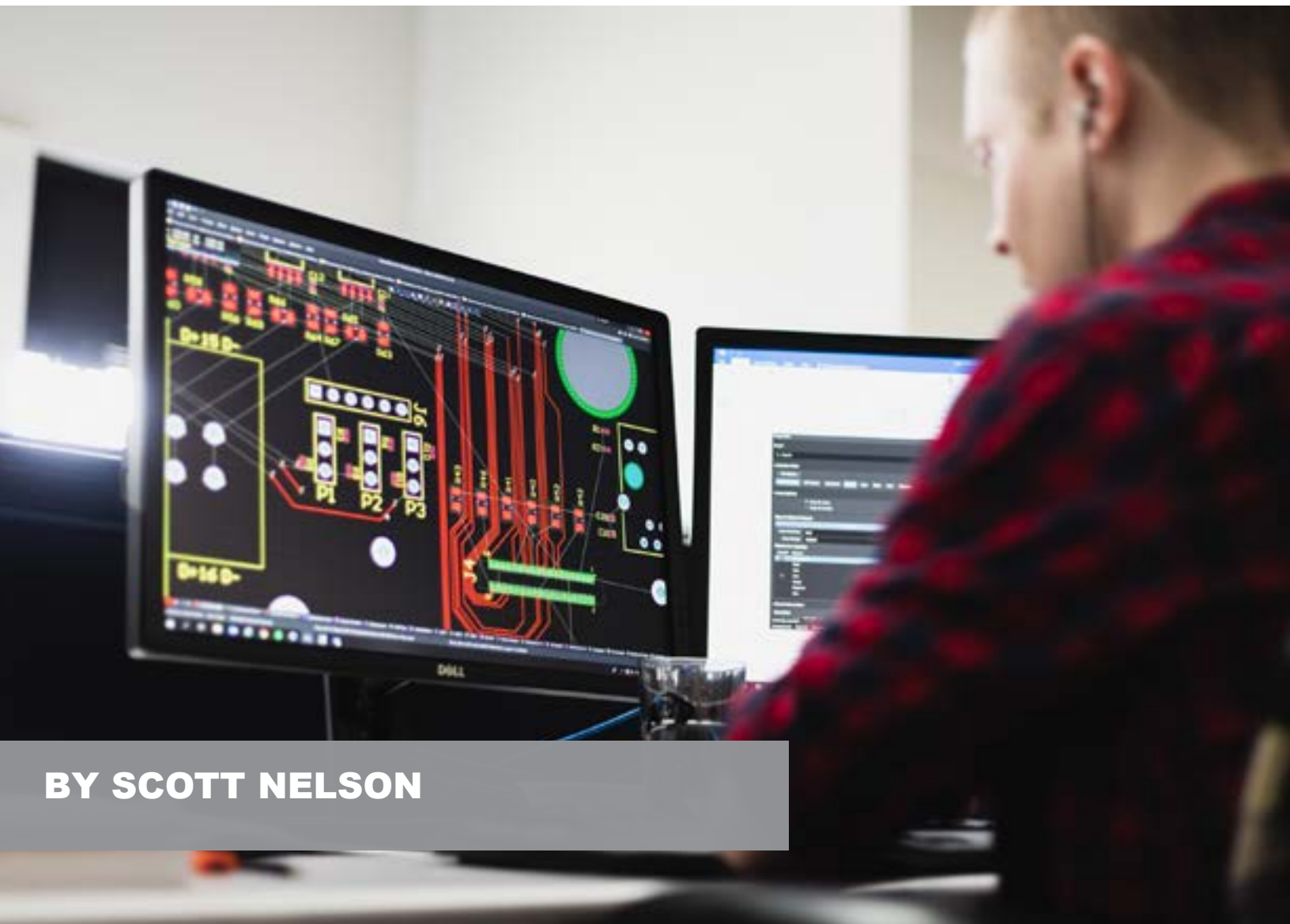


# ACHIEVING PRODUCT EXCELLENCE

*WITH THE SYNCRONESS  
PRODUCT DEVELOPMENT  
PROCESS*



**BY SCOTT NELSON**

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# INTRODUCTION

**“WE ARE STUBBORN ON VISION. WE ARE FLEXIBLE ON DETAILS.”**

**- JEFF BEZOS, AMAZON**



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A [study](#) by the McKinsey Global Institute provides the following insight: more than 50% of new products fail to hit business targets. Products fail for reasons ranging from pricing strategy and revenue forecast errors to misunderstanding of the target consumer and what they want, or poorly communicating the best aspects of the new product and the value for the end customer.

With so many opportunities for failure, coupled with a free market and a global economy, product development has never been more challenging. Despite these challenges, companies have learned through experience to develop methodologies, processes, and team roles that give the development project a higher chance for success. There are many approaches to product development, but development partners with a demonstrated record of winning give you a much higher chance of success.

This book explains the Synchroness Product Development Process, which collects more than 20 years of company experience and best practices learned through thousands of projects while developing products for more than 700 clients. Through our experience, we've developed a process that has a strong, proven vision, but remains flexible to client needs and evolving industry demands.

## PHASE 0:

# PROJECT EXPLORATION

The first step of product development is project exploration. Project exploration rapidly brings the development team up to speed on the project.

### Technical Q&A

Through interaction with technical SMEs, the product development team reviews the formal Request for Quote (RFQ) and any supporting slides, market research, CAD data, and critical product and project requirements that help define project objectives. This communication forms a relationship between technical experts and all of the stakeholders involved, which is critical for the project's success. The respective technical groups must work like a collective team to address issues and questions rapidly – and they must be on the same page as far as project goals and potential tradeoffs that may arise throughout development.

### Detailed Estimation to Define Overall Project Cost

After Synchroness has a clear understanding of the technical aspects of the project, we develop a Work Breakdown Structure (WBS) that captures the cost and schedule involved with executing the development effort. Because product development is what we do, all day every day, we understand what it takes to get the program scoped from end to end. A resulting proposal consists of the following:

- Executive Summary
- Project Plan or Execution Strategy
- Work Breakdown Structure (WBS)
- Assumptions
- Risks
- Deliverables
- Schedule
- Budget

We create proposals that capture each phase of the project and include the critical items identified above to help ensure alignment with our client. The proposal relates directly to the client's RFQ and also identifies mitigation strategies for known risks.

## HOW TO WIN THIS PHASE

Product development is an explorative journey, not an automated process. Once the team delves into the project, hurdles invariably come up, and they have to change course. Synchroness navigates these challenges through our Agile project development approach.

# AGILE PRODUCT DEVELOPMENT

**AGILE AND SCRUM HELP TO DELIVER THE DEVELOPMENT SPEED OF A STARTUP WITH THE TECHNICAL QUALITY OF AN ISO-CERTIFIED MANUFACTURER.**

The [Agile Manifesto](#) describes values that deliver tangible value to the customer. These values are:

- Individuals and interactions over processes and tools
- Working software [product] over comprehensive documentation
- Customer collaboration over contract negotiation
- Responding to change over following a plan

The benefits these values provide are:

- Technical debt does not accumulate within the project
- The team addresses high-risk aspects of the project first
- SMEs provide useful feedback can when there is still time to incorporate it
- There are more opportunities for stakeholders and team members to get together and gain a common understanding of the project and product
- The status of all tasks is transparent and visible to all team members and stakeholders, and each task has a single owner for accountability
- Technical databases are not allowed to have error-laden components checked into them
- Design reviews are formal and rigorous, without being personal

Synchroness applies Agile to our projects with Scrum methodology. This approach breaks development tasks into two-week sprints. These mini-projects undergo a planning phase, intermediate touchpoint meetings, and a review at the end. The sprints allow rapid execution of course corrections and maintain technical accuracy while adhering to a defined timeline. We collaborate with your team throughout the process to incorporate the evolving expectations during development, inspiring confidence in the deliverable at every step.

Scrum empowers development team members to react to problems as soon as they arise. Identifying the issue expedites the time required to correct it. Agile and Scrum help to deliver the development speed of a startup with the technical quality of an ISO-certified manufacturer. Because this project management style includes rapid starts, checks, and stops, you can modify or add some requirements to improve the final product without delaying the launch.

## PHASE 1:

# REQUIREMENTS ELICITATION

The development team begins with the review of customer-defined requirements and generates additional requirements based upon project inputs. The Synchroness team extracts these requirements by thorough review of inputs and careful, but deliberate dialogue with the customer. This acts as the first step in requirements elicitation and helps to set direction for project objectives.

### Regulations

When applicable, standards that apply to a given project are reviewed and distilled into additional requirements to ensure the end product meets the specified standard. The Synchroness team applies this expertise to a wide variety of regulatory landscapes and it allows us to integrate compliance into the development, rather than risk a late-project redesign to meet a regulation.

Standards such as IEC [60601](#) (medical electrical equipment), IEC [62304](#) (medical device software), and [DO-254](#) (airborne electronic hardware) are examples of standards that Synchroness has implemented in product design. Additionally, ISO [13485](#) (medical device quality management system) and AS9100 (aerospace quality management system) provide a tremendous value to customers, giving them the confidence their design partner is developing products consistent with industry best practices to assure quality, and proper documentation.

### KPIs

In the same way, we identify KPIs to monitor design goals throughout the design process. Potential KPIs are mass, cost, takt time, and yield. These metrics, while soft requirements only, help to guide any development assumption to ensure the project is moving toward your desired outcome.

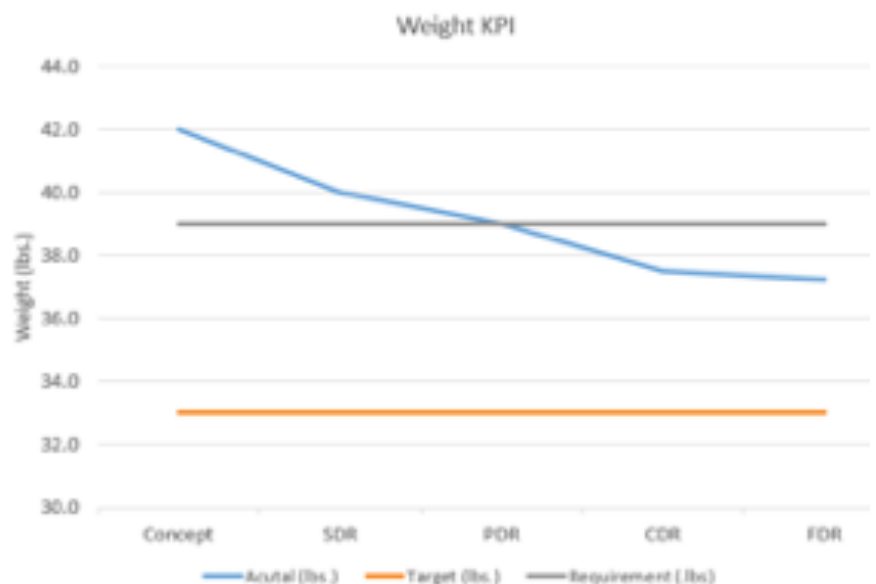


Figure 1: Example KPI chart.



## TRL Designation

To quantify the general level of subsystem risk, we prescribe a technology readiness level (TRL) approach to a given attribute or solution. These values align the combined project team relative to how close the design features are to being production-ready. KPIs can be used to help monitor TRL progress.

## Verification Plan

Once our team elicits the initial requirements, checks applicable regulations, defines KPIs, and assesses technology readiness, we create a verification plan. This allows us to test the product against defined success criteria to confirm that it meets the technical requirements. One of the ways Synchroness ensures technical requirements and assesses market viability is to delineate “verification” from “validation” as is done by quality systems:

- **Verification** confirms that the Synchroness design meets your technical requirements
- **Validation** is an action you take to confirm that the product we designed meets user, stakeholder, and business needs

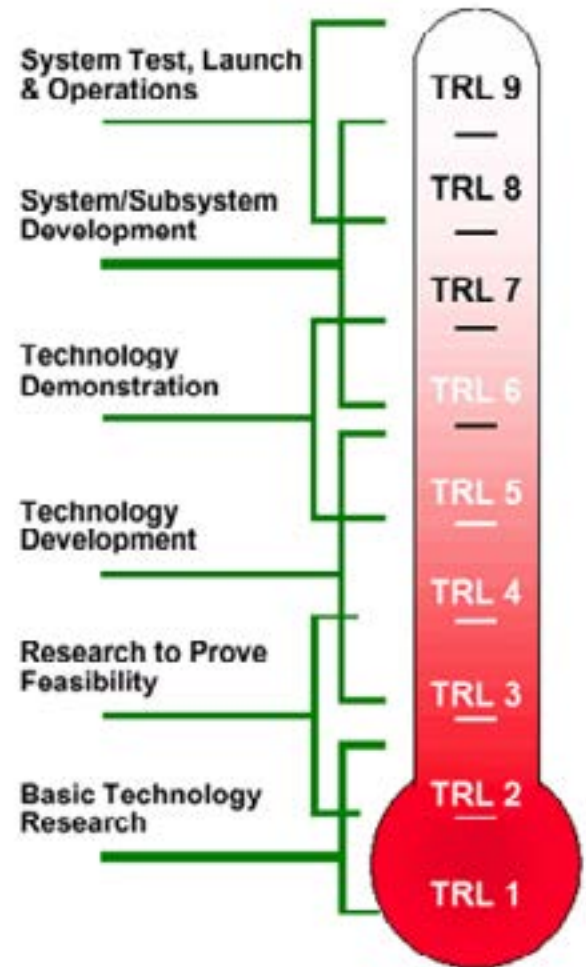


Figure 2: NASA technology readiness levels.

## HOW TO WIN THIS PHASE

If the aim of a development project is not on target, it is highly likely the outcome will be unsuccessful. Having a designated person to own this process can be extremely valuable. Companies have devised numerous approaches and rigid processes to try to dictate the desired result. However, these traditional approaches lack the flexibility required for a successful launch. Synchroness has incorporated a dedicated role to bridge technical accuracy with project management: the Systems Engineer. Collaboration between the Systems Engineer and Project Manager is the most critical part of achieving the desired result on time and within budget.

# THE SYSTEMS ENGINEER

The Systems Engineer functions as the product owner and technical leader. They work closely with the Project Manager to ensure the technical direction aligns with schedule and budget considerations and leads the Agile development process.

The Systems Engineer also leads the elicitation of requirements, oversees their implementation, and ensures they are verified prior to delivery. They consider all aspects of the product, from how its subsystems interface and communicate, to how the system should look, feel, and respond during a failure. The Systems Engineer owns the overall technical performance of the product.

A Systems Engineer uses a variety of techniques to refine poorly defined requirements or identify completely new ones. These tools include trade studies, Key Performance Indicators (KPIs), Technology Readiness Levels (TRLs), and Model Based Systems Engineering (MBSE). These tools can help stakeholders align if competing requirements or opinions exist.

The Systems Engineer is also responsible for assessing technical risk and formulating mitigation plans for the product's development. At Synchroness, we empower the Systems Engineer to take a holistic view of the technical project deliverables to ensure all requirements and stakeholder needs are met.

**THE SYSTEMS ENGINEER CONSIDERS ALL ASPECTS OF THE PRODUCT, FROM HOW ITS SUBSYSTEMS INTERFACE AND COMMUNICATE, TO HOW THE SYSTEM SHOULD LOOK, FEEL, AND RESPOND DURING A FAILURE.**



## PHASE 2:

# SYSTEM ARCHITECTURE

After completing the Requirements Elicitation phase, the Systems Engineer creates the system architecture.

Systems engineering is a broad discipline that encompasses many facets of product design. The Systems Engineer utilizes multiple inputs such as trade studies, concept design explorations, and requirements, to drive the creation of a block diagram, capturing the various subsystems and the environment that define the end product. This ensures comprehension and accounts for all interlinking facets of the product. Additionally, they may create flow charts to detail more complex processes or deploy a designer to develop concept CAD for the product.

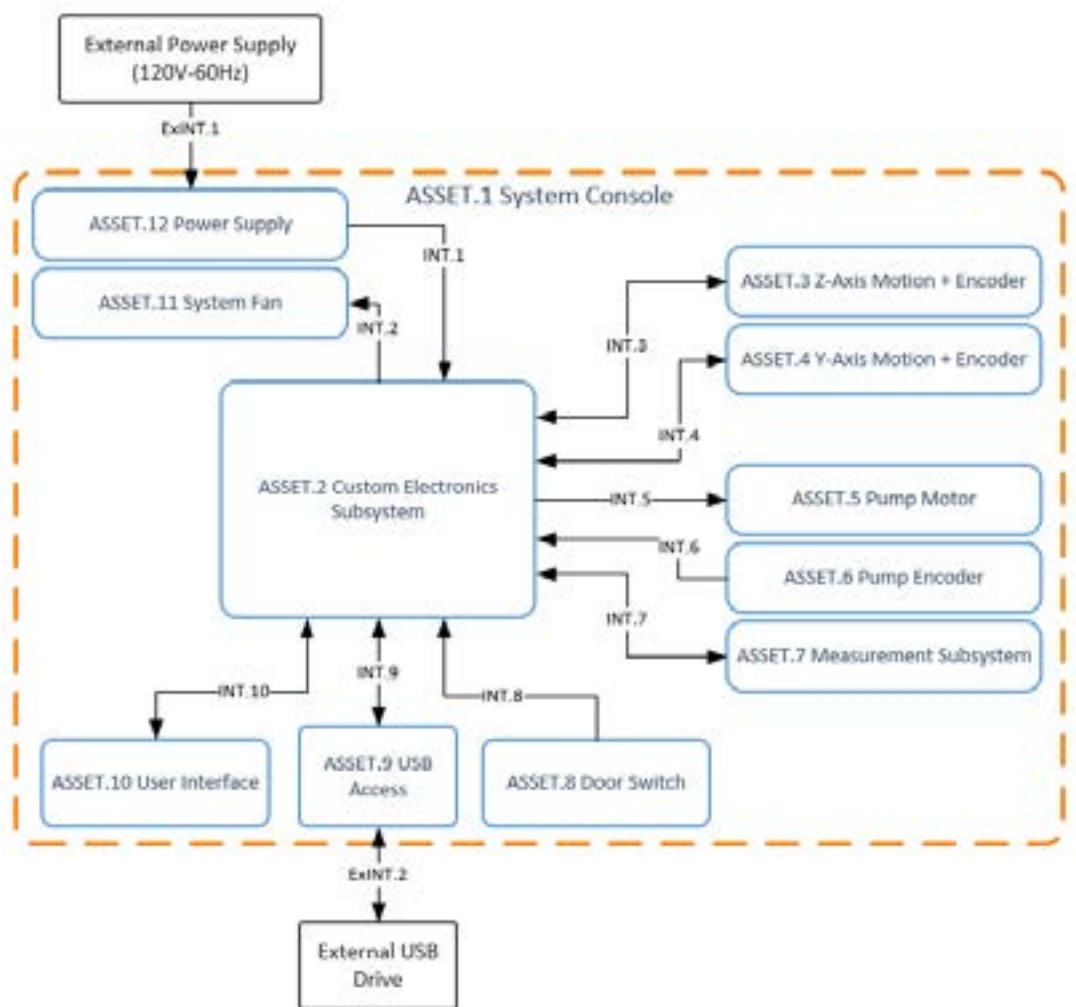


Figure 3: Example system architecture design.

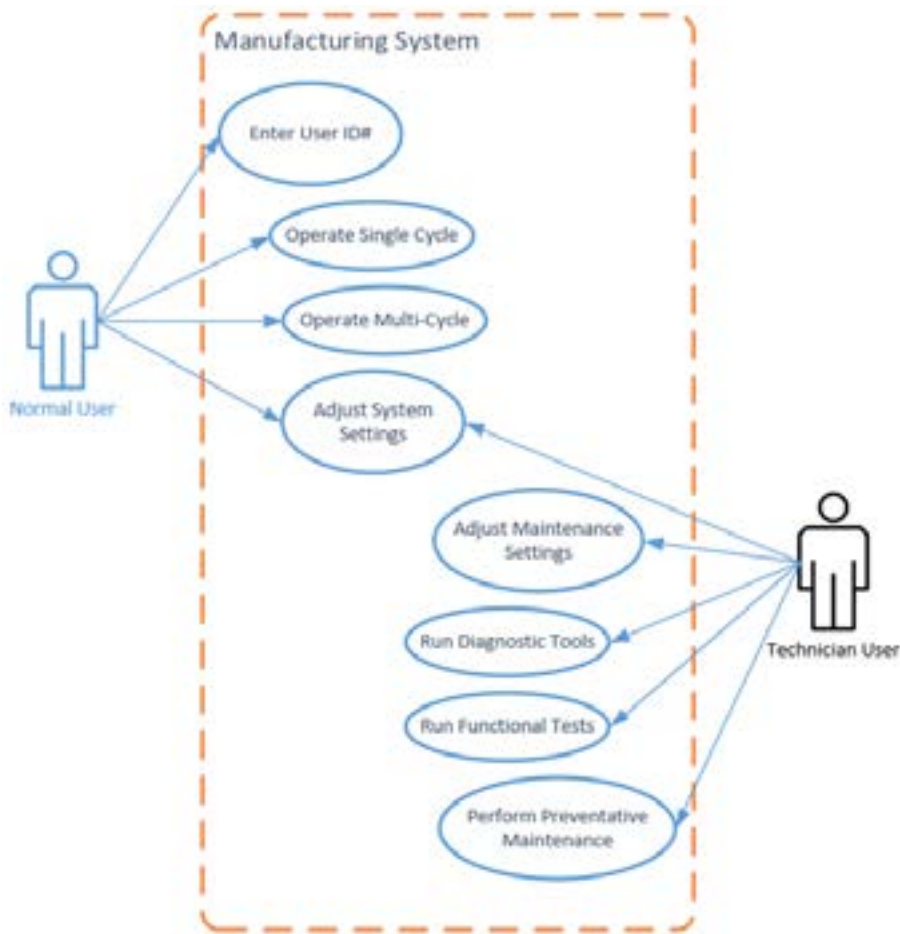


Figure 2: Example of use-case personas.

Synchroness operates differently than traditional engineering firms in this phase as well, as we define use-case personas based on your input to confirm the product actually does help the intended users and support staff. Four examples of use cases are:

1. End-user
2. Maintenance personnel
3. Service technician
4. Design engineer

While the end-user is a critical customer, how the support roles interact with the product speaks directly to how willing your staff might be to support it. At the end of the project, your firm owns the design and end-user relationships, so we integrate product usability and serviceability into the design.

## HOW TO WIN THIS PHASE

Creating the right framework for the project before diving in is a guiding principle in our approach. Conventional methods employ ideation or uncontrolled concept development and often lead to project tangents when a team member expresses an intriguing, but unrelated thought. If left uncontained, the project team will run off track.

In our method, a strong framework of tasks is used to formulate a roadmap that leads the development team from request to deliverable. With structured decision making methods, we set clear direction which guides the development toward the overall project goal.

## PHASE 3:

# DEVELOPMENT

Once we capture the system architecture and any associated concept(s), the team begins to develop the detailed product design. This phase is often the most challenging of the program, as it is where the idea truly encounters physics. The development team, however, uses the System Architecture to provide clear guidance for the prime project path and keep the project on track and on schedule.

### Design for X

Design for X (DfX) supports the development effort and includes a myriad of design principals and guidelines to account for process steps such as manufacturing, assembly, reliability, and more. Following these principals early allows potential problems to be fixed in the design phase when it is the least expensive place to address them. The Synchroness process takes these concepts into account to ensure product success.

A sampling of major development tasks includes:

- 3D CAD
- Finite element analysis
- PCBA design
- Software coding
- Documentation capture

### A SAMPLING OF MAJOR DEVELOPMENT TASKS INCLUDES:

- 1 3D CAD
- 2 FINITE ELEMENT ANALYSIS
- 3 PCBA DESIGN
- 4 SOFTWARE CODING
- 5 DOCUMENTATION CAPTURE

The most significant outcomes in development are achieving a quality design that meets the requirements within the least possible time (while maintaining the schedule and budget constraints) and gaining the customer's approval through detailed design reviews.

## HOW TO WIN THIS PHASE

Maintaining a balance between pushing innovative thought and mitigating risk is an art that expert design firms continually strive to achieve. Often, though, the Project Manager and the technical lead are at odds, with the project manager looking to pull up the schedule while the technical lead pulls back to deliver all of your nice-to-haves.

Synchroness again addresses this conflict with the role of Systems Engineer. Taking a holistic view of the technical project deliverables, the Systems Engineer provides the Project Manager one point of contact to define the technical risk caused by scheduling pressure. The development team employs Agile principles throughout, so the Project Manager is confident his product has cleared all the hurdles and that your team has sufficiently vetted it.

Effective interaction between the Systems Engineer and the Project Manager focuses the team on the primary mission. It also employs a process framework flexible enough to adapt to change and improvements, saving time in the long run. In other words, slowing down on the front-end speeds the back-end development time.

## PHASE 4:

# VERIFICATION AND VALIDATION

Once the team completes Development, it takes the product through verification testing to confirm it meets design requirements. Verification test failures go through failure reporting, analysis, and corrective action process (FRACAS) to address the issues. With this range of tests, the design is also checked against the regulatory landscape to ensure it has the appropriate compliance for certifications.

Once we complete our internal verification, the product sample goes to you for validation. This step is the first formal check that the deliverable meets the initial project goals for the end user. Questions to consider include:

- Do the mounting and packaging work as intended?
- How is the marketing/curb appeal of the product?
- Is the design consistent with your brand image?

Iterations in this late phase of the work can be time consuming and costly so it is important to enter V&V on the right track.



**Figure 5:** Ensuring that the deliverable meets expectations is a critical aspect of product design.

## HOW TO WIN THIS PHASE

Bringing Design for X considerations into the Development phase and having sound requirements defined in the System Architecture phase sets V&V up for success.

Similarly, employing a Quality Management System in parallel to the Synchroness Product Development Process brings critical considerations to the forefront of the program where they can be addressed inexpensively.

## PHASE 5:

# DESIGN TRANSFER FOR LAUNCH

When the product passes both development verification and customer validation, and any required regulatory submissions, it is ready for launch.

The design team collects all design outputs such as CAD drawings, electrical schematics, software code, and test reports that were stored via the formal configuration management process. Adhering to a standard process at this phase facilitates a smooth handoff to manufacturing engineering. The manufacturer can either be an arm of your company or another contract partner.

If selecting a contract partner, consider businesses that:

- Employ properly trained specialists
- Uses a formal Quality Management System (QMS), and ideally is ISO-certified
- Monitors and incorporates compliance practices to industry regulations

## HOW TO WIN THIS PHASE

Quality Assurance has numerous benefits beyond delivering a product that meets the technical specification. It is another way to show your customer or end-user that your brand represents superior products. You can demonstrate the level of rigor you followed throughout the entire development cycle.

Finally, providing QA documentation to your customer takes the burden off of them, while affording them peace of mind that they are getting a product they can trust.

# QUALITY MANAGEMENT SYSTEM (QMS)

**INTEGRATING  
OUR QUALITY  
SYSTEMS  
WITH THE  
SYNCRONESS  
PRODUCT  
DEVELOPMENT  
PROCESS  
ENSURES  
EFFICIENCY IN  
PARALLEL WITH  
COMPLIANCE.**

At Synchroness, we incorporate quality throughout each project phase. We view it as an ongoing activity, as necessary to the product integrity as any design feature.

Synchroness has achieved certification in the following quality standards:

- ISO 13485 – Medical Devices Quality System
- AS9100 – Aerospace Quality System
- ISO 9001 – the international standard for QMS

Integrating our quality systems with the Synchroness Product Development process ensures efficiency in parallel with compliance. In doing so, our engineers capitalize on the process, which we have refined over 20 years of development.

Another aspect of Synchroness QMS is vendor management. Our process mandates the use of qualified vendors that employ a high-quality level themselves. We are happy to work with supplier partners you have used in the past, provided they meet the requisite level of quality.



## OTHER CONSIDERATIONS:

# IN-HOUSE VS OUTSOURCED PRODUCT DEVELOPMENT

Innovation is the key to a company's sustainability, and in perpetuating a competitive advantage in the market.

It is easy to find ways to reduce cost, but it is an art to develop a new or improved product that the market will value. There are many ways to approach product design, polished and improved over product launch cycles, to arrive at what works best for a specific product category or industry. The challenge to businesses is that adequate development of a product requires investment, in both time and cash, before they can realize a return. Throughout this eBook, we've outlined how to approach product de-

velopment – whether you're developing a product internally or looking for what to expect when an outside partner develops the product for you.

Developing the product internally can save cost, but typically stretches the internal team and results in opportunity costs due to production launches missing their target. Both methods have their benefits, but if you're still wondering which route to take, consider the following:



**Figure 6:** Consider all costs and timelines when deciding to design and develop a product in-house, or to outsource.

## OUTSOURCING PRODUCT DEVELOPMENT

The first time a company outsources product development can be unsettling. They must relinquish some control over the project execution, but the benefits can far outweigh that discomfort. Outsourced product development is ideal when a client needs access to multiple engineering disciplines, manage regulations or certifications, or meet aggressive deadlines.

When externally developing a product, the contracted firm expands the project team's expertise on a "rental" basis, without the client having to absorb fully burdened overhead for a single project. This model provides on-demand access to experts in multiple disciplines at a fraction of the cost of a full-time equivalent. They can receive general information and leverage the team's collective experience to develop specific product solutions and Minimum Viable Products (MVPs) to aid in the packaging design and concept approval early in the development cycle.

The most significant benefit of outsourcing product design is when a company faces an aggressive deadline. The specialized design firm can move quickly with an appropriately scaled and flexible team that is not distracted by other internal obligations. Additionally, an ideal external partner can navigate the regulatory space and complete the project much faster than handling it internally while also introducing innovation into your product.

## DEVELOPING PRODUCTS IN-HOUSE

It is not possible to outsource all projects. The ever-increasing level of connectivity between disciplines makes internal team members valuable. Without consistent process and design specifications in place, it is difficult to transfer "tribal knowledge" outside. Additionally, for products requiring specialized test equipment, developing the product externally may be more difficult.

Moreover, when a highly specialized technology is the keystone of the new product, the learning curve might be too long for an outside partner. It is important not to discount an external firm's expertise in a related area, though, before committing to taking on the development project in-house.

## HOW TO WIN THIS PHASE

Companies most familiar with new product development know that that path to designing a new product is far from a straight line. The decision to outsource product design is attractive, in that it offloads the internal project team from the headaches that can arise from unplanned design challenges. Though the effective hourly rate of outsourcing is higher than an internally-quoted cost, the development time is often much less, making the total spend significantly less than managing the project in-house. Employing on-demand expertise provides higher value and more flexibility per dollar invested.

## CASE STUDY:

# WEARABLE HEART MONITOR

**CHALLENGE: SYNCRONESS WAS TASKED WITH MODIFYING THE DESIGN FOR AN EXISTING WEARABLE ELECTRO-CARDIOGRAM (ECG) DATA RECORDER TO EXTEND ITS BATTERY LIFE FROM 24 HOURS TO 7 DAYS, WHILE AT THE SAME TIME ADDING THE CAPABILITY TO PERFORM REAL-TIME ANALYSIS ON THE ECG WAVEFORM TO DETECT VARIOUS KINDS OF INTERESTING CARDIAC EVENTS.**

## DEVELOPMENT PROCESS

### Phase 0: Project Exploration

Syncroness worked with the project manager to understand that making a device wearable almost inevitably means that the device must be battery-powered, which makes managing the energy budget of the device a key concern.

### Phase 1: Requirements Elicitation

Syncroness identified that the constraints on the project were such that there was little opportunity for changing the hardware design or batteries. As a consequence, any additional battery life had to come from optimization of the firmware to reduce the amount of time that the microcontroller is awake and consuming power, and to minimize the frequency or duration of operations that have a high energy cost.

### Phase 2: System Architecture

The Syncroness team began by conducting an analysis to understand which parts of the firmware were execution-time and energy consumption hotspots, along with preliminary testing of the device to characterize its power consumption profile.

**SOLUTION:  
THE FINISHED  
SYSTEM RESULTED  
IN A LOW POWER,  
LONG-TERM ECG  
RECORDING AND  
ANALYSIS DEVICE,  
TESTED AGAINST  
THE ANSI/AAMI  
EC57 STANDARD. IT  
EXCEEDED LIFETIME  
REQUIREMENTS  
AND RECEIVED FDA  
APPROVAL TO GO TO  
MARKET.**

### **Phase 3: Development**

Synchroness software engineers tackled the task of reducing power consumption by applying a variety of different optimization techniques.

### **Phase 4: Verification and Validation**

Throughout the optimization process, Synchroness performed regular testing against the ANSI/AAMI EC57 standard for Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms to confirm that we were maintaining the performance of the ECG detection and processing algorithms. Synchroness also measured on actual hardware the difference in power consumption created by each proposed optimization to ensure that the changes we were making had their intended effect.

### **Phase 5: Design Transfer to Launch**

The end result of these optimization efforts was an extension of the device lifetime from 24 hours to 7 days without changing the battery capacity and without compromising device performance.

[Read more about this application.](#)

## CASE STUDY:

# AEROSPACE LIDAR SYSTEM

**CHALLENGE:  
SYNCRONESS WAS TASKED WITH DEVELOPING AN AIRBORNE LIDAR SYSTEM FOR THE DETECTION OF GAS LEAKS AND MEETING STRINGENT REQUIREMENTS FOR MITIGATING HIGH-VIBRATION AND THERMALLY AGGRESSIVE ENVIRONMENTS FOR A SENSITIVE OPTICAL SYSTEM.**

## DEVELOPMENT PROCESS:

### Phase 0: Project Exploration

A client developed a unique light detection and ranging (LIDAR) technology in their lab. Ultimately, they came to Synchroness to package the technology into a system that could be placed aboard a plane.

### Phase 1: Requirements Elicitation

The optics, crystals, and laser required to make the LIDAR technology work were highly sensitive to vibration and thermal influences, which impacted the overall requirements.

### Phase 2: System Architecture

Synchroness invented new mounting and thermal techniques to pull heat out of all optics benches while allowing them to breathe due to large altitude changes.

**SOLUTION:  
SYNCRONESS WENT  
FROM CONCEPT  
TO FLIGHT IN  
18 MONTHS,  
INTEGRATING THE  
CLIENT'S BENCHTOP  
LIDAR PROOF OF  
CONCEPT INTO  
AN AIRBORNE  
LIDAR SYSTEM  
ABLE TO SURVIVE  
HIGH VIBRATION  
AND THERMALLY  
AGGRESSIVE  
AIRCRAFT  
INSTALLATION.**

### **Phase 3: Development**

Synchroness engineers worked closely with the client's electrical engineers and optics and laser experts to evaluate designs for the chassis that would hold the device.

### **Phase 4: Verification and Validation**

Through thermal and vibration analysis, Synchroness tested the footprint and weight of the final device.

### **Phase 5: Design Transfer to Launch**

Synchroness reduced the weight and footprint of client's benchtop system by 50%, and most importantly, successfully mitigated the high vibration and thermally aggressive environment in which the device would operate.

[Read more about this application.](#)

# CONCLUSION

We developed and refined the Synchroness Product Development Process more than 20 years. It allows for structured and predictable project execution while flexing to invite creative solutions and improvements.

Our process employs a cross-functional team of diverse industry experience to promote open minds and creative solutions, leveraging broad expertise in all areas of the product life cycle. Synchroness captures these functions in integrated engineering disciplines that have served our clients over the two decades:

- **Mechanical Engineering**  
Mechanical Development Planning, Requirements Elicitation, Brainstorming, Concept Development, Detailed Design & Analysis, Engineering Prototype Fabrication & Evaluation, Design Revision, Detailed Documentation, Verification Testing, Validation Testing (customer), Document Transfer
- **Electrical Engineering**  
Electrical Development Planning, Requirements Elicitation, Electrical Architecture, Design & Analysis, Design Implementation, Engineering Prototype Fabrication & Evaluation, Design Revision, Verification Testing, Document Transfer
- **Software Engineering**  
Software Development Planning, Requirements Elicitation, Software Architecture, Design Implementation & Unit Test, Software Integration & Integration Testing, Verification Testing, Documentation & Program Transfer



- **Systems Engineering**  
Develop System Requirements, Develop System Architecture, Product Risk Assessment, Requirements Management, System Integration, [Failure Reporting, Analysis, and Corrective Action System (FRACAS)]
- **Project Management**  
Sales Support, Project Setup, Project Plan, Execute to Project Plan, Deliver, Closeout
- **Quality Assurance**  
Quality Process Planning and support, Development Planning Support, Requirements Validation, Risk Management Planning support, Tool Qualification, Verification & Validation Planning, Testing, Reporting, Design Transfer Support

## THE SYNCRONESS PRODUCT DEVELOPMENT PROCESS

### Proven Practices

We have a polished, modern approach to product development that has generated great results for our customers for over 20 years. Marching toward a shared vision, while organizing the management structure to adapt to change and improvements, is how Synchroness develops products that exceed customer expectations without compromising budget and schedule.



At Synchroness, we are passionate about engineering and new product development. With profound expertise in highly-regulated industries, we leverage our knowledge and transfer proven processes into success that spans across industries and into a multitude of market segments.

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