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Project Proposal of a Safe Vial Transportation System for Biomedical Industry Use

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Abstract
With the current uptick in bio-medical field due to COVID-19 activities bio-medical industries are turning to the automation world to help improve their productivity. With events like COVID-19 this specific bio-medical company required a quick yet effective transportation system for their vials between the lab and clean room. This paper will introduce this need. Describe constraints that the biomedical field has put into place. Finally, the paper presents the final design proposal for this system.
Keywords: *Biomedical, Vial Transportation, Proposal, Engineering, Automation*

1. Introduction

During a Kaizen event, to identify the 8 wastes of lean, a local bio-medical company realized a need for a transportation system for moving reagents from their Bio Lab to the clean room in order to reduce waiting, motion, extra processing and non-utilized talent. The highly skilled lab and clean room workers must unknown from their respective outfits and transport these reagents. The extra processing results in the clean room manufacturing waiting for the reagents, having to perform unnecessary motion. Furthermore, the company is not fully utilizing their employee's talent by having them transport these vials. All this results in high waste of company's resources.

For the system to be successful, transportation of the vials must not introduce contamination and have a smooth motion. Contamination introduced during the transport would result in quality and performance of the final product. To add, any agitation resulting from a rough transport would result in air bubbles being introduced to the liquid in the vials. Verification utilizing the barcodes on each vial that all contents have been delivered is also a requirement. At last, ready, in route and delivered status lights are vital. After validation of the initial requirements the system will address the customers need and assist in reducing their wastes. Consequently, it will help to reduce the use on one time use inventory items such as gloves, hair nets and shoe covers which must be brand new every time one of the areas is entered resulting in saved costs. For the bio-medical company to reduce the 8 wastes of lean in their manufacturing a safe transportation system between the Bio Lab and Clean Room must be developed to safely transport vials and eliminate this non-value adding task.

2. Management Planning.

2.1 Subheadings

This project will require a group organization with defined roles both within the production facility and with the client's organization. These roles are defined as follows and structured as shown in Figure 1.

Client

- Quality Manager: In charge of conveying what the quality needs are for the system.
- Engineering Manager: In charge of approving any technical requirements.
- Facilities Manager: In charge of approving any infrastructure requirements.
- Production Manager: In charge of approving any process requirements.
- Logistics Manager: In charge of transport and delivery.

Production Facility

- Program Manager: Overlooks the whole process clients' main contact.
- Engineering Director: Overlooks the engineering team, which includes the following:
  - Systems Engineer: In charge of the software side.
  - Design Engineer: In charge on the concept and design.
  - Production Engineer: In charge of the assembly, and manufacturing of product.
  - Production Technicians: In charge of executing the assembly and manufacturing processes.
- Principal Engineer: To provide guidance to any of the teams and overlook the project.
- Logistics Manager: Will organize delivery of parts, delivery of finished product and installation.
- Integration Manager: Will make sure product can easily integrate with client's system, and will help with final installation and implementation..
- Quality Manager: Will make sure all quality standards and operational requirements are met.

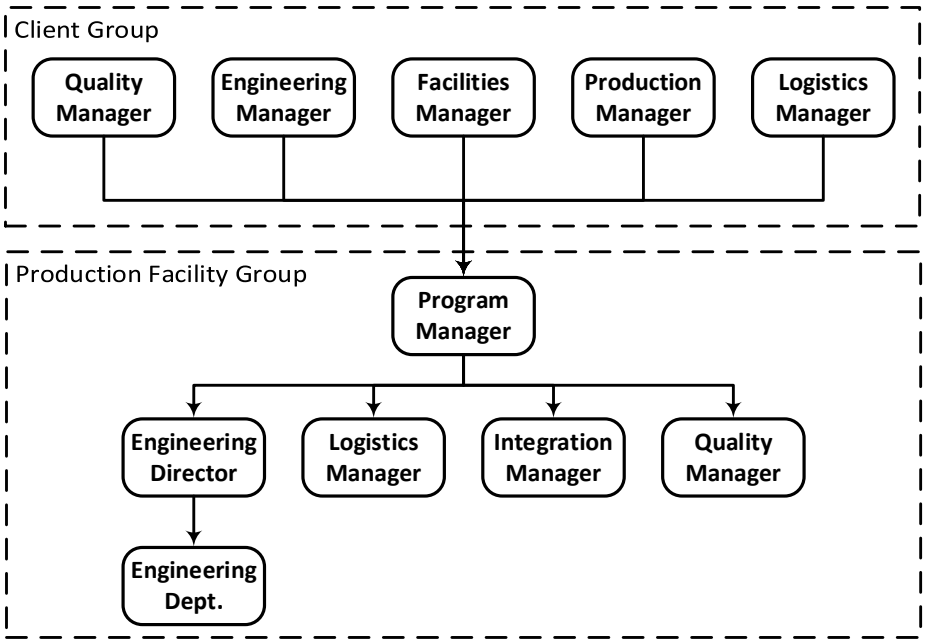

Fig. 1 Group Organization Chart

2.2 Procedures for Performing Tasks

Meeting Plans

The meeting plans will need to be defined and scheduled at the onset to ensure that targets and due dates are met. This will include internal meetings at the production facility, which begins with the Program Manager having a 10-minute morning meeting with direct reports: Engineering Director, Logistics Manager, Integration Manager, and Quality Manager. Subsequent to this, the Engineering Director will have a daily morning meeting with his direct reports. A Program Meeting with all team members will be conducted once a week at a time that ensures everyone's commitment.

Meetings for members from the Client and Production Facility groups will be led by the Program Manager. This will include a meeting with each individual client department, at the beginning, middle and end of every milestone. Any individual intergroup (client and production facility) department meetings shall include or be led by the Program Manager.

Individual Work

All individual work must be documented and submitted into a controlled document control system, which is set up and maintained as directed by the Program Manager. Each team or individual will prepare work, presentations and present their work to their own group prior to presenting at one of the meetings.

2.3 Project Plan

This project will have the milestones and phases defined as per Figure 2, as well as the functional flow diagram shown in Figure 3. This will be presented, finalized, and agreed upon in the first Program Meetings. Any changes shall be presented in the Program Meeting and require consensus by all team members.

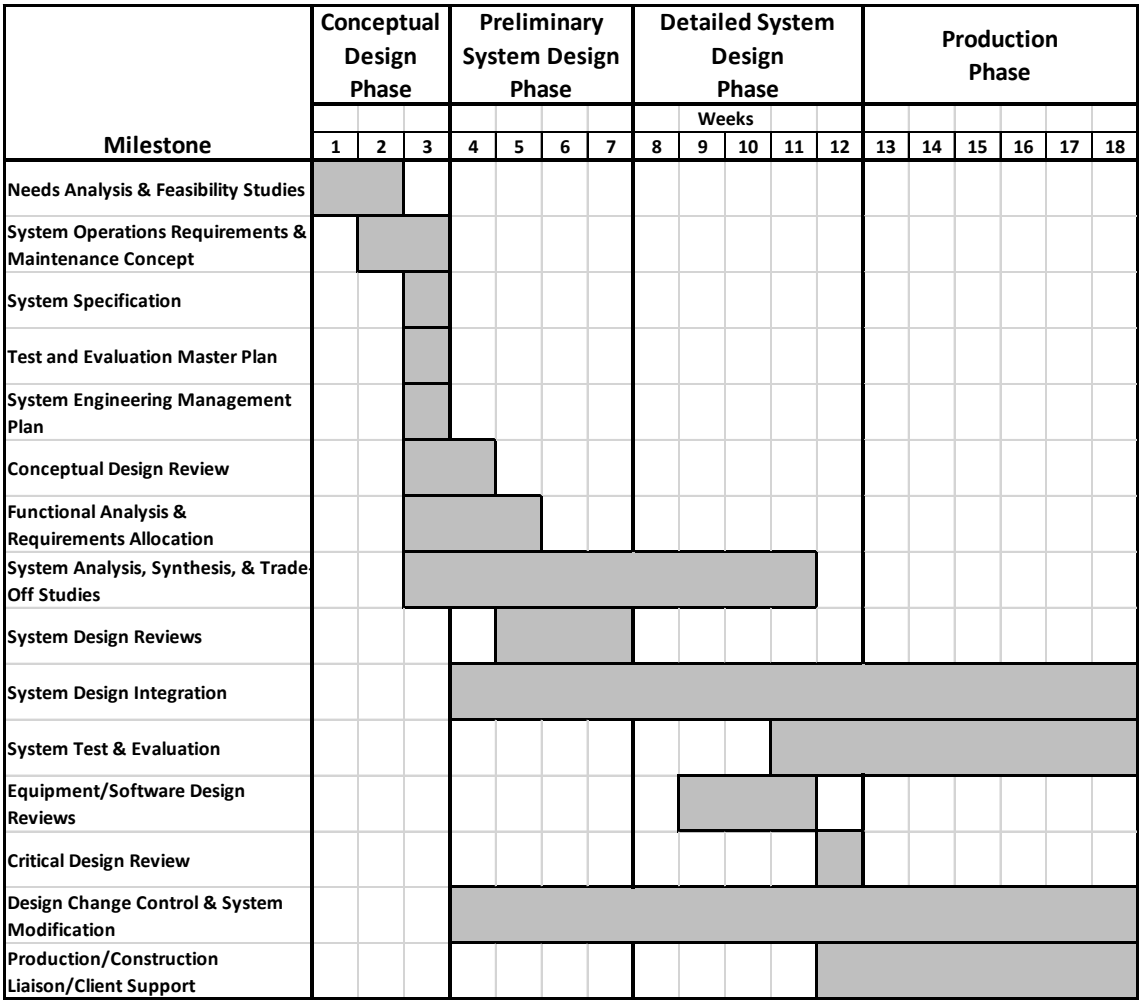

Fig. 2 Project Plan

2.4 Resources

This project will require both existing technology as well as technology to be developed. Development of new technologies will require extensive use of 3D printing to test and visualize prototypes. Additionally, an electronics lab will be required for developing electronics for these technologies. Software for programming and 3D modeling will be required as well. Any new materials, components, and software will be included in the preliminary budget, to be agreed upon in the opening Program Meeting.

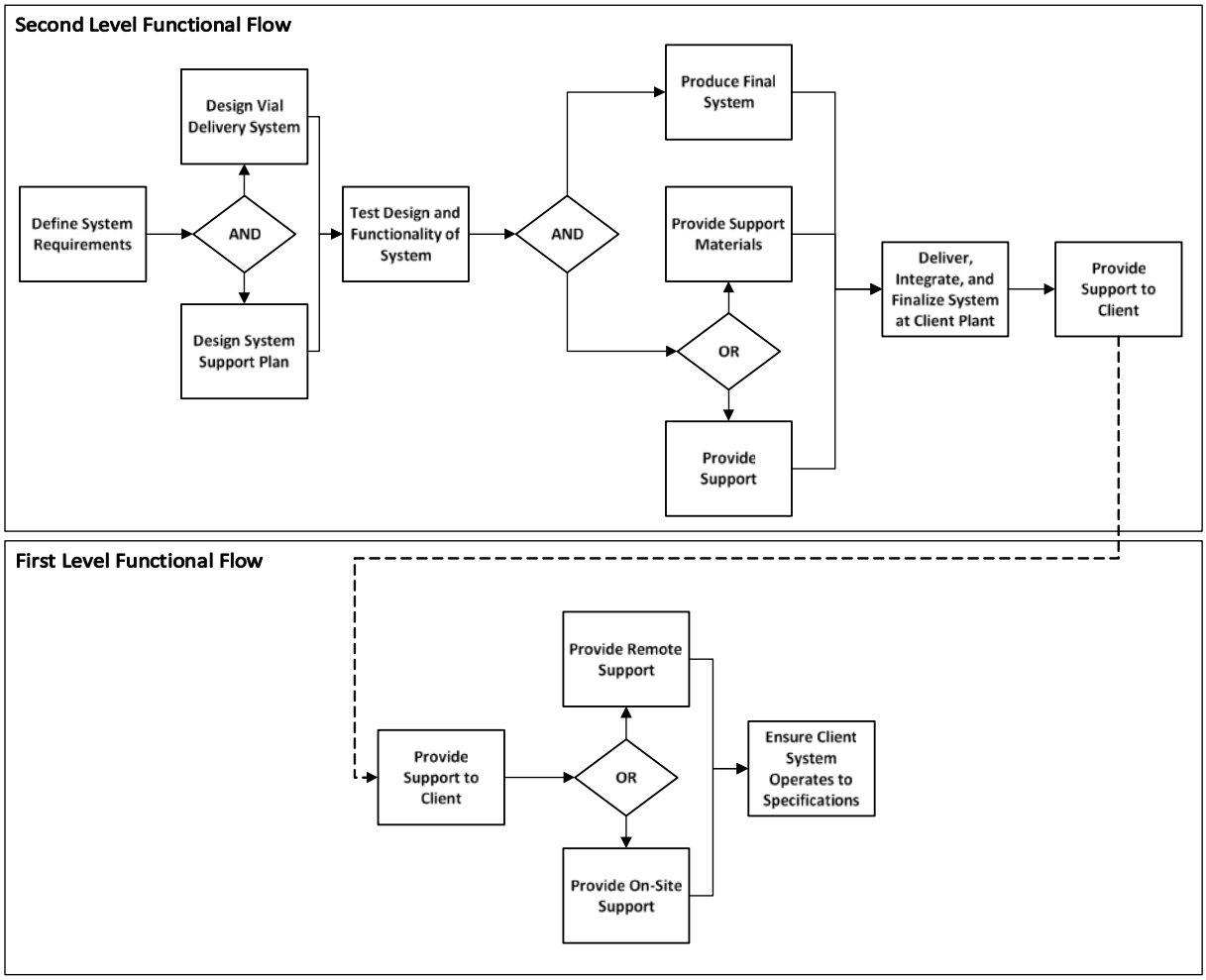

Fig. 3 Functional Flow

III. System Design and Feasibility Analysis

3.1 System Requirements

This system will be designed and developed with the following fundamental and overall system requirements. These requirements shall be part of the final review for this system design prior to construction, as well as evaluation after any trial implementation.

- No Contamination:
  While transporting the system is transporting the vials it must not introduce any contamination to the outside of the vial. Such as dust or static material. This kind of contamination could make its way into the final product and to the customer.
- Smooth Motion:
  During the transport there must be no jerking, fast acceleration, falling or dropping of the vials. This would agitate the product and introduce air into the liquid.
- Verification of Vials:
  The system must be able to verify using barcodes that the vials that left the initial area are all present and the same in the destination area.
- Status Lights
  The system must have lights that identify users ready, in route and delivery status.

- Vertical and Horizontal
  Must be able to go up into the ceiling, over and back down to not waste space. This would take use of otherwise unused space between the roof and drop ceiling.
- Temperature:
  The environmental temperature of the system must not exceed 74 degrees Fahrenheit.

3.2 Design Approaches or Alternatives and Feasibility Evaluation

There are a variety of design approaches and alternatives which may or may not be included in this system. This includes, but is not limited to, the following alternatives.

- Air Vacuum (Bank):
  Pneumatic tube system under the operation of a blower located at the one side of the terminal, which supplies air for pressure or vacuum movement of the contents through the tube [1]. This is the least feasible design, due to the use of pressure and vacuum to propel the vial through the tube. This could cause uncontrolled acceleration and speed resulting in possible damage to the vial and/or the contents.
- Conveyer Belt in Tunnel
  Pressurized tunnel with a conveyor belt would keep out any particles or contamination from coming inside. Usually, the air differential should be 2.5 Pa but more ideally 8 Pa is desired [2]. This alternative would be high in initial cost, maintenance, and cleaning.
- Conveyor belt with Transportation Boxes
  Transportation box would be used on the conveyor belt to prevent contamination from the belt. Conveyor belts can have cuts, scratches, surface abrasions and cracks which are hard to decontaminate. The box would help to prevent this contamination to some degree [3]. This alternative would be high in initial cost, maintenance, and cleaning.
- Tunnel with Wheeled Cart
  Use of an unidirectional wheel in order to kinetically move the cart in any direction in the tube by spinning left or right[4]. This is the most feasible alternative, as described in the next section.

3.3Recommend design description

The use of a positive pressure tube would keep contaminates from entering the system. The use of self- propelled carts will reduce the use of many moving parts as in a conveyor belt. Using a gyroscopic sensor, the contents can be always kept upright during the transport. Since the cart is self-powered with sensor-based controls. An accelerometer and programming can be used to include motion profiling and ensure smooth accelerations and decelerations. The system will be tested in its normal operating conditions, both upon implementation and during Preventative Maintenance (P.M.) intervals, to ensure that it meets the System Operational Requirements, as outlined in Section IV.

IV. System Operational Requirements

4.1 Mission definition and performance parameters

This system shall adhere to guidelines determined by the Technical Performance Measures as outlined in Table I. The proposed system must be designed and completed within 4.5 months, from acceptance of project parameters to full implementation of the system. The operational life will be up to 20 years, allowing for any modifications due to technology or product changes.

There will be a maximum number of 8 vials per batch that will need to be transported. The transporting fixture must accommodate vials of both 0.5 inch and 1.5 inch diameter. The system will allow for a maximum of 4 transportation instances per hour. Overall, this will accommodate a total of 32 vials per hour.

Table I. Technical Performance Measures

Technical Performance Measure	Quantitative Requirement ("MATRIC")	Current "Benchmark"	Relative Customer Importance
Process Time	3 min	20 min	15
Availability	24/7	8 hrs/day weekdays	15
Human Factors	<1%/yr	5%/yr	20
Contamination	35,200 particles >0.05 μm/ft^3	35,200,000 particles >0.05 μm/ft^3	25
Temperature Control	±2ºF	±8ºF	25
			100

4.2 Operational deployment and distribution

The proposed solution will transport the vials from the lab to the clean room. Must start in the lab, go up into the ceiling between the ceiling tiles and the roof, run to the clean room and back down through the ceiling. The height of the loading and unloading stations will be as a result of a study done with the lab and clean room personnel.

The target Mean Time between Maintenance (MTBM) of the system is 6 months, which will be the proposed P.M. schedule. The Maintenance Down Time (MDT) should be 2 hours or less for both P.M. as well as any component failures could happen outside the regular maintenance schedule. Further maintenance details, around which this system shall be designed and implemented, are outlined in Table II.

Table II Maintenance Plan

Criteria	Organization Maintenance	Intermediate Maintenance	Supplier/MFR Maintenance
Done Where?	Operator interaction points	Anywhere in the facility	
Done by Whom?	Operators	Production Technician	Specialized outside personnel
With Who's Equipment?	Organization's Equipment		Servicing company
Type of Work Accomplished?	Autonomous Maintenance Visual Inspections Adjusting System Settings Minor Services	Detailed Inspections Major Services Major Repairs Minor P.M.	Factory Adjustments/Upgrades Calibration Major P.M. Overload from Intermediate Maintenance

4.3Utilization Requirements and Environmental factors

The system must be in stand by and ready to be used all day, up to the previously defined maximum of 4 transportation events per hour. The system will need to accommodate environmental variances that may occur due to the unregulated space between the drop ceiling and the roof, causing local variations across the shop floor. While this will only be operated during business hours when the working area is controlled, humidity and temperature variations from the ceiling space may affect this. In the summer days there can be high humidity and temperature; whereas in the winter there might be colder temperatures, but still above 32 degrees Fahrenheit.

4.4Economic Factors

The system cost should not exceed twice the amount of the average yearly salary of a material handler. The planned maintenance costs and annual operation should be less than 2% of the system cost. This will ensure that the system is economically viable and justifiable in comparison to manual material handling operations.

5. Conclusions

The paper introduces the idea of a vial transportation system designed and implemented for a biomedical company. This system would reduce the labor time and costs required to manually transport vials. Potential product damage and contamination would be reduced as well. As a preliminary system design, a pressurized tube with a controlled-motion cart is proposed here to the client. With the provided proposal the end user can identify whether they believe it will meet their demand and constraints. Finally, a complete system design can be created with full details, specifications, and drawings, which will allow the project team to begin work on the design and implementation process described herein.

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