SENG 321

Final Report

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Glossary

Aorta	The main trunk of the arterial system, conveying blood from the heart to all of the body except the lungs.
Data Acquisition System	A family of quality data acquisition software products (ViViTest, HiTest and QCTest) to aid in collection of data to meet ISO 5840 requirements.
Doppler Effect	Also known as a Doppler shift, it is the change in frequency that occurs when a wave emitter is moving relative to an observer.
Flowmeter	A sensor for measuring the flow rate of a fluid in a tube.
Fluid Viscosity	Measure resistance to gradual deformation by shear stress or tensile stress.
ISO	An abbreviation for the International Standardization Organization.
Magnetic Field	The magnetic area of effect created by a magnet, electric current, or moving charged particle.
Mitral Valve	The valve between two sections of the heart. Consists of two triangular tissue flaps which prevent blood from flowing backward.
Pulse Duplicator	A system that simulates the function of the heart by generating pulsatile flow through prosthetic heart valves placed in the Model Left Heart.
Transducer	A device that converts a signal from one type of energy to another.

1 Introduction

1.1 Overview

The team participated in four meetings with ViVitro over the course of two months. Our discussions with Joe (Project Manager) and Gerry (General Manager), and the product meeting we attended provided valuable insight into ViVitro's product specification and internal management processes. ViVitro provided a unique perspective within the class due to their hardware focused project, in contrast to the other companies who were primarily software focused. ViVitro must be extremely thorough while documenting the entire process of developing and testing their products because they design medical devices. This document explains the requirements engineering process at ViVitro Labs Inc., and how it relates to the requirements engineering class.

1.2 The Company

ViVitro Labs Inc. is one of the leading companies in cardiovascular testing equipment. They are known for their expertise, accuracy, and the quality of their heart valve, LVAD, TAH, stent, and graft testing. Their sister company, Starfish Medical, is a medical device engineering firm known for their innovative work in the life science and medical communities. ViVitro stays ahead of their competition through careful use of a gated waterfall system and the cooperation of the Starfish Medical engineers.

1.3 Involvement with Company

When we arrived at ViVitro they were just beginning the requirements elicitation process for a new flowmeter. Outside of the our meetings we assisted with ViVitro's current project by conducting research into different types of flowmeters and into their competitors. The time during the meetings were spent learning about their requirements specification process. Below a table of our involvement measured in time with ViVitro is displayed for each individual team member.

Team Member	**Travel and Meetings**	**Meeting / Presentation Prep**	**Post Meeting Work**	**Final Presentation & Prep**
Joe Czepil	7.5 hours	8 hours	3 hours	6 hours
Sarah Nicholson	7.5 hours	6 hours	3 hours	6 hours
Mitchell Rivett	5 hours	6 hours	3 hours	6 hours
Miles Barr	5 hours	6 hours	3 hours	6 hours
Jakob Roberts	7.5 hours	8 hours	3 hours	6 hours
Dennis Honey	5 hours	6 hours	3 hours	6 hours

Table 1: Time log

The current Pulse Duplicator uses an electromagnetic flowmeter made by Carolina Medical Electronics. The device measures the flow channels of either the aortic or mitral sites of the Model Left heart. The unit provides reliable operations in accurately measuring 2-15.4 l/min spectrum of blood flow. A panel meter indicates mean volumetric flow in ml/min and the frequency response is selectable up to 100 Hz. The system works with the data acquisition system. Below (Figure 1) is a figure of ViVitro's current flowmeter.

Figure 1: Current Flowmeter from Carolina Medical Electronics

ViVitro is planning to develop a new flowmeter for their Pulse Duplicator system. As requested, we conducted research on different technologies that could be used. Additionally, an analysis of similar products by ViVitro's competitors was conducted to determine their products specifications currently released.

Different Flowmeter technologies have advantages and disadvantages relating to fluid viscosity, measurement accuracy, and price. The research indicates that electromagnetic, ultrasonic doppler, and laser doppler flowmeters are feasible sensors for the Pulse Duplicator. These flowmeters have no effect on the pressure or temperature of the fluid, they have no moving parts, and cannot be clogged which makes them reliable and low-maintenance.

1.3.1 Electromagnetic Flowmeter

Electromagnetic flowmeters measure the voltage induced when a conductor, in this case a liquid, passes through a magnetic field. An electromagnet generates a magnetic field using an electric current; electromagnetic flowmeters do the reverse. They produce an electric current by passing a conductor through a magnetic field in what is called the electromagnetic induction process.

1.3.2 Ultrasonic Flowmeter

An ultrasonic flow meter measures the velocity of a fluid using ultrasonic transducers. The flow meter can measure the average velocity along the path of an emitted beam of ultrasound. This is done by averaging the difference in measured transit time between the pulses of ultrasound propagating into and against the direction of the flow. Another method of measuring the average velocity is by measuring the frequency shift from the Doppler effect.

1.3.3 Laser Flowmeter

A laser doppler flowmeter works similarly to the ultrasonic doppler flowmeter, but uses the doppler shift of light, rather than sound. A laser is passed through a moving fluid, and the light's frequency is changed by the doppler shift. Often, two lasers are used: a measurement beam, and a reference beam.

1.3.4 Pros and Cons

In this section, the pros and cons of each flowmeter are discussed in relation to ViVitro's requirements. The table below summarizes the pros and cons of electromagnetic, ultrasonic and laser flowmeters.

Flowmeter Type	Pros	Cons
Electromagnetic	● No moving parts ● No obstruction of flow ● Almost zero pressure change ● Accurate to +/-0.25% of reading ● Responds well to rapid flow changes ● Service life of 75 years	● Accuracy affected by air space in pipe ● Water must contain a certain amount of Microsiemens (uS)
Ultrasonic	● No obstruction of flow ● Does not contaminate processes ● Flow range typically 100:1 ● Can be used with corrosive fluids ● Low costs of installation ● Insensitive to changes in temperature, viscosity, density or pressure, however sensor chosen must be able to work with desired temperatures	● The accuracy of ultrasonic flow meters becomes much less dependable when the flow rate drops below 2 ft/s ● Any number of unknown internal piping variables can shift the flow signal and create inaccuracies ● Scaling, pitting, and fouling that can occur over time in older piping systems can be problematic
Laser	● No obstruction of flow ● Very high frequency response ● Very high accuracy when used correctly	● Sufficient transparency is required between the laser source, the target surface, and the laser receiver. ● Accuracy highly dependent on alignment of emitted and reflected beams. ● Expensive (Prices have dropped due to commercial lasers maturing)

Table 2: Flowmeter Research Comparison

After we had completed our research, our recommendation was the electromagnetic meter. Having completed his own research, the team at ViVitro was also leaning towards electromagnetic. Our recommendation came almost purely from general research about flowmeters as ViVitro's competitors did not make their products information easily accessible. The following sections discuss ViVitro's competitors.

1.3.5 BDC Labs

BDC Labs has created a pulse duplicator known as the HDT-500 Pulse Duplicator System. The HDT-500 is designed to generate physiological flows and pressures for testing heart valves while giving full visibility of the device [1]. This device is analogous to ViVitro's Pulse Duplicator. BDC Lab's flowmeter uses either Ultrasonic or Electromagnetic technologies. When monitoring flow, their flowmeter measures a flow rate of 0-10 L/min with a frequency of 2-240 bpm [1].

1.3.6 BoseElectroForce

BoseElectroForce created a pulse duplicator of their own known as the DuraPulse. However, no significant evidence showed that BoseElectroForce also manufactures a flowmeter [2].

1.3.6 Dynatek

Dynatek has also created a pulse duplicator known as the MP3 Pulse Duplicator. However, no significant evidence showed that Dynatek also manufactures a flowmeter [3].

1.4 Document Management Tools

ViVitro keeps all of it's documentation organized and available to employees using DBWorks. DBWorks is software that allows for revision control of documents and notes. Information can be split into categories and milestones, and can be organized in a large array of ways. ViVitro's documentation is in a variety of formats including plain text, use cases, flow diagrams, sticky notes, storyboards, sketches, spreadsheets, and drafts. They must be able to compile a design history file (DHF) that outlines the entire history of a product to verify it's safety to be compliant with the necessary standards of the product based on given FDA and Health Canada standards.

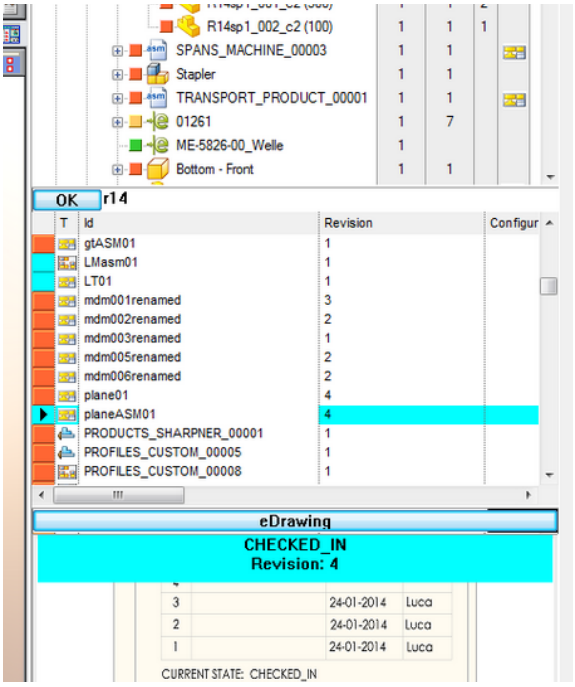

Figure 2: DBWorks Software

1.5 Requirements Documentation

Requirements specification and documentation at ViVitro is a very well thought out process. The template ViVitro uses for their requirement specification is designed to outline all possibilities within any project including business requirements and specifications. The template is filled out with preliminary information and is amended based on employee and customer feedback.

1.6 Stakeholders

ViVitro's customers belong to a niche market. Most of their customers use the products as expected, but twenty to thirty percent have been known to use the devices for special cases, one of which includes organ growing. For the special cases, customers often make requests for modifications. For such requests, ViVitro weighs the costs and customer demand in order to determine whether they should put it into development. In general, ViVitro puts an effort to involve their customers in the cycle as much as possible while changes to requirements can still be made.

ViVitro often visits their customers unannounced after releasing a product. Their focus is to get contextual information by asking relaxed questioning when visiting their users. Using this technique, users are more likely to voice their concerns and feel more confidence in ViVitro's attention to them.

2 The Development Process

ViVitro uses a gated waterfall method for product development for several reasons. Medical devices need backwards traceability and verification of requirements throughout the entire development process. Additionally, ViVitro mainly creates hardware products where rapid and iterative prototyping would be prohibitively expensive. Consequently, ViVitro finalizes several tasks at each phase of development before continuing onto the next phase. Specific phases of the development process are explained below.

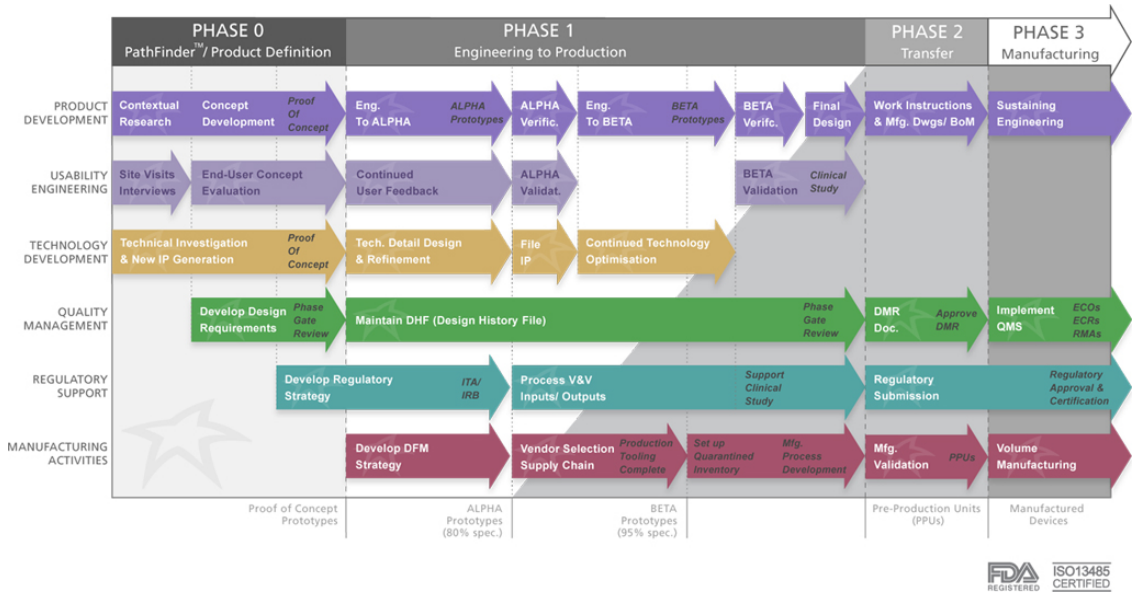

Figure 3: Process Overview

2.1 Elicitation

Developing an explicit requirements specification template is ViVitro's initial primary goal for new projects. The template is designed to consider all possibilities of all aspects when designing their products However, before the document can be filled out, information must be gathered about their base requirements.

Due to the maturity of the company and the niche market, ViVitro does not have any formal elicitation procedures. ViVitro is experienced developing products in a very specialized market, so they have an understanding of the requirements and product specifications needed for a new product. The steps between elicitations at ViVitro are discussed in the requirements specification section below.

2.2 Requirements Specification

Management initially gathers information about competitors and available technologies, and then creates a first draft of the requirement specification. The draft includes features and requirements that may not be feasible to ensure nothing is forgotten. It also contains any medical standard protocols that must be followed. Upon completion, the draft is shared with employees for review. Continuously, employees review the document, and then meet to discuss changes.
The meetings help to ensure nothing is missed and create a general consensus with the document.

After the company is confident about requirements specification, it is shared with customers through conference calls and sometimes in person meetings. The customers can give feedback to help management find missed or unforeseen requirements. Management also uses the customer feedback to gauge if the product is moving in the right direction.

On completion of the meetings and customer interaction, a refined document will have been generated. This version of the requirement specification document will be detailed and it will hold all of the information necessary to move into feasibility studies and prioritization.

2.3 Feasibility Studies and Prioritization

Feasibility studies are conducted multiple times throughout the project. Meetings are organized in which management and the engineers can discuss the cost and the return on investment for each feature in the specification document. Management can display their desire for various features and requirements while the engineers can calculate and give their best estimates. In these meetings every single requirement and feature will be completely discussed and estimated before moving on. From here the requirements and features will have to be prioritized.

ViVitro has to keep a number of things in mind when prioritizing features and requirements. The chosen features and requirements must not prevent the product from evolving secondary features, cost should be minimized where possible, engineers should deem it feasible, and mandatory requirements must not be compromised. Management also questions themselves such as “Do we care about this?” and “Does this branch too far from the product line?”. The prioritization process is held through a number of meetings between management and the Starfish Medical Engineers. If it is decided that the mandatory requirements cannot be completed in the required time limit and budget the project will be canceled at this point.

Once the features and requirements have been prioritized, they will be shared with a select few customers. This will give the team an opinion on the features and requirements already generated as well as any other features that the customer may want. ViVitro relies on one or two of their lab technicians to determine whether a requested feature or requirement may be

out of scope or not. Management also asks itself if the new feature follows the company goal and who the company wants to be. After discussion, some features and requirements may change priority or be added to the list from the customers input. Features and requirements that make it to the first release are recorded for future reference.

Once the entire feasibility and prioritization process is complete the document will be refined further and nearing completion. More meetings may be held to fine tune the specifications document. Once the requirements specification document is completely finished it will be given to the engineers again. If the engineers agree with everything on the document then the document is used like a contract, the engineers agree they can do all points mentioned with the resources mentioned and that's what they abide by. During this process a multiple hundred page test document will be completed that will outline all of the testing that has to be completed on prototypes and everything that has to be re-tested if a change is made to the product. After, both documents are completed they have to be verified due to necessary standards of the product based on given FDA and Health Canada standards.

2.4 Prototyping

ViVitro's prototyping begins with an alpha test that transitions to a beta product and ends with a production quality item. Prototypes are built at each step of their process to reassess the design.

The alpha prototype concentrates on the main features of the product. In the case of the electric flow meter, this would be measuring flow. If the prototype cannot do that, then they know if the project is worthwhile or not. Once the alpha prototype is finished, ViVitro will present it to select customers and let them provide constructive feedback. This is arguably the source of their most important feedback. These prototypes are also used for marketing. Taking the product to the customer and getting their opinion makes the customer feel involved in the design of the system. This will result in a tendency for the customer to brag about the equipment and the company.

The alpha prototype will be used to aid the next iteration, the beta prototype. The beta prototype will include all of the changes needed from the alpha prototype. Once tested and confirmed to be safe for the public a final version can be developed. Sometimes, depending on the situation, more or less prototypes will be needed. The final version includes a detailed list of parts, an accurate representation of pricing, and instructions. Once all of these components are verified to be complete the product will be ready for manufacturing.

2.5 Change Management

Physical changes to a product can occur at two points in its lifecycle. During the prototyping phase, issues in a product's design can be revealed. In order to make a change, the change must first be evaluated in terms of cost, importance, and value. If the change is decided to be made it it will be completed for the next prototype. Sometimes there will be divisions in the market for the desired use of the product, in this case the product may be broken into two versions for each customer base. All variables affected by the change must then be retested.

Occasionally, ViVitro will change a product after it has been released. A change can be initiated by either a customer submitting a complaint, or an engineer submitting an Engineering Change Request (ECR). In both cases, management evaluates the cost, importance, value, and other relevant aspects of making the change. The product's models and documents are revised and approved internally, and the updated information will be sent back to engineer for review. Once all pertinent factors in the change in product are reviewed by management and the engineers all standards and protocols correlated with the product will have to be re-evaluated. After being approved, the changes will be released to the public. If management does not make the change the request is documented for future review. It should be noted that most it is rare for a hardware change to be made to the product after release. However, all customers will be contacted if any change is released to the public for the current version of the product.

If the change or upgrade to the product is unique to the 20-30% of their customers that do not use the product for its foreseen value, the upgrades will be advertised on their website. This shows that ViVitro is versatile, which is admirable for potential customers.

2.6 Product Maintenance

Requirements and features that were deemed secondary goals and therefore left out of the initial product release are archived and drive development of future releases. ViVitro also receives feedback from their customers who have experience with the previous and current versions. These insights are integrated into successive releases of future products.

ViVitro provides support and service with their products, which includes replacements and repairs depending on a product's warranty status. It is common for customers to have problems with a product without contacting ViVitro for help. ViVitro management often tries to visit customers on the fly when they are nearby. These impromptu visits do a great job of promoting customer loyalty and satisfaction. ViVitro chooses a time with all products when support and service will be discontinued.

3 Recommendations for Improvement

While working with ViVitro we found that their requirements specification process followed many of the same procedures we learned in class. Due to this, it was difficult to think of or research anything that may help ViVitro with their requirement specification process. Any new documentation programs can be painful and take time to learn and they use as many of the requirement specification methods we learned in class as they can. However, we were able to find one thing that was mentioned in one of the meetings.

The most demonstrable benefit that the team was able to provide to ViVitro, other than aforementioned research, was to suggest a more efficient and encompassing method of creating and tracking meeting minutes. Our contacts, Gerry and Joe, reported that their meeting notes were not as effective as they want. After conducting research, the team decided that Minutes.io would best solve these problems. The team made recommendations to Joe and Gerry and recent meetings have since included the use of better meeting minutes techniques.

4 Comparison to Class

The Seng 321 lectures were mostly concentrated on the waterfall development process and many of the techniques learned in class are also used at ViVitro. Below, some of these techniques will be mentioned and discussed.

4.1 Elicitation Techniques

One of the largest differences between what was learned in class and what ViVitro does is their elicitation process. In class we participated in interviews and we also learned about a variety of other studies such as questionnaires, longitudinal studies, and observation. At ViVitro elicitation begins with research of competitors and current technologies in the current market. ViVitro does not want to go to customers for information at the beginning because if the product is canceled customers will be left in false desire. However, once ViVitro completes their own elicitation they will move onto gathering information from customers as well.

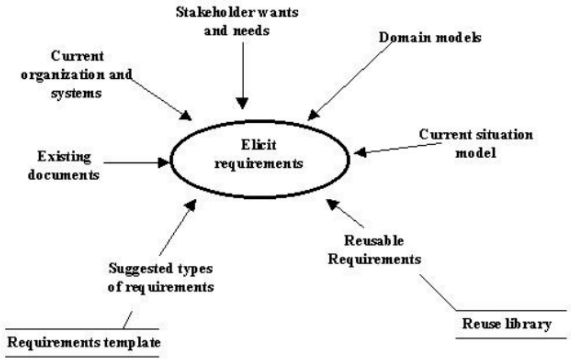

Figure 4: Elicitation Techniques

Above, a diagram taken from class gives a good overall representation of how ViVitro does elicitation.

After ViVitro gathers all the elicitation information and starts to form their Requirements Specification (RS). In class, we constructed a Request For Proposal (RFP) followed by the RS.

4.2 Requirements Specification

Initially, ViVitro uses a requirements specifications document to communicate with their stakeholders and clients. The document confirms functional and non-functional requirements of the various project devices. Below is a table listing a subset of the functional and non-functional requirements ViVitro considers.

Functional	Non-Functional
User Interface Technology / Platform Input / Output signals Power Supply and other connectors Linearity System Vibration AC and DC Voltages Power Consumption Accuracy ...	Physical Environment Users and Human Factors Resources Compatibility System Interfaces Mobility System Assembly Safety Reliability Regionalization Budget Timeframe ...

Table 3: ViVitro's Functional and Non-Functional Requirements

4.3 System Modeling

ViVitro mainly engineers hardware devices; therefore, their system modeling techniques are different than discussed in class. In their requirements specification they have basic use case modeling. Instead of determining each input and output the user can perform on the system, they summarize by listing the main actions that the user will do with the system.

Before constructing a prototype, ViVitro designs and builds their product in solidworks. This technique was not discussed in class as a modeling technique; however it is very powerful when used for hardware-based systems. After building, testing, and simulating their product in solidworks, they can move to developing their alpha prototype.

The intent of the alpha prototype is to be heavily criticized; this way ViVitro gains lots of feedback. The alpha prototype would fall into the high fidelity category because ViVitro needs to build a complete system to get proper feedback. For example, how would they know if the texture of the controls is correct if they didn't build the system and use the controls with slippery gloves? It is later that ViVitro develops a beta prototype which acts more as a finalized product that can be heavily tested.

4.4 Feasibility Studies

ViVitro performs various feasibility studies including focus on such topics as Operational, Technical, and Economic feasibility.

1. **Operational Feasibility** is the likelihood of success of a software/hardware solution in its operational environment.
2. **Technical Feasibility** is the likelihood the product will meet the performance requirements, deliver the necessary data, and also determines if the technologies to implement the project exist.
3. **Economic Feasibility** is the likelihood of the gains outweighing the costs.

As part of Economic Feasibility, ViVitro conducts cost analysis and estimation studies to determine if the monetary outlook allows development to continue while also considering the inevitable ongoing maintenance and update costs into the future. They use an informal expert judgement to perform cost estimations. Their process usually involves gathering expert employees and making estimates on the requirements.

4.5 Validating Requirements

To validate their requirements, ViVitro develops a test plan approach that contains test cases that are reproducible by anyone. The test plan measures most of the requirements with the test cases, and upon completion, it is reviewed by quality assurance. Management receives the feedback and makes any appropriate changes. The test plan, ViVitro's test results, and the raw data are subsequently shared with the customer.

Having this type of test plan is important so the customer can perform the same tests, and share the data with ViVitro. This technique benefits both ViVitro and the customer; ViVitro's product receives additional testing, and the customer receives verification that their product is functioning properly. A customer who suspects that their product is faulty can reference the test plan and compare their results.

4.6 Prioritizing Requirements

ViVitro prioritizes requirements based on the value they bring to the product, customer demand, engineering feasibility, and cost to implement. The priorities of each feature can change between each elicitation step as more information becomes available.

4.7 Change Management

As mentioned in previous sections, ViVitro handles change management through customer requests, prototype testing, and engineer requests. A change will only occur after a thorough evaluation of the costs and benefits. It is uncommon for changes to happen on versions of the product that are already released; however, changes to the requirements documentation are quite frequent.

In class we spent some time learning about the requirements traceability during change management. When changes are made in the requirement specification management has to be careful to coordinate those changes with all other documentation; if one changes causes other documentation to be incorrect, then it must also be updated. This is an important step in order to keep the progress of the project visible. We learned that some companies use formal procedures for change management and in a way ViVitro does do this by keeping organized and consistent requirements documentation.

5 Conclusion

The requirements engineering process at ViVitro is very similar to the process shown in class. The class puts emphasis on the well documented requirements engineering processes, and at ViVitro, due to the strict nature of medical device licensing, backwards traceability is needed throughout the entire development cycle. This backwards traceability ensures that any encountered issues are able to be linked to their source. ViVitro designs hardware that must meet specific goals and must be well tested, which is appropriate for a gated waterfall method.

The checks and balances that restrict the waterfall method to a series of discrete ‘gates’ are necessary in the medical field to prevent catastrophic anomalies. A contamination of the product manufacturing phase may affect large quantities of clients. If a product was improperly purified and shipped to a client, remaining biocontaminants may cause bio-growth inside the testing vessels which results in damaged equipment and dangerous conditions that promote future growth. A strictly implemented gated-waterfall process impedes instances such as this from occurring.

ViVitro’s software component has a substantial track record of success and reliability over long timeframes. Without a need for rapid turnaround and fast development cycles, ViVitro harmonizes with the stringent protocols of the medical industry. There is no contradicting influence from required software upgrades that would create blocks in the process due to constraints from safety checks. Because of this, the methodical process ViVitro adheres to allows for products to be thoroughly tests to a high degree of confidence over significant timescales.

6 References

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