LOW-RISK IOT DESIGN:

How to Manage IoT Design Risks from Planning to Manufacture

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OVERVIEW

The IoT market is growing and many innovators are participating in the IoT revolution by designing IoT products for different use cases. According to a recent survey, the number of start-ups and innovators developing IoT solutions is 7% higher in 2019 compared to 2018[1] with respondents citing security (47%), communication reliability (23%), ecosystem (13%), edge device reliability (10%), and ease of data review and analysis (7%) as the most important aspects of IoT design.

Creating an IoT product, however, is more than just writing specs and finding the right mix of electronics — the design risks and challenges are not purely technical. IoT product development also requires project management skills. Without it, IoT innovators will fail to proactively identify and mitigate design risks — both technical and non-technical — that will surface along the way. Project management is critical to keep a project on budget and on schedule.

[1] Farnell Global IoT Survey. https://uk.farnell.com/global-iot-survey-2019

IOT DESIGN RISKS

In the interest of moving their IoT projects forward, many IoT innovators tend to overlook the areas they are unsure of and focus on what they know. They think they are doing it right when they see that the first 90% of the project is completed in just 10% of the time. But as they move forward, various risks, such as the following, become more visible and harder to mitigate:

MAJOR IOT DESIGN RISKS

Budget overrun. Lack of foresight, poor project cost estimation due to lack of data when formulating the budget, and poor project management can result in an over-budget IoT project.

Unmet deadlines. Staying on schedule requires carefully managing the design process and clear communication among the participants.

Unmet specifications. This happens when requirements are not clearly written or technical risk is not identified early.

Unmet user needs. The design meets specifications but not user needs.

Difficult to manufacture. This can be a result of poorly defined specifications, poor design hand-off, poor documentation, and lack of training.

Poor quality. Failure to do careful design often leads to poor-quality IoT products. Carefully written requirements and good project management are needed.

Failure to meet FDA or CE documentation requirements. The FDA documentation maze can be extremely difficult to handle. But carrying it out at the latter stages of the IoT project can result in various risks and costly consequences.

If you fail to proactively mitigate these risks, the last 10% of your IoT project will take 90% of the time. But with careful project management, these risks can be avoided.

HOW TO MANAGE IOT DESIGN RISKS

Successful IoT projects start with good design planning, regular and effective review and communication among all parties, proper design hand-off, and competent engineers.

1. ENSURE GOOD DESIGN PLANNING

Identify the specific design objectives as well as the members of the design team. Determine trade-offs affecting risk levels or the factors that can increase project risks such as short schedules and tight specifications. Once risk is identified, mitigate it early. Understand the priority of these factors and identify and manage slack in each. For example:

Good schedule

A good schedule is realistic, measurable, attainable, and time-bound. A realistic schedule has short milestones (see Figure 1).

When creating a schedule, include review meetings and get buy-in from all team members. Add slack time in the end to be able to manage risks across all milestones. Always work to beat the schedule because lost time can never be recovered.

Description	Hours	Ending Week
User Requirements Spec	100	4
Product Requirements Spec	50	6
Design Review	5	6
Analog circuit design	10	7
Digital circuit design	30	7
Schematic	10	8
Preliminary mechanical design	20	7
Design Review	5	8
Firmware	100	14
Parts purchasing	5	10
Breadboard assembly	10	10
Mechanical design	40	10
Breadboard testing	20	11
Design Review	5	11

Description	Hours	Ending Week	3rd Party Cost
Layout preparation	20	12	
Layout	40	13	
Layout checking	5	13	
PCB fabrication		14	$1,000
PCB assembly		15	$1,000
Fabrication of prototype enclosure		14	$2,000
Testing of PCB	20	16	
Testing of prototype unit	40	17	
Design Review	5	18	
Electrical design changes	5	18	
Mechanical design changes	5	18	
Layout changes and checking	20	19	
PCB fabrication (final)		20	$1,000
PCB assembly (final)		21	$1,000
Fabrication of enclosure (final)		21	$10,000
Testing of PCB (final)	20	22	
Testing of complete unit (final)	10	22	
Final design review	5	23	
Transfer to Manufacturing	50	27	

Figure 1. Example of A Good Schedule

Good Specifications

Specifications should be detailed enough that even someone new or unfamiliar with the project can complete the design with just the specifications. Plan for the verification test and include the final manufacturing test. Note that risks flow from requirements that are incomplete, ambiguous, and conflicting.

THREE KEY SPECIFICATIONS

1. **Marketing Requirements Document (MRD).** The description should be independent of the implementation. The specification should also be from the user's point of view. Get data directly from users or tap the Marketing team to provide inputs.
2. **Product Requirements Document (PRD).** The description implies a particular implementation. Clearly describe hardware and software functions. Match MRD item by item and ensure that they are easy to verify (test). Each item in the PRD needs to be testable with a pass/fail outcome.
3. **Software specifications.** Include a clear description for all team members and not just for engineers. Pictures of each display screen are invaluable.

Spec No.	Applicability (see note Set. 3)	Ending Week	Verification Method	Priority M=Mandatory A= Additional (see note Sect. 3)
5		**Environmental and Adaptation Requirements**		
5.1	System	e.g., The system shall be designed to operate between 15-40C, 5-95% Relative Humidity (non-condensing) at less than 3000 meters altitude.	Bench Test per ABC test method TBD	M
6		**Constraints and Quality Factors**		
6.1	System	e.g., what reliability and maintenance schedule shall the device require: Mean time between failures (MTBF) equal to or greater than 8000 hours operation.	Reliability strategy, model analysis/ Bench testing	M
6.2	System	e.g., The **device** shall require an expected lifespan of 10 (in years).	Reliablity Analysis	M
7		**Computer Resources (incl. HW resources, SW constraints), internal data, computer and printer interfaces)**		
7.1	PC Subsystem	e.g., The device shall have the following external interfaces: RS232, Ethernet, keyboard, modem.	Inspection	M
7.2	PC Subsystem	e.g., The software within the device shall be upgradable via internal CD ROM **reader**.	Inspection	M
7.3	PC Subsystem	Software devel. to existing stds., regs, including SW-68, FDA Guidelines on Software Validation and Off-the-Shelf SW Validation, IEC 60601-1-4	Verification and Validation protocols	M

Figure 2: Example of Good Specifications

2. ENABLE EFFECTIVE REVIEWS AND COMMUNICATION

Design changes and issues may surface along the way. This is why it is crucial to hold regular meetings to keep everyone posted on changes and to proactively address problems. Here are some practical tips for communicating with the team:

Always have an agenda

Use checklists, which are useful even for experts. Build it using post-project assessments. Get everyone to talk by asking questions such as "If we had a problem, what would be the cause?" Confirm if they heard and understood what they heard.

Communicate effectively

Use different channels such as in writing (e.g., specifications and review meeting notes) or verbally (e.g., through review meetings and impromptu discussions). And remember, communication is what is understood. It relies on dialog and not just transmission.

Accept that changes are unavoidable

Unexpected events such as sudden changes in user requirements and errors in planning may surface at any time. What's important is that changes are communicated promptly so they can be resolved early.

3. ENSURE GOOD DESIGN HAND-OFF

Hand-off takes place when the product design has reached the implementation or production stage. This is often a point of communication breakdown usually due to poor communication and collaboration between engineers and manufacturers.

For optimal hand-off procedures, practice the following:

Involve the Manufacturing team early

Involve them early in the sketching stage and always loop them in all conversations. This helps remove ambiguities and confusions during the implementation stage.

Keep the Design team involved as volume ramps

They can help ensure that everything is implemented according to design and clarify unclear descriptions. It is also crucial that they are aware of any adjustments to the product specs during manufacturing so they can document them accordingly.

Understand that engineers create documents, not products

They create the design documents that the manufacturing team will then translate into the actual product. Engineers, however, must provide manufacturing with thorough and understandable documents.

Ensure that manufacturing formally accepts the design documents

The hand-off must be organized. Schedule a meeting for the formal hand-off and prepare a checklist for guidance and reference of parties involved. This is the time when manufacturing should identify shortcomings in the documentation.

Ensure detailed documentation and training

Communication gaps can lead to poor implementation. Engineers and manufacturers don't speak the same language, so proper documentation and training should be implemented.

4. HIRE COMPETENT ENGINEERS

Good engineers have proven experience as well as the ability and willingness to learn new things. They are flexible in handling new and unexpected events that may arise during the design process. They can effectively communicate, both verbally and in writing.

Competent engineers, however, can be hard to find. According to Microsoft's 2019 IoT Signals survey, lack of knowledge (35%) and staff resources (34%) prevent businesses from implementing IoT.

Use consultants where appropriate, such as when you require specialized skills or for your short-term projects. Hiring consultants offers you the following benefits:

- Faster ramp for new opportunities
- Specialized expertise
- Broader perspective
- Relationships with new partners/ vendors

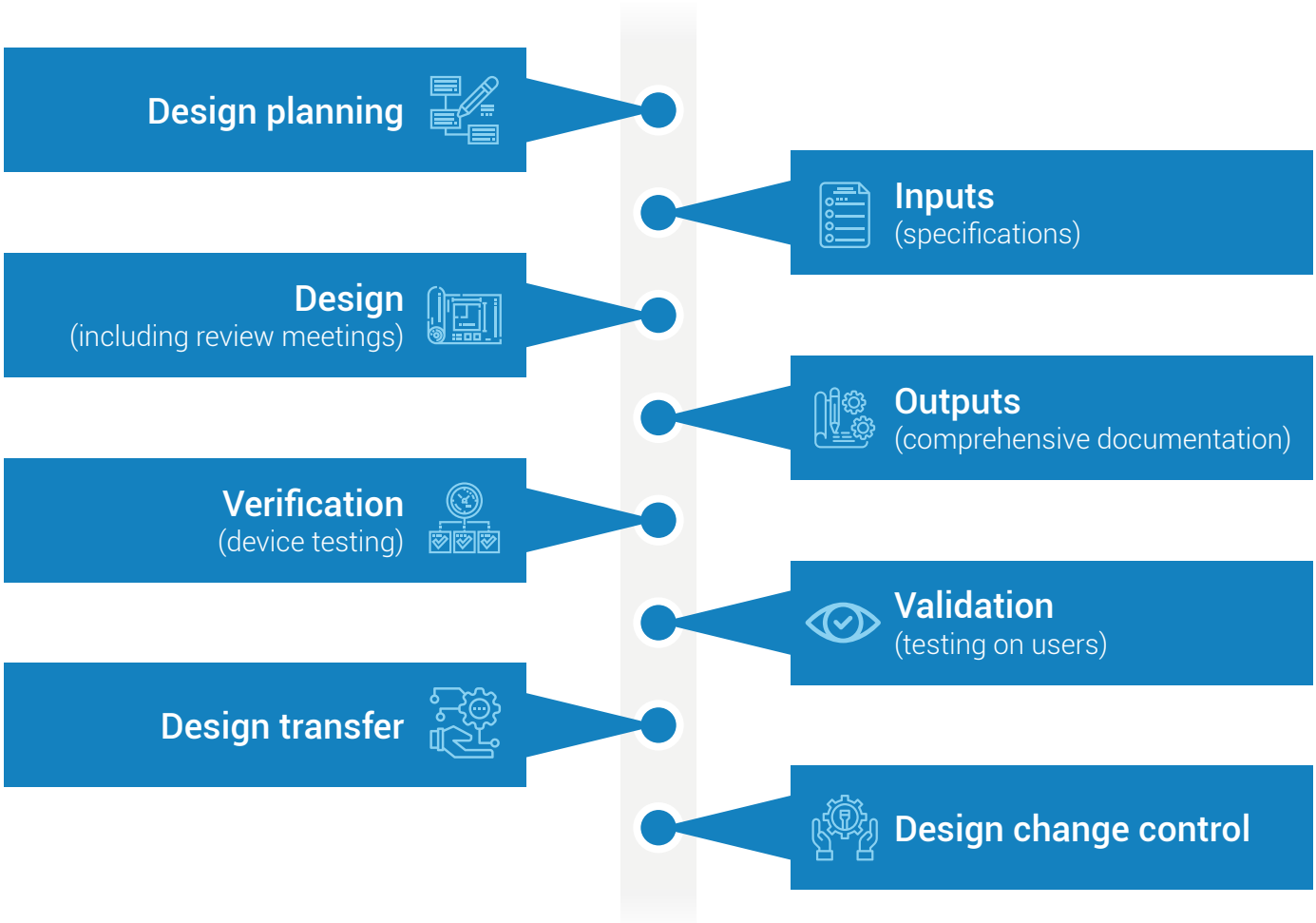
But before hiring consultants, take note of these tips to get the most out of a technical consultant:

- Clearly define your goals.
- Specify the outcomes that you need.
- Identify constraints, such as schedule and budget.
- Set regular meetings at milestones so you can address problems early.
- Determine if the compensation is hourly or fixed price.
- Understand that every consultant is different.

5. MEET FDA OR CE DESIGN CONTROL

Meeting medical device design control requirements is part of good design risk management. It is not a separate process. It should be addressed right from the beginning (or during the design stage) because failure to include this during design management can result in costly consequences later on. Understand the design control processes for FDA and CE and implement them effectively.

DESIGN CONTROL PROCESSES FOR FDA AND CE



Design, Outputs, Verification, and Validation processes can be much easier and less complex if the Input process is performed well. Time spent creating specifications, communicating, and having review meetings is well worth the investment. It can help you avoid major design risks and ensure successful design and implementation.

FINAL THOUGHTS

The Internet of Things is now an integral part of modern businesses. But while IoT adoption is growing, IoT implementations are often slow, and in some cases, have been put on hold due to various risks that businesses overlooked and failed to mitigate. At Voler, we practice careful project management to help businesses ensure that their IoT projects are on time, on budget, and easy to implement. We help various businesses across different industries with their IoT projects, providing them with competent engineers to ensure successful IoT design and implementation.

Here's what our clients say about us:

> *Voler has great resources, low overhead, and high accountability. As a result, I know what you are doing, and you are good at what you do.*
>
> *John Colombo, CALA Health*

> *Voler Systems was able to provide key engineering resources that we needed quickly for our instrument development. They are easy to work with and are genuinely concerned with our success. They have positively contributed to our engineering efforts and have been a valuable partner in helping me achieve my goals as an engineering professional.*
>
> *Scott Helgesen, Director of Engineering, Roche Sequencing Solutions*

> *Voler engineers are fantastic! They were helpful in giving direction and fine-tuning product requirements. I really appreciated the weekly calls and their candid feedback.*
>
> *Sameera Akhtar, SiTa*

> *The Voler team is impressive, knowledgeable, and responsive. They are open to suggestions and also to offering suggestions. Voler's reporting is great, and the communication is also great. I am pretty blown away by Voler's technical ability. We will certainly use Voler again. Thank you for an outstanding job!!*
>
> *Kevin Maloney, CEO of Xeeda*

Voler Systems provides R&D consulting from concept through smoothly moving new products into production. Since 1979, clients have turned to us for reliable new products involving sensors and measurement electronics. Our highly experienced team delivers high-quality products on time and on budget. We have developed wearable devices, IoT devices, medical devices, consumer products, and other specialized sensor-based electronics and prototype circuits.

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