



Align Portfolio Management with Agile Engineering

How lean portfolio management adds strategic direction – and other benefits – to your agile product development lifecycle

- A lot of our clients struggle with their research & development activities. Especially when it comes to highly regulated products like medical devices or health software, different interest groups try to influence the feature set of a new product with their own – very expertise-specific – strategy in mind. Even with a waterfall approach, developers find it complicated to bring all stakeholders in line and, more importantly, to align them behind

a broader product vision and strategic direction. The situation can become even worse when simple agile practices like Scrum come into play. The issues start when the agile team starts with defining the product. The product owner is empowered to discuss and define product specifications directly with and for the development team. This introduces a breakpoint in the product development lifecycle (PDLC) at a large organization,

where detailed decisions about these specifications are often handed down from people not embedded in the agile team. ➔

This can lead to a conflict between the strategy team (portfolio or marketing management) and the execution team (technical project management, product owner and development team), with other stakeholders like medical, regulatory affairs, field service, etc. adding even more complexity to the scenario. Introducing lean portfolio management (LPM) can help resolve this conflict, adding clarity by defining different roles and areas of responsibilities for specific features and aligning those features with the overall strategy. It can also fix some problems inherent to a big-bang portfolio approach executed on an annual basis.

Why traditional portfolio management does not work, at least some of the time

Traditional portfolio management is basically all about allocating the right amount of funding to a select number of projects. As part of the annual budget process, medical device manufacturers fix an R&D budget for the financial year as a whole. They distribute these funds to several new (or already in progress) projects with a fixed amount going to the various programs or projects that apply for funding. The standard process includes the following steps:

AI-specific legislation

- At a certain point in time, senior managers decide the business strategy for the upcoming fiscal year and break it down into specific objectives. Each of these objectives are allocated a fixed portion of the available budget. – that this does not lead to discrimination. Developers can manage these risks as part of the standard risk management process (ISO 14971), even if they are not technically related to patient risk.
- They also field proposals for pipeline projects (the demand) in the coming financial year. Depending on the company, these proposals can be more or less detailed and may come with in-depth business cases or market studies already completed upfront.
- They assess and rate these proposals according to a fixed set of factors (or as part of an in-person negotiation) to make

sure they fit the overall objectives. The final rating indicates how well the proposal aligns with or drives the broader business strategy.

- The projects with the highest rating pass the quality gate and enter into a more detailed evaluation phase or proceed directly to realization
- In the simplest case, funding is approved until the money runs out.

The process – as simple as it seems - rarely works well in the real world, mainly due to the following issues:

• Strategy not defined

There is no clearly defined strategy that the portfolio management team can understand. The issue is often less that the enterprise lacks an overall strategy and more that it hasn't been broken down into meaningful objectives in a practical way. There are no defined criteria to rate projects, leaving room for negotiations and bypassing the defined process.

• Development timeline too long

The development of a new medical device can often take years and impact the budget beyond a single financial year. With little chance of a launch within the first year, there is not much to learn in terms of a business case. But simply throwing funding at a project for the foreseeable future is as bad as scrapping it and taking the write-off. Often, it simply isn't an option for management to take the P&L hit from expensing significant project costs.

• Unclear business focus

When your R&D projects are large-scale and fairly infrequent, it's tempting to include everything under the sun. However, these projects often have more features than are actually needed for a dedicated use case. Some features are hidden or implicitly financed in bloated cost estimates. It is difficult to assess the business value of a proposal that combines strategically important features with insignificant extras.

• Conflicts with regulatory emergencies and maintenance work

Dealing with complaints and other emergencies can shift the high priority workload in unforeseen ways. Maintenance work, which companies often underestimate, may compete with scheduled development work for expert resources. When hardware is discontinued or other production issues arise, it may lead to cannibalization.

• Top-down technical decision-making

Portfolios are often vague when it comes to business evaluation or justification, but at the same time they are packed a lot of mainly technical details. Engineering teams may feel their freedom constrained by so much detail, which may lack important context at the same time.

• Utilization-based planning

Budgets are often linked to specific corporate units (e.g., departments). Regardless of the feature set that is required, most project proposals are constructed in a way that makes sure that department has sufficient work for the next financial year. In other words, the project is based on what the team can deliver, rather than what the strategy or market really demands.

• Key resources not available

As a rule, it isn't easy to convert budget into resources (especially when it comes to highly skilled staff), which results in cash-rich but talent-poor projects that go nowhere. The resulting budget underruns are spent on additional projects (often bypassing the formal portfolio management process and causing even more stress at the resource level).

• Market uncertainty not reflected

Business strategy and project success may not be stable throughout the entire financial year, and the project team might need more flexibility to respond to market volatility or technology advances.

Why agile practices add even more stress to the situation

At the functional and technical level, most organizations attempt to confront uncertainty by introducing agile practices. Unfortunately, agile teams tend to accept uncertainty and a scope that has yet to be defined. Their focus is not on planning for a horizon of one full financial year. And what is worse, agility claims to give the agile team full control over their own destiny (or product specifications), which can lead to an even bigger conflict with the portfolio team.

How lean portfolio management can help

Lean portfolio management (LPM) makes budget planning a lot more flexible and more frequent. It empowers agile teams to take part in budget planning and enforces transparency with regard to “atomic” features. Known as “epics”, these features each come with their own business value and justification. More importantly, lean portfolio management expands the budgeting process into the execution space and adds missing elements like governance and portfolio operations to the pure budget funding activities. This not only changes the way strategy is converted into budget, but also makes lean portfolio management a full, end-to-end lifecycle activity. Lean portfolio management has a much broader scale than traditional portfolio management. It is more focused on the

concept of end-to-end portfolio management. To better compare both methods, we are focusing more on the strategy and investment funding pieces here. Deloitte also has deep expertise in applying LPM in highly regulated environments, where not only control over the portfolio is vital, but also mastering the idiosyncrasies of the medical device industry.

A smart application of the framework and its layered approach as well as MVP-based frontloading has even more advantages for the medical device industry, such as:

- stabilizing patient risk management
- solving certain conflicts introduced by model-based engineering
- harmonizing slow-going hardware development with fast, agile software development

Fig. 1 – Disciplines of Portfolio Management



Funding projects with lean portfolio management

As a core process, lean portfolio management – much like its traditional counter-

part – has to make sure that funding is allocated to developing the right features and derived from the overall enterprise strategy. To mitigate the issues inherent

in traditional portfolio management, LPM takes a different approach as outlined in the following:

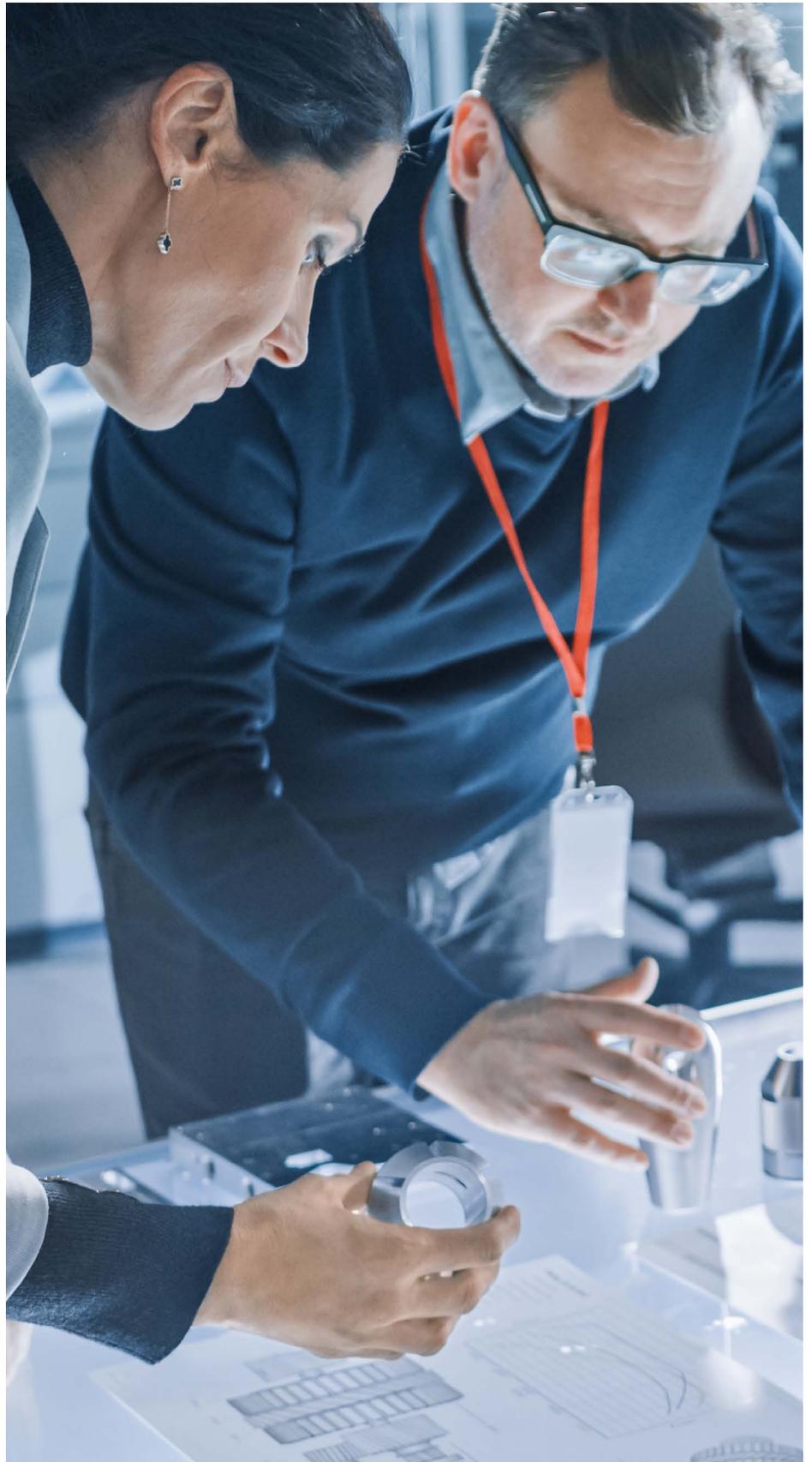
Fig. 2 – Improvements by Lean Portfolio Management

Common Pitfall	Mitigation
 <p>Strategy not defined well</p>	<p>The enterprise strategy is translated into OKRs (objectives and key results), which force management to define goals in a precise and measurable way. They see these OKRs as the starting point to a budget structure centered on value streams as well as portfolio visions, guardrails, etc.</p>
 <p>Development timeline too long</p>	<p>The products funded as part of lean portfolio management (LPM) are much smaller in scope, leading to reduced batch sizes and shorter evaluation times. With LPM built to work within a full SAFe implementation, tasks are scaled so that they can be done in short iterations. The overhead for building medical devices may stretch the timeline, but development time should easily fit into a single financial year.</p>
 <p>Unclear business focus</p>	<p>The starting point for a new development is a business hypothesis that is validated by a minimal viable product (MVP). This method forces the project team to define a clear business value and prove it during realization. Thanks to participatory budgeting, planning is a team effort and aligned among stakeholders, which prevents overzealous personalities from pushing their interests too much.</p>
 <p>Conflicts with regulatory emergencies and maintenance work</p>	<p>Lean portfolio management can be implemented with a priority track that accommodates the needs of complaint management or work for unforeseen emergencies. The guardrails set up in LPM strike the right balance between new business features and the need to continuously invest in architecture and code quality or replace obsolete hardware. Thanks to a focus on portfolio context, management makes sure there is a closed feedback loop of KPIs collected during portfolio realization that will feed into the subsequent year's strategy. This helps them better understand unforeseen events and how to plan for them.</p>
 <p>Top-down technical decision-making</p>	<p>The process of portfolio management comes in different layers (portfolio, solution, program, team), each of which owns some guidance and some budget responsibility. This leaves room for the engineering team, for example, to decide on technical features. Higher layers (usually carrying more medical or business expertise) still have the option to impact important decisions on functionality up to MVP realization. This approach de-centralizes the decision-making process, while allowing higher layers of the organization to make decisions on important strategic or medical issues.</p>
 <p>Utilization-based planning</p>	<p>The engineers are organized in stable value streams, with a high number of small epics – rather than full projects – ready to feed those streams. Portfolio management makes sure the streams always have meaningful work.</p>
 <p>Key resources not available</p>	<p>The whole SAFe set-up works on a pull system, which keeps engineering teams busy without overloading them. Experts work in dedicated organizational units so that they remain available when duty calls, managing them as split resources. That said, most engineers are full-time members of a dedicated value stream and are allowed to focus on their work in scheduled increments. This keeps overhead and staff stress levels low.</p>
 <p>Market uncertainty not reflected</p>	<p>Lean portfolio management relies on rolling wave planning. Even if a portfolio roadmap exists, the structure is flexible enough to respond to changing budgets and to reflect market or strategy changes. As new products are implemented in smaller increments (epics), the value streams implementing these budgets can better react to changes.</p>

Conclusion

There are a lot of benefits to deploying lean portfolio management, and we recommend it strongly for modern engineering environments in particular. Enterprises must, however, ensure they implement LPM carefully as part of the full product development life-cycle and in line with sequential engineering practices. Robust policies for operations and governance, which we only touched on briefly in this article, form a closed feedback loop and add additional value.

In short, LPM can address most of the downsides of traditional portfolio management when applied "by the book". Enterprises that take a smart LPM approach may also be able to solve additional issues specifically relevant for medical device manufacturers. Deloitte is perfectly set up to assist you in defining and implementing your own modern way of Lean Portfolio Management.



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