0	0	0	0	0	0	0	0	730	0	730	1095	2555
Net Sales		0	0	0	0	912.5	1825	2737.5	4562.5	8395	13687.5	17520	26280	75920
	(Cost of Goods Sold)	0	0	0	0	365	730	1095	1825	3650	5475	7300	10950	25800
GROSS PROFIT		0	0	0	0	547.5	1095	1642.5	2737.5	4745	8212.5	10220	15330	44530
EXPENSES - General and Administrative														
	Salaries and wages	0	0	0	0	0	0	0	0	0	0	0	0	0
	Employee benefits	0	0	0	0	0	0	0	0	0	0	0	0	0
	Payroll taxes	0	0	0	0	0	0	0	0	0	0	0	0	0
	Professional services	500	500	500	500	500	500	500	500	500	500	500	500	6000
	Marketing and advertising	200	200	200	200	200	300	300	300	300	300	300	300	3100
	Rent	500	500	500	500	500	500	500	500	500	500	500	500	6000
	Equipment	3500	0	0	0	0	0	0	0	0	0	0	0	3500
	Maintenace	0	0	0	0	0	0	0	0	0	30	0	90	120
	Depreciation	27.78	27.78	27.78	27.78	27.78	27.78	27.78	27.78	27.78	27.78	27.78	27.78	333.36
	Insurance	100	100	100	100	100	100	100	100	100	100	100	100	1200
	Utilities	40	40	40	40	40	40	40	40	40	40	40	40	480
	Office supplies	50	50	50	50	50	50	50	50	50	50	50	50	600
	Travel	0	0	0	100	0	0	0	0	0	0	0	0	100
	Postage and shipping	0	0	0	0	15	30	45	60	150	180	300	450	1230
	Interest on loans (monthly payment)	617.54	617.54	617.54	617.54	617.54	617.54	617.54	617.54	617.54	617.54	617.54	617.54	7410.48
	Other	0	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL EXPENSES		5535.32	2035.32	2035.32	2135.32	2050.32	2165.32	2180.32	2195.32	2285.32	2345.32	2435.32	2675.32	30073.84
Net Income before taxes		-5535.32	-2035.32	-2035.32	-2135.32	-1502.82	-1070.32	-537.82	542.18	2459.68	5867.18	7784.68	12654.68	14456.16
	Provision for taxes on income													
NET PROFIT		-5535.32	-2035.32	-2035.32	-2135.32	-1502.82	-1070.32	-537.82	542.18	2459.68	5867.18	7784.68	12654.68	14456.16

INCOME STATEMENT				price	912.5		markup	1.5		Cost per Unit	365			
		2019	Year 1											
INCOME		Jan	Feb	March	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total 2020
# of sales		40	40	45	50	50	60	70	80	90	100	120	150	895
Gross Sales (dollars)		36500	36500	41062.5	45625	45625	54750	63875	73000	82125	91250	109500	136875	816687.5
	(Commissions)	900	900	1012.5	1125	1125	1350	1575	1800	2025	2250	2700	3375	20137.5
	(Returns and Allowances [estimated 3.5% Returns])	365	365	365	365	365	730	730	730	1095	1095	1460	1825	9490
Net Sales		35235	35235	39685	44135	44135	52670	61570	70470	79005	87905	105340	131675	787060
	(Cost of Goods Sold)	14600	14600	16425	18250	18250	21900	25550	29200	32850	36500	43800	54750	326675
GROSS PROFIT		20635	20635	23260	25885	25885	30770	36020	41270	46155	51405	61540	76925	460385
EXPENSES - General and Administrative														
	Salaries and wages	10317.5	10317.5	11630	12942.5	12942.5	15385	18010	20635	23077.5	25702.5	30770	38462.5	230192.5
	Employee benefits	440	440	440	440	440	440	440	440	440	440	440	440	5280
	Payroll taxes	825.4	825.4	930.4	1035.4	1035.4	1230.8	1440.8	1650.8	1846.2	2056.2	2461.6	3077	18415.4
	Professional services	500	500	500	500	500	500	500	500	500	500	500	500	6000
	Marketing and advertising	300	300	300	300	300	300	400	400	400	400	400	400	4200
	Rent	500	500	500	500	500	500	500	500	500	500	500	500	6000
	Equipment	3500	0	0	0	0	0	0	3500	0	0	0	0	7000
	Maintenace	60	90	120	150	180	210	240	300	360	390	450	540	3090
	Depreciation	27.78	27.78	27.78	27.78	27.78	27.78	27.78	27.78	27.78	27.78	27.78	27.78	333.36
	Insurance	100	100	100	100	100	100	100	100	100	100	100	100	1200
	Utilities	60	60	60	60	60	60	75	75	75	75	75	75	810
	Office supplies	75	75	75	75	75	75	100	100	100	100	100	100	1050
	Travel	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	12000
	Postage and shipping	600	600	675	750	750	900	1050	1200	1350	1500	1800	2250	13425
	Interest on loans (monthly payment)	617.54	617.54	617.54	617.54	617.54	617.54	617.54	617.54	617.54	617.54	617.54	617.54	7410.48
	Other	0	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL EXPENSES		18923.22	15453.22	16975.72	18498.22	18528.22	21346.12	24501.12	31046.12	30394.02	33409.02	39241.92	48089.82	316406.74
Net Income before taxes		1711.78	5181.78	6284.28	7386.78	7356.78	9423.88	11518.88	10223.88	15760.98	17995.98	22298.08	28835.18	143978.26
	Provision for taxes on income													
NET PROFIT		1711.78	5181.78	6284.28	7386.78	7356.78	9423.88	11518.88	10223.88	15760.98	17995.98	22298.08	28835.18	143978.26

Code Index Identifier	Description	Covered on pg(s)	Reviewed By	Date of Review	Action Needed	Action Taken	Date
ISO 9001							
4.1	The standard requires the organization to implement and maintain a quality management system in accordance with the requirements of ISO 9001. This includes insurance of control of any outsourced processes that affect product conformity with requirements and to identify such control within the QMS.	*4-21*	PF BK	11/25/2018	No Action	None	11/26/2018
4.1a	The standard requires the organization to identify the processes needed for the quality management system and their application throughout the organization.	3,4,5,17	PF BK	11/25/2018	Add chart for making changes to QM	Created chart; will add to company processes	11/27/18
4.1b	The standard requires the organization to determine the sequence and interaction of the identified processes.	5	PF BK	11/25/2018	This may relate better to page 5	Changed pg # to 5	11/27/18
4.1c	The standard requires the organization to determine criteria and methods required to ensure the effective operation and	4-21	PF BK	11/25/2018	No Action	None	11/26/18

	control of the identified processes.						
4.1e	The standard requires the organization to measure, monitor and analyze the identified processes.	3-6	PF BK	11/25/2018	This may pertain more to organizational processes	Organizational processes cited	11/27/18
4.1,4.2.1	The standard requires the organization to document a QMS in accordance with the requirements of ISO 9001.	3-21	PF BK	11/25/2018	No Action	None	11/26/18
4.2.1b	The standard requires a quality manual to be established and maintained that includes the scope of the QMS, the documented procedures or reference to them and a description of the sequence and interaction of processes included in the QMS.	4-21	PF BK	11/25/2018	No Action	None	11/26/18
4.2.1c	The standard requires the management system documentation to include documented procedure required by ISO 9001. These include: Document control, the control of record, conducting audits, non-conformity control, corrective action and preventative action.	26-30	PF BK	11/25/2018	Add audit, non-conformity, corrective action and preventative action section. Reference page 11 flow chart.	Made and implemented an audit system for the company which is added to our company processes.	11/27/2018
4.2.1d	The standard requires management system documentation to include	4-21	PF BK	11/25/2018	No Action	None	11/26/18

	the current revision status of documents to be identified.					including process flow chart	
4.2.3d	The standard requires that relevant versions of applicable documents are available at points of use.	28	PF BK	11/25/2018	No Action	None	11/26/18
4.2.3e	The standard requires documents to remain legible and readily identifiable.	30	PF BK	11/25/2018	No Action	None	11/26/18
4.2.3g	The standard requires the unintended use of obsolete documents to be prevented and a suitable identification to be applied to obsolete documents retained for any purpose.	27	PF BK	11/25/2018	No Action	None	11/26/18
5.1	Top management must provide evidence of its commitment to the development and implementation of the QMS and continually improving its effectiveness	3	PF BK	11/25/2018	More specific QMS reference	Added reference to QMS in policies	11/27/18
5.1b	The standard requires that top management establish the quality policy.	3	PF BK	11/25/2018	add quality policy	Quality policy added	11/27/18
5.1c	The standard requires that top management ensure that quality objectives are established.	3	PF BK	11/25/2018	add quality policy	Quality policy added	11/27/18
5.1d	The standard requires that top management conduct management reviews.	3	PF BK	11/25/2018	Add mention of reviews	reference to reviews in policies	11/27/18

5.2b	The standard requires customer requirements to be met with the aim of enhancing customer satisfaction.	3-14, 22-24,	PF BK	11/25/2018	No Action	None	11/26/18
5.3c	The standard requires the quality policy to provide a framework for establishing and reviewing quality objectives.	4, 5, 7, 8, 20,	PF BK	11/25/2018	No Action	None	11/26/18
5.4.1	The standard requires that top management ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization.	4-8, 20	PF BK	11/25/2018	Add page 6	Page 6 added	11/27/18
5.51a	The standard requires that the responsibilities and authority be defined.	5	PF BK	11/25/2018	Identify specific pages	Specific page identified	11/27/18
6.2.2b	The standard requires the organization to provide training or take other actions to satisfy these needs.	15	PF BK	11/25/2018	Add training to resource management process	Training added to resource management process	11/27/18
6.2.2c	The standard requires the organization to evaluate the effectiveness of the actions taken.	6	PF BK	11/25/2018	Identify specific pages	Specific page identified, auditing section will be added	11/27/18
6.3	The standard requires the organization to determine, provide and maintain the infrastructure needed to	16	PF BK	11/25/2018	No Action	None	11/26/18

	achieve conformity to product requirements.						
6.4	The standard requires the organization to identify and manage the work environment needed to achieve conformity of product.	16	PF BK	11/25/2018	Mention conformity of product	Chart edited to mention product conformity	11/27/18
7.1	The standard requires the organization to plan and develop the processes required for product realization consistent with the other requirements of the QMS. The product realization planning must be in a form suitable for the organization's method of operations.	22-24	PF BK	11/25/2018	No Action	None	11/26/18
7.1a	The standard requires the organization to determine the quality objectives and requirements for the product.	22-24	PF BK	11/25/2018	No Action	None	11/26/18
7.1b	The standard requires the organization to determine the need to establish documents specific to the product.	21, 26-29	PF BK	11/25/2018	No Action	None	11/26/18
7.1.b-2	The standard requires the organization to provide resources specific to the product.	13, 14, 16-18	PF BK	11/25/2018	No Action	None	11/26/18

7.1c	The standard requires the organization to determine the required verification, validation, monitoring, inspection and test activities specific to the product.	24-25, 36-37	PF BK	11/25/2018	Cite only 24, 34-35	Updated to new appropriate page #s	11/27/18
7.1c2	The standard requires the organization to determine the criteria for product acceptance.	32-33, 48	PF BK	11/25/2018	No Action	None	11/26/18
7.1d	The standard requires the organization to determine the records needed to provide evidence that the realization processes and resulting product meet requirements.	11, 20, 25, 36-37	PF BK	11/25/2018	Cite specific pages	Correct, specific pages cited	11/27/18
7.2.1a	The standard requires the organization to determine requirements specified by the customer including requirements for delivery and post-delivery activities.	12, 23, 46	PF BK	11/25/2018	Cite 22	New page number cited	11/27/18
7.2.1b	The standard requires the organization to determine product requirements not specified by the customer but necessary for known intended use.	22-24	PF BK	11/25/2018	No Action	None	11/26/18
7.2.1c	The standard requires the organization to determine statutory and regulatory requirements related to the product	50-53	PF BK	11/25/2018	Add other regulatory orgs. Such as ASTM, IEEE and UL	Looked through ASTM, IEEE and UL. Added relevant standards	11/27/18

7.2.1d	The standard requires the organization to specify additional requirements determined by the organization.	22-24	PF BK	11/25/2018	No Action	None	11/26/18
7.2.2b	The standard requires the review to ensure that contract or order requirements differing from those previously expressed are resolved.	36	PF BK	11/25/2018	No Action	None	11/26/18
7.3.1	The standard requires the organization to control design and development of the product. This includes the requirement to plan design and development of the product. Interfaces between different groups involved in design and development are to be managed to ensure effective communication and clarity of responsibilities. Planning output is to be updated as appropriate as the design and development progresses.	26-27	PF BK	11/25/2018	Replace with page 26	New page numbers referencing Gantt chart design and development plan	11/27/18
7.3.1a	The standard requires the stages of design and development to be determined.	22-25	PF BK	11/25/2018	No Action	None	11/26/18
7.3.1b	The standard requires the review, verification and validation activities	34-35	PF BK	11/25/2018	No action	None	11/26/18

	appropriate to each design and development stage to be determined.						
7.3.1c	The standard requires the responsibilities and authorities for design and development activities to be determined.	26-27	PF BK	11/25/2018	Change to page 26	Page number changed	11/27/18
7.3.2a	The standard requires design inputs to include functional and performance requirements.	22-24	PF BK	11/25/2018	No Action	None	11/26/18
7.3.2b	The standard requires design inputs to include applicable statutory and regulatory requirements.	50-53	PF BK	11/25/2018	No Action	None	11/26/18
7.3.3	The standard requires that the outputs of design and development be provided in a form that enables verification against the design and development inputs. Outputs are to be approved prior to release.	22-24, 43	PF BK	11/25/2018	No Action	None	11/26/18
7.3.3a	The standard requires that design and development output meet the input requirements.	22-24	PF BK	11/25/2018	No Action	None	11/26/18
7.3.3d	The standard requires design and development output to define the characteristics of the product that are essential to its safe and proper use.	22-24	PF BK	11/25/2018	No Action	None	11/26/18

7.3.4a and b	The standard requires design reviews to be conducted to evaluate the ability of the results of the design and development to fulfill requirements, identify problems and propose required actions.	20	PF BK	11/25/2018	No Action	None	11/26/18
7.3.5	The standard requires design and development verification to be performed in accordance with planned arrangements to ensure the output meets the design and development inputs. The results of the verification and any required actions are to be recorded.	22-24, 36	PF BK	11/25/2018	Mention record keeping	Mentioned record keeping in the verification testing procedures	11/27/18
7.3.6	The standard requires design and development validation to be performed in accordance with planned arrangements to confirm that resulting product is capable of fulfilling the requirements for the specified application or intended use where known. Validation is to be completed wherever applicable prior to the delivery or implementation of the product. Results of the validation and subsequent	22-25, 36-37	PF BK	11/25/2018	Cite pages 34-35	Correct new pages cited	11/27/18

	follow-up actions are to be recorded.						
7.3.7	The standard requires design and development changes to be identified and records maintained. Changes are required to be verified and validated as appropriate before implementation. Changes are required to be reviewed and approved before implementation, including the evaluation of the effect of changes on constituent parts and delivered product.	21, 22-24, 28-31	PF BK	11/25/2018	Cite document control	Document control cited (pp. 30-31)	11/27/18
7.5.1f	The standard requires the implementation of release, delivery, and post-delivery activities.	12, 43-44, 48	PF BK	11/25/2018	No Action	None	11/26/18
7.5.3	The standard requires the organization to identify the status of the product with respect to measurement and monitoring requirements.	12-13	PF BK	11/25/2018	Not covered	None	
7.5.3.2	The standard requires the organization to control and record the unique identification of the product, where traceability is a requirement.	12, 46	PF BK	11/25/2018	no Action	None	11/26/18
7.5.5	The standard requires the organization to preserve conformity of product during	12,46	PF BK	11/25/2018	no action	None	11/26/18

	internal processing and delivery to the intended destination including identification, handling, packaging, storage and protection.						
7.6a	The standard requires the organization to identify the measuring and monitoring devices needed to provide evidence of conformity of product to determined requirements.	22-24, 34, 35	PF BK	11/25/2018	No Action	None	11/26/18
7.6b	The standard requires processes to be established to ensure that monitoring and measuring can be carried out and are carried out in a manner consistent with the measuring and monitoring requirements.	22-24, 34, 35	PF BK	11/25/2018	No Action	None	11/26/18
7.6c	The standard requires measuring and monitoring device to be calibrated or verified at specified intervals or prior to use, against measurement standards traceable to international or national standards.	34-36, 43, 44	PF BK	11/25/2018	No action	None	11/26/18
7.6.2	The standard requires records of the results of calibration and verification to be maintained.	47	PF BK	11/25/2018	no action	None	11/26/18

7.6.3	The standard requires confirmation of the ability of software used for measuring and monitoring of specified requirements to satisfy intended application to be undertaken prior to initial use and reconfirmed as necessary.	34, 35, 43	PF BK	11/25/2018	no action	None	11/26/18
8.1	The standard requires the organization to plan and implement the monitoring, measurement, analysis and improvement processes needed to demonstrate conformity of the product including determination of applicable methods such as statistical techniques and the extent of their use.	34-36, 43, 44	PF BK	11/25/2018	no action	None	11/26/18
8.2.1	The standard requires the organization to monitor information relating to customer perception as to whether the organization has met customer requirements and requires the methods of obtaining and using this information to be determined.	20, 22-24	PF BK	11/25/2018	no action	None	11/26/18
8.2.2a	The standard requires the organization to conduct internal audits at planned intervals to determine	3	PF BK	11/25/2018	Add audit section/schedule	Audit section created	11/27/18

	whether the quality management system conforms to the planned arrangements and to the requirement of this International Standard.						
8.2.2b	The standard requires the organization to conduct internal audits at planned intervals to determine whether the quality management system is effectively implemented and maintained.	3	PF BK	11/25/2018	Add audit section/schedule	Audit section created	11/27/28
8.3a	The standard requires the organization when appropriate to deal with nonconforming product by taking action to eliminate the detected nonconformity.	20, 36-37	PF BK	11/25/2018	cite validation/verification sections	Sections cited	11/27/18
8.4a	The standard requires analysis of data to provide information relating to customer satisfaction.	7, 20	PF BK	11/25/2018	No action	None	11/26/18
8.4b	The standard requires analysis of data to provide information relating conformity to product requirements.	20, 34-35, 43, 49	PF BK	11/25/2018	No action	None	11/26/18
8.5.2	The standard requires the organization to take action to eliminate the cause of nonconformities in order to prevent recurrence and	20, 36-37, 45, 51	PF BK	11/25/2018	Cite 34-35, 43, 49	New correct pages cited	11/27/18

	requires the actions to be appropriate to the effects of the nonconformities encountered.						
8.5.3	The standard requires the organization to determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence and for such actions to be appropriate to the effects of the potential problems.	20, 36-37, 45, 51	PF BK	11/25/2018	Cite 34-35, 43, 49	New correct pages cited	11/27/18

Code Index Identifier	Description	Covered on pg(s)	Reviewed By	Date of Review	Action Needed	Action Taken	Date
FDA							
US Code Section #	Section Name						
	U.S.C. SUBCHAPTER III -- Prohibited Acts and Penalties						
331	Prohibited acts	--					
332	Injunction proceedings	--					
333	Penalties	--					
334	Seizure	--					
335	Hearing before report of criminal violation	--					
335a	Debarment, temporary denial of approval, and suspension	--					
335b	Civil penalties	--					
336	Report of minor violations	--					
337	Proceedings in name of United States; provisions to subpoenas	--					
337a	Extraterritorial jurisdiction	--					
	SUBCHAPTER V						
	PART A-- DRUGS AND DEVICES						
351	Adulterated Drugs and Devices	Addressed by ISO 9001: 4.1, 8.b	PF BK	12/2/18	None	None	12/3/18
352	Misbranded Drugs and Devices	52; ISO 9001: 7.2.1.b	PF BK	12/2/18	None	None	12/3/18
353	Exemptions and consideration for certain drugs, devices, and biological products	--					

355-1	Risk evaluation and mitigation strategies	n/a					
355b	Adverse-event reporting	n/a					
355c	Research into pediatric uses for drugs and biological products	n/a					
355c-1	Report	n/a					
355g	Utilizing real world evidence	n/a					
360	Registration of producers of drugs or devices	--					
360c	Classification of devices intended for human use	--					
360c-1	Reporting	30-33	PF BK	12/2/18	None	None	12/3/18
360d	Performance standards	26-27	PF BK	12/2/18	None	None	12/3/18
360e	Premarket approval	--					
360e--1	Pediatric uses of devices	--					
360e--3	Breakthrough devices	--					
360f	Banned devices	--					
360g	Judicial Review	--					
360g-1	Agency documentation and review of significant decisions regarding devices	6-9, 11, 15-17, 20-24, 30-34,	PF BK	12/2/18	None	None	12/3/18
360h-1	Program to improve the device recall system	21, 27, 38, 39	PF BK	12/2/18	None	None	12/3/18
360i	Records and reports on devices	30-31, 36-37	PF BK	12/2/18	None	None	12/3/18
	PART C--Electronic Product Radiation Control						
360kk	Performance standards for electronic products	38-39	PF BK	12/2/18	None	None	12/3/18
360ll	Notification of defects in and repair or replacement of electronic products	Addressed by ISO 9001: 8.3a	PF BK	12/2/18	None	None	12/3/18
360nn	Inspection, records, and reports	Addressed by ISO 9001: 4.2.1c	PF BK	12/2/18	None	None	12/3/18

360oo	Prohibited acts	--					
360ss	State standards	--					
	Part E--General Provisions Relating to Drugs and Devices						
360bbb	Expanded access to unapproved therapies and diagnostics	--					
360bbb-1	Dispute resolution	--					
360bbb-2	Classification of products						
360bbb-3	Authorization for medical products for use in emergencies	--					
360bbb-3a	Emergency use of medical products	--					
360bbb-3b	Products held for emergency use	--					
360bbb-6	Risk communication	--					
360bbb-8c	Patient participation in medical product discussion	8, 21, 25,	PF BK	12/2/18	None	None	12/3/18
	SUBCHAPTER VII						
	Part A: General Administrative Provisions						
371	Regulations and Hearings	--					
372	Examinations and Investigations	3, 6-24,	PF BK	12/2/18	None	None	12/3/18
372a	Transferred	--					
373	Records	--					
374	Inspection	--					
375	Publicity	--					
379	Confidential information	--					
379a	Presumption of existing jurisdiction	--					
379b	Consolidating administrative and laboratory facility	17	PF BK	12/2/18	None	None	12/3/18
379c	Transferred	--					
379d-1	Conflicts of interests	--					

379d-2	Policy on the review and clearance of scientific articles by FDA employees	--					
379d-3	Streamlined hiring authority	15, 16	PF BK	12/2/18	None	None	12/3/18
379d-3a	Hiring authority for scientific, technical, and professional personnel	15, 16	PF BK	12/2/18	None	None	12/3/18
379d-4	Reporting requirements	--					
379d-5	Guidance document regarding product promotion using the internet	--					
	Part B: Colors						
379e	Listing and certification of color additives for foods, drugs, devices, and cosmetics	--					
	Part C: Fees						
	Subpart 1: Freedom of information fees						
379f	Recovery and retention of fees for the freedom of information requests	--					
	Subpart 3: Fees relating to devices						
379j	Authority to assess and use device fees	--					
379j-1	Reauthorization; reporting requirements	30-33	PF BK	12/2/18	None	None	12/3/18
	Subpart 9: fees relating to outsourcing facilities						
379j-62	Authority to assess and use outsourcing facility fees	--					
	Part E: Environmental impact review						
379o	Environmental impact	4	PF BK	12/2/18	None	None	12/3/18
	Part G: Safety report						

379v	Safety report disclaimer	52	PF BK	12/2/18	None	None	12/3/18
	U.S.C. SUBCHAPTER VIII -- Imports and Exports						
381	Imports and exports	--					
382	Exports of certain unapproved products	--					
383	Office of International Relations	--					

Code Index Identifier	Description	Covered on pg(s)	Reviewed By	Date of Review	Action Needed	Action Taken	Date
ASTM							
E102-14	Standard Practice for Verification of Testing Frame and Specimen Alignment Under Tensile and Compressive Axial Force Application	26-27	PF BK	12/2/18	None	None	12/3/18
F3127-16	Standard Guide for Validating Cleaning Processes Used During the Manufacture of Medical Devices	26-27	PF BK	12/2/18	None	None	12/3/18
F594-09(2015)	Standard Specifications for Stainless Steel Nuts	--					
G190-15	Standard Guide for Developing and Selecting Wear Tests	25	PF BK	12/2/18	None	None	12/3/18
G98-17	Standard Test Method for Galling Resistance of Materials	25	PF BK	12/2/18	None	None	12/3/18