8 POINT ASSESSMENT CHECKLIST

key tech

Staying Focused on De-risking Early and Throughout Product Development in the Medical Device Industry

Performance | Performance at the Limits | Sensitivity | Repeatability | Reliability | Scalability | Practicality | Interfering Claptrap

You're excited about an innovative new technology that's been proven to work in controlled settings. But will it work when incorporated into a product in real-world conditions? Key Tech's 8-Point Assessment Checklist is your blueprint for finding out. Follow it early in development and it can save you time, money and frustration.

1 PERFORMANCE

Does it work in the most basic sense?

Start by establishing a set of performance requirements that the technology is expected to meet. If you detect a gap between performance and requirements, make sure that gap can be closed and understand what it takes to close it. If a gap can't be closed, stop now.

2 PERFORMANCE AT THE LIMITS

Does it work outside best-case scenario?

Identify the good performance limits for your technology. Think of environmental annoyances like temperature, humidity, orientation, vibration and elevation. Does your technology work well on a horizontal surface, but not in the many orientations necessary for a mobile application? Does it work well in an air-conditioned building but not in a similar unconditioned lab?

3 SENSITIVITY

How sensitive is it to changes conditions?

Do you know which parameters in your technology are more skittish than others, and how to reduce that sensitivity or prevent the related environmental changes? How steady is that bias you observe in your prototype that you are planning to "calibrate out" in the product? Is it really constant or will it change with time and degrade performance?

4 REPEATABILITY

Will your technology work the same way every time?

If performance is not sufficiently repeatable in your prototype, it's OK as long as you understand why and how to prevent the variability as development continues. If you built another prototype would it work the same way as the first one? What if someone other than your core team built an identical prototype?

5 RELIABILITY

Will it last?

It is always helpful to ask early on: Is the promise of your technology based on an assumption that it will be sufficiently reliable in its product form? What is behind this assumption? Can you test against it with early prototypes?
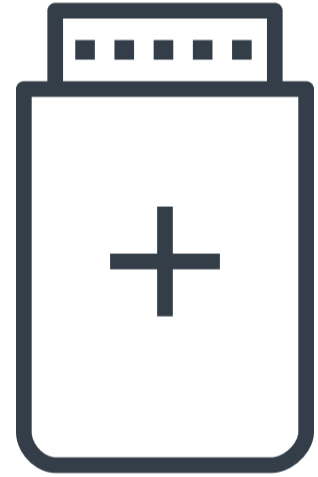
6 SCALABILITY

Will it work on a final product?

The ability to scale from several prototypes to hundreds of thousands in mass production is a concept often understood too late in the development process. One hopeful misconception is that the shortcomings of manual steps undertaken in an early prototype will be improved once that step is automated. In fact, automation does make performance more consistent, but it doesn't always improve performance.

7 PRACTICALITY

Can it work with fewer features?

As infatuated as you might become with a clever design, it's important to rein yourself in with the reality that the end user of your product only cares about how well it works and how easy it is to use. Users won't pay extra for nifty design that doesn't enhance performance. So do you really need a facial recognition feature when a barcode scan will do?

8 INTERFERING CLAPTRAP

Can it work with added features?

Product features can be added because they are required for safety reasons, or just because they are desirable. Regardless, new features can degrade performance and increase cost. Also, the more features added, the less likely they will all work. That's just statistics.

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