The hidden challenges of new product development in the MedTech industry

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Introduction

New product development in MedTech is characterized by its complexity, regulatory requirements, and the need for precision and speed of innovation. Timely completion of these projects is essential to ensure that innovative technologies reach patients sooner. However, the journey from concept to commercialization is often fraught with obstacles that can derail even the most promising endeavors. Regardless of whether it is a simple disposable injection molded part or a highly complex capital piece of equipment, these hurdles stumble even the most mature MedTech organizations. According to research published by the National Institute of Health, "Current [Medical Device Development] processes have to respond to several process challenges; projects seldom advance as scheduled, and often modifications are introduced during the course of project development and implementation."

Why is time-to-market so critical for MedTech products?
First, new technologies are slow to be adopted, as the healthcare sector is often skeptical until clear clinical evidence is shown. Second, the costs of market delay outweigh additional costs of development by 3X or more.

Regulatory hurdles, technological complexities, and unexpected challenges during clinical trials are among the most common issues encountered. These types of challenges can be factored into a schedule quite easily. So why are projects still getting delayed further, even accounting for these known risks? The reasons often boil down to these three "hidden" risks that companies overlook until it is too late.

1. A lack of skillset in ancillary areas outside of core competencies.
2. Optimism bias, leading to resource underutilization.
3. Inability to understand resource loading changes throughout the program.

Each of these is "hidden" because most project teams do not anticipate them until it is too late. Even then, these aren't identified as the root causes, so systematic improvements are never made, and the cycle repeats itself. In this article, we will explore each of these challenges and how companies can mitigate them, along with the help from Quest Global.

Skill set shortfalls

Skill set shortfalls are significant contributors to project delays and overruns. The shortfalls do not occur in the skill sets that are core to a MedTech OEM's business. It's the complimentary skills that are often an afterthought which end up delaying projects. According to research by Falahat, Chong and Liew, "Emphasizing on full squad participation for activities that are organically smaller than core duties is inefficient, which is why only a few NPD teams embody the 'real team' notion, hence raising the coordination barrier in favour of more efficient resource utilization."[2]

For example, an orthopedic company may be very skilled in material and mechanical designs when creating a new implant. However, whether it is due to past success or faulty assumptions, they fail when the implants are sterilized. Or a cardiovascular company that would like to develop the next generation of aortic valve repair. They have the core capability to design the mechanics of the product. However, when the digital solution is incorporated into the design phase, the OEM discovers, all too late, that they did not understand the full scope of the requirements.

The optimism bias in project planning

Optimism bias is the human tendency to assume projects will "go well", in general. It could be particularly true with MedTech development projects, due to the high pressure to reduce time to market along with the many unknowns of a successful medical product.

Managing optimism bias can be tricky. For instance, when project teams look at where projects can fail on an individual risk basis, they are often very accurate estimating the likelihood and impact of the risk. The problem arises is when the risks are viewed in aggregate (along with the business pressures), the summation of the risk likelihoods and consequences gets diluted.

Resource loading challenges

Regularly, project teams are put together with a set number of resources devoted to the entire project. Specific tasks (such as sterilization validation) may be outsourced, but the core project team usually does not fluctuate. However, in most cases the project requirements don't obey a fixed resource rule. Critical path analysis is essential therefore to identify where along the project timeline more (or less) resources will be needed.

Even if critical path analyses are completed, resources are frequently incorporated too late, only after peaks are needed. And often incorrect resources are allocated. For instance, many R&D organizations use design engineers to perform verification testing. While this may seem to be logical (who better to test the product than the people who designed it?), this can be extremely inefficient. Those engineers may not be as effective at establishing testing protocols as they are at designing products.

Solutions

The skill set gap, optimism bias and improper resource planning can all be overcome with proper foresight to improve your project outcomes. Utilizing project management tools, along with seeking additional support can mitigate these risks.

The first step in any new development program is to identify the skills needed and clearly define the ones that are core capabilities to an organization vs. those that are not. For those that are not, teams should then identify if those capabilities are a key requirement for success or if they are just needed for support. Any that are key for success should immediately be evaluated for partnering with a vendor that is strong in those capabilities. Even if the critical non-core capabilities exist within the organization, those resources are undoubtedly stretched or working on cross-functional projects already.
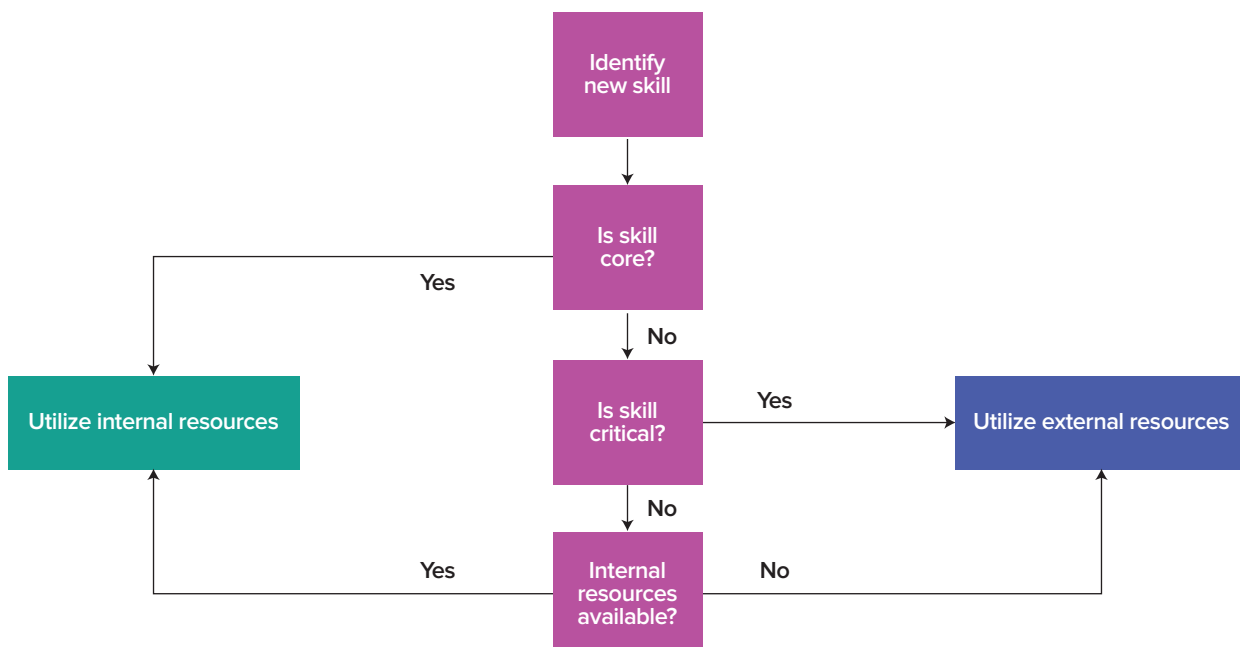
Next is to ensure the team is mitigating against optimism bias in the project plan. Individual project risks should be summative with their likelihood multiplied by their impact. This will, along with vendor partners' inputs, provide an unbiased assessment of the true project impact.

$$\Sigma \text{ Risk Probability (RP)}^1 \text{ X Risk Impact (RI)}^1 + RP^2 \text{ x } RI^2 + RP^3 \text{ x } RI^3 + ... = \text{Total Project Risk Impact}$$

Even when this step is often performed, the inevitable question arises, "What can we do to improve the time to market?" The solution team leaders often mistakenly, "Fast Tracking"[3] the timeline by seeing if tasks can be done concurrently. However, the problem is that resources then get overloaded and/or other risks are introduced that nullify the gains and the project will undoubtedly encounter further delays.

A better solution is to "crash" the program with resources that are solely devoted to mitigating risks. For instance, if a big risk is that a certain aspect of the product might fail a verification test, the team should devote resources specifically to design aspects of the product to mitigate that risk. This will allow the current design team to continue moving forward with the design of the product's main functions. Most companies assign sub-teams around different systems/processes of the product. Instead, aligning around risk factors can improve timelines.

Both the above solutions naturally help manage the resource-loading challenge. Identifying the non-core critical capabilities early and then recognizing when they will be on the critical path will show where additional resources will be required.

How Quest Global can help

Quest Global can be your partner to help you navigate these hidden challenges and improve time-to-market. At Quest Global, we have been working with top medical device manufacturers to help develop their leading-edge products for over 20 years. This has given us unique capabilities which many manufacturers desire. We will quickly bring in expertise in digital solutions, AI, cloud technology, board design and much more, helping companies avoid trying to internalize skill set gaps.

Similarly, Quest Global can be your resource partner for areas where additional resources may be required. Whether it is performing V&V testing, industrial design, DHF documentation, or other critical-path work packages that require resource loading, Quest Global can be your partner throughout the development cycle. And because we have been involved in so many development projects, our team can help your organization avoid optimism bias by providing guidance on where and how much additional resources may be needed for a given project.

References

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3. PMBOK, 7th Edition

For further information or queries, please reach out to us at info@quest-global.com