THE ART OF MAKING GOOD ENGINEERING DECISIONS

OVERVIEW

Engineers all over the world make decisions day in, day out. Whether it is selecting a material for a component of a medical device, specifying mechanical properties required for a spacecraft sub-assembly or defining the amount of stress a bridge can withstand, engineers are expected to make decisions as it is a crucial element of their job. But how does one make good engineering decisions? More importantly, what makes a decision a "good engineering decision"? In this white paper we'll walk you through a systematic approach to good decision making in the field of product engineering.

The three areas of engineering decision-making we discuss in this white paper include:

- Knowing what's important
- Gathering and leveraging data
- Understanding relevant regulations

KNOWING WHAT'S IMPORTANT

Regardless of the activity the engineer or the engineering team is undertaking, understanding the important pieces of the activity is crucial. Only when one has understood the critical pieces, i.e. things that really matter, can one plan and execute those activities successfully. Some of this comes intuitively and some of it requires deep investigation and analysis, therefore striking a good balance between applying common sense and performing engineering work, in the true sense of the word, is what works best most of the time.

An example of this could be an engineer tasked with designing a medical device; he or she needs to understand the critical functions the device needs to fulfill and translate those critical functions into critical engineering specifications. Those specifications would in turn need to reflect device function, which meets those specifications resulting in a properly functioning device whereas not meeting them would result in product failure. What could go wrong here? A few scenarios:

- If not, the true user needs and clinical requirements are identified, the critical device functions may not address the true clinical need, and the device will be of no utility.

- If the engineer fails to translate the critical device functions into the right engineering specifications, the focus will not be on the most important device functions, which could compromise the design.
- If the specifications are incorrectly, or arbitrarily, defined, they could be overengineered, wasting time, money and resources.

Bottom line, identifying what is and what is not important for your design, process, system or whatever it is you are working on is one of the elements of good engineering decision-making.

GATHERING AND LEVERAGING DATA

"In God we trust, all others must bring data." – W. Edwards Deming

Deming was one of the great quality gurus to ever walk this earth, and this quote of his hits home.

Needless to say, good engineering decisions are factual or, in other words, based on data. Whether it is measurements, calculations, estimations or simulations, gathering and analyzing data about the problem of interest is a crucial part of making an engineering decision. Simulations, especially in designing a product or process, can be extremely useful when there is little known about certain factors. A few examples of simulations include Finite Element Analysis (stress analysis), flow analysis (e.g. how a molded component behaves) and Monte Carlo simulations (statistical simulations for probability of events occurring).

One thing to note here is that in gathering, analyzing and applying data, logic should still prevail over relying solely on calculations or statistics. Meaning, a healthy amount of common sense always, always comes in handy.

UNDERSTANDING RELEVANT REGULATIONS

Although this one should be a no-brainer, it is important to note that by understanding relevant regulations we don't mean being able to recite them. What we mean by 'understanding them' is understanding the intent. Most standards and regulations are a framework rather than black-or-white orders. Yes, you will probably find some black-or-white clauses (shall or shall not, must, must not and the likes) in a standard, but remember that most of them leave room for how one may be able to meet them. There is rarely ever only one avenue or approach that can be applied to comply with a standard or regulation.

The engineer's role here is to understand the intent of the standard and come up with a way that both meets the standard and best applies to their particular problem, organization and situation. All in all, a cookie-cutter approach to making decisions, especially engineering decisions that affect lives is never a good thing. Following the above guard rails will help stay on the right course.

CONCLUSION

As a quality engineer by profession I'm passionate about fixing problems and making things better. As part of my professional journey, I recently authored an eBook on a specific subject within quality engineering; Measurement Systems Analysis, or MSA, is a collection of statistical engineering techniques and tools to identify, estimate and ultimately unconfound measurement error from the characteristic being measured. Characteristic here could be anything physical (such as the length or height of something), mechanical (e.g. the strength of something) or literally anything that can be measured (e.g. time, on-time delivery rate, time to hire etc.).

Some of these characteristics can in fact be critical to the business, be safety-related or otherwise important. Remember the example of the engineering designing a medical device and identifying critical device functions. If those functions cannot be measured accurately or precisely, that could lead the engineer down the wrong path; on the other hand, a good measurement process can help tell a bad design from a good design, or an OK design from a breakthrough design. Also, if the device ends up being mass produced, there are typically inspections made on critical elements of it before it gets shipped to the customer. The goal here is to be able to tell a good device from a bad device.

In my book, I refer to three phases of planning and executing measurement systems analyses.

The approach mirrors the above guidelines for making good engineering decisions, but they are more specific to the world of MSA. They are as follows:

- Apply Common Sense: just like the Know What's Important section above, this phase is about understanding what is important for your study by asking practical questions about the problem you are trying to solve.
- Visualize Your Data: in this phase, you plot your data into different charts with the goal of drawing conclusions from them. Most of the time this works as the graphical representation of a problem is almost always easier to interpret than just looking at the data itself.
- Calculate Metrics: finally, you do some math and calculate summary statistics for your study to further enhance the analysis and help make better engineering decisions.

REFERENCES

[1] Practical MSA: Laying the Foundations, ebook by author Gabor Szabo; https://www.practicalmsa.com

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ABOUT THE AUTHORS

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Gabor is a quality engineer and medical device leader in the quality management and continuous improvement space with fourteen (14) years of international experience ranging from medical device, automotive and manufacturing. Gabor is author of the ebook - Practical MSA: Laying the Foundations, which provides an online platform for engineering and scientific professional education on concepts, practical tools and techniques for measurement system analysis.

ABOUT DEVICEALLIANCE

DeviceAlliance is the only multi-disciplinary, non-profit, professionals' association serving the medical device industry in Orange County, CA. We strive to be the one-stop-shop at the center of the medical device ecosystem helping drive career development, community collaboration and innovation for all device professionals in Orange County, CA. We offer engaging educational programs, mentoring, collaborative events, knowledge sharing and much more.

As a result we're the ideal place to help support medical device professionals, of all backgrounds and educational disciplines, as they formulate start-ups, expand market share for a Fortune 500 corporation or grow their individual careers.

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