HEALTHCARE & LIFE SCIENCES

APPLYING AGILE SOFTWARE DEVELOPMENT CONCEPTS TO PHARMACEUTICAL MANUFACTURING AND DISTRIBUTION FOOTPRINT OPTIMISATION

A&M Perspectives: How pharmaceutical companies can take learnings from high-growth technology businesses to continuously optimise their footprint and pay down footprint design debt

Introduction

Continued aftereffects of the COVID-19 pandemic, Russia's invasion of Ukraine and surging inflation are the latest triggers for pharmaceutical companies to rethink how they manufacture and distribute products to their customers. Shaped by factors such as market access and regulatory requirements as well as cost and tax efficiency, pharmaceutical companies have complex, capital intensive and inflexible global footprints that continue to be exposed to heightened operational and financial risk. Against a background of shifting geopolitical, demand and supply patterns, those companies with the capability to rapidly implement changes to their manufacturing and distribution footprint have the upper hand.

What is a footprint?

A company's geographic presence or footprint is more than real estate. It is a top-level strategic question. Where companies locate their assets is fundamental to not only their operating cost base and effective tax rate but also the strategic risk factors incurred in managing their supply base and accessing the markets they serve. Crucially, from a growth perspective, a company's footprint is a major factor in determining access to capital and talent and ability to develop and protect intellectual property.

The optimum manufacturing and distribution footprint design is one that is fit for today but also ready to meet the needs of tomorrow's product portfolio and customers. However, understanding tomorrow means looking forward, not one day but five to seven years; the typical lead-time for building and bringing on line new pharmaceutical manufacturing assets. Changing sales growth assumptions, patent expiries and pipeline successes and failures in that timeframe mean that it is inevitable that none of the business scenarios considered in designing the footprint fit the eventual reality. Footprint design is therefore fraught with risk.

An analogous situation is faced by fast moving technology businesses bringing new digital products and features to market. However, the widespread adoption of agile methods and thinking mean that these companies manage the situation very differently.

Why is agile thinking relevant?

Many people working in supply chain and operations roles are familiar with the 'The Goal' by Goldratt and Cox. In this 1980s business-oriented novel, the main character is the manager of an underperforming production plant

> There are two questions that keep me awake at night. The first is do we have sufficient manufacturing capacity? The second is do we have too much?"

who learns about and applies the theory of constraints to address bottlenecks and turn around the plant under the guidance of Jonah, a former physics professor. 'The Phoenix Project' by Kim, Behr and Spafford is in many ways a homage to 'The Goal'. It was published in 2013 and written in the same business-oriented novel style. The main character, Bill, is the newly appointed head of an IT Operations function that is in the midst of delivering a strategically important and complex IT application with millions of lines of code. The application will be tightly coupled with other key operational systems meaning that any software defects have the potential to prevent the business from transacting with customers, which, unfortunately the company recently experienced during a botched upgrade. This incident coupled with the project being massively over budget and very late led to the unscheduled departure of Bill's predecessor. Taking inspiration from the company's manufacturing plant, Bill is led towards a DevOps[1] way of working. By applying 'The Three Ways' of flow, feedback and continual learning, he is ultimately able to deliver on promises to the business.

DevOps is a philosophy, like a cellular set up in manufacturing, that combines agile software development, testing and deployment. It is what enables technology companies such as Meta to release Facebook updates and new features multiple times per day with no impact on its millions of users. This is in contrast to traditional waterfall build, test, deploy approaches that are still commonly used for enterprise resource planning (ERP) solutions, which take weeks, months or even years to deliver usable software and features.

How can agile methodology be applied to footprint design and optimisation?

Optimising a global pharmaceutical footprint is a complex undertaking. Deep operational and financial insight for the as-is footprint is essential but not sufficient. Global product flows and therefore footprints are shaped by a constantly evolving myriad of regulatory, market access, tax and legal constraints (*see figure 1*). On top of which, the as-is footprint will include a patchwork of assets acquired through strategic acquisitions that are not yet fully integrated, and a network of external manufacturing and distribution partners resulting from make vs buy decisions that are likely suboptimal and have never since been revisited.

[1]Under a DevOps model software engineers work across the entire application lifecycle, from development and test to deployment to operations, and develop a range of skills not limited to a single function.

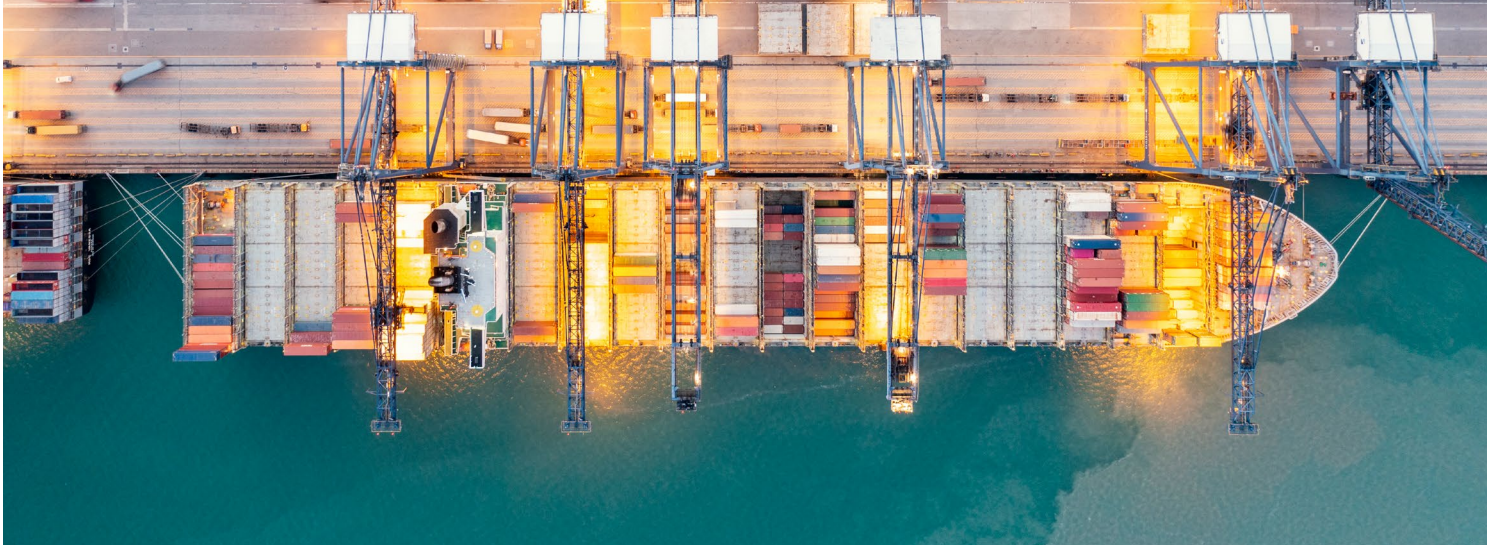
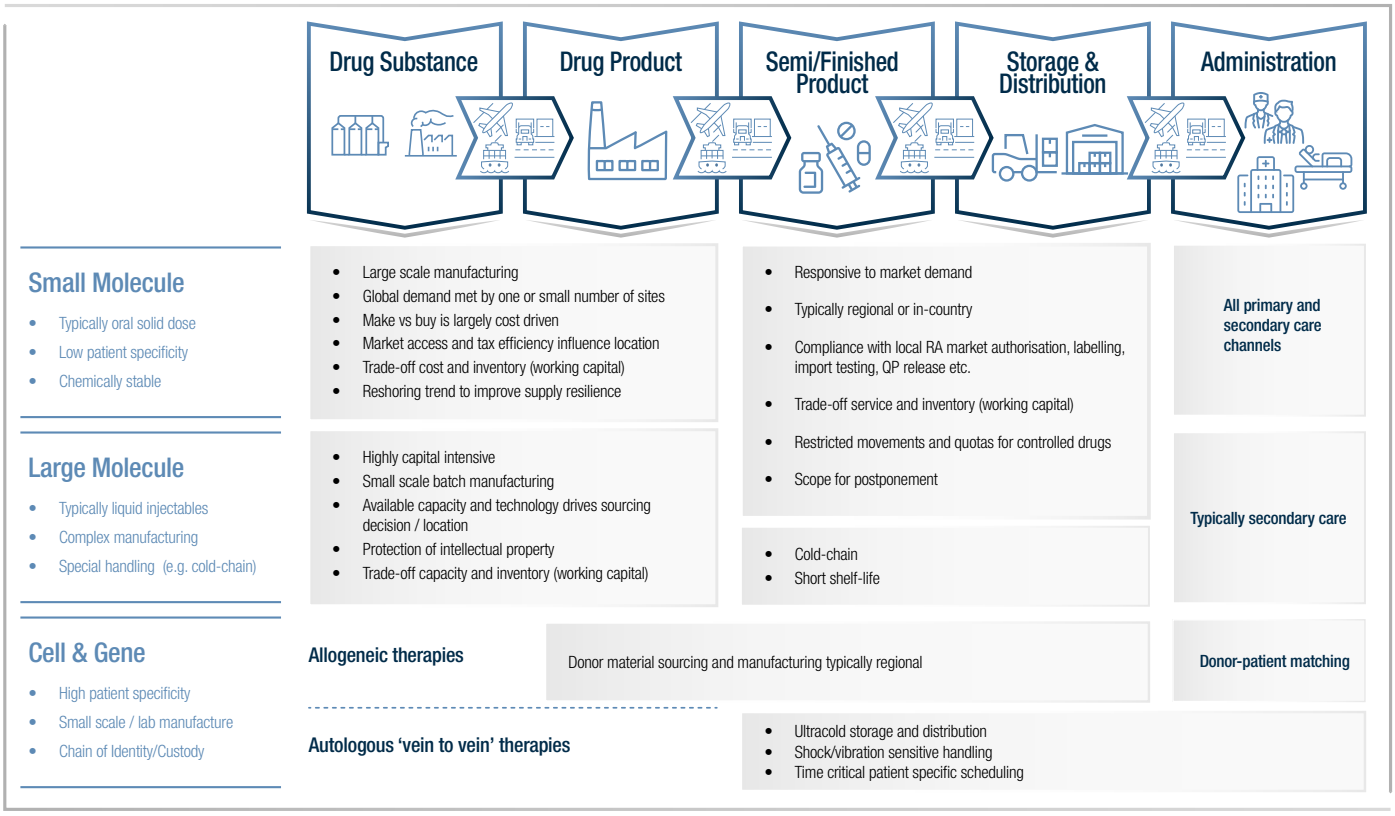


Figure 1 – Factors influencing pharmaceutical company footprint design



Like any business, operating costs are an important driver for a pharmaceutical company's footprint design and more so for later lifecycle products and manufacturers in the highly cost-competitive generics sector. However, there are always vital trade-offs to be made with supply chain resilience, high service levels and maintaining a licence to operate. Risk averse technical operations functions have little appetite to meddle with the footprint unless it is in reaction to significant strategic developments such as a new product launch, patent expiries or external supply chain shocks that necessitate a review of regional or even global operations.

What happens to footprints over time?

Footprints ossify over time to the point where changes become complex undertakings that typically necessitate the mobilisation of a multi-year programme at a huge expense and risk to the company. In a dynamic business environment, there is a very high likelihood that the goals will have moved considerably before the programme delivers, leading to delays and cost overruns.

A pharmaceutical company's ability to develop and adapt its footprint can be transformed by taking three core elements from agile software development and DevOps. These elements are flow, continual feedback and the management of technical debt.

1. Flow

In software development, as in manufacturing (e.g. single-piece flow), small batch sizes result in faster cycle times and lower work in progress (WIP). In the context of footprint optimisation, this means establishing an operating model and a rhythm to make changes little and often. This does not mean that the entire footprint is in a constant state of flux. All changes must be underpinned by a long-range footprint strategy that describes, like user stories[2] in agile software development, what is required from the footprint in terms of capacity, manufacturing technology and performance (e.g. cost over the longer term). The footprint strategy provides direction and determines how changes are prioritised and sequenced.

In practice, this means using tools like Kanban[3] where each card represents a discrete task that must be completed to make a change to a company's network. Tasks could, for example, represent steps in a technical or product transfer. Tasks are categorised and visualised by phase using a physical Kanban board or a virtual equivalent. At its most simple, phases should include to-do, in-progress and complete. More granular phasing could be helpful depending on the type of change and delivery team set-up. To-do tasks are regularly prioritised and launched according to the footprint strategy. Executing in a series of small steps (low WIP and short cycle time) accelerates change while the opportunity to reduce bottlenecks and short-term reprioritisation continually focuses on and increases value delivered to the business.

2. Continual feedback and learning

Most organisations conduct reviews at the close of large programmes. The reviews summarise what went well and what could be improved in future projects. In agile delivery, which is at the heart of fast-moving technology companies, projects are delivered in a series of short, often two weekly, delivery cycles. Reviews – known as retros – happen every delivery cycle and can be immediately applied to the next cycle. Furthermore, by shifting from a one-and-done project approach to a product[4] concept (*see table 1*), a permanent capability can be established that is constantly problem solving and learning. Fine-tuning over time increases both the velocity and quality of delivery.

Defining a company's footprint capability as a product rather than conducting a series of distinct programmes, provides clear ownership and the possibility to make long-term investments in talent, data management and tools. Establishing a long-term capability and conducting footprint analyses at frequent intervals allows for smarter, more informed decisions to be made as product strategies, manufacturing technologies, long-range forecasts and business strategies change and evolve.

Table 1 – Project vs Product

	Project		Product
Timeframe	One-time, fixed duration	>	Routine
Planning	Upfront, detailed, large work packages	>	Small increments
Talent	Temporary	>	Long-term stable
Success measures	Project deliverables	>	Business outcomes
Prioritisation	Fixed scope/objectives	>	Business need, continuous
Funding	Project-based	>	Incremental, capacity-based
Design debt	Accumulates during project	>	Managed continuously

[2]A user story is a general explanation of a software feature written from the perspective of the end user or customer. The purpose is to articulate how a piece of work will deliver value back to the customer.

[3]Developed by Toyota in the 1940s, Kanban is well-known pull production method that was adopted as a project methodology in the 2000s

[4]A product refers to any service or item that an organisation creates to serve a customer need

3. Manage design debt

In software development, technical or design debt occurs where an easy or quick solution is implemented versus a solution that complies with existing software architecture and design standards, but would take longer to implement. The debt is the implied cost of future rework needed to unpick and redevelop the quick solution. Like financial debt, design debt accrues interest over time making it harder to implement future changes and it eventually erodes the performance of the software. The unfortunate reality is that many pharma company footprints are mired in footprint design debt (FDD). FDD builds up in three ways: deliberate, accidental and long-term entropy.

Not all FDD is bad. Like financial debt and gearing, it enables the business to move faster. Deliberate FDD occurs where the business needs to move faster than the footprint can adapt. A good example is inorganic growth where new manufacturing and distribution sites are added to the footprint. These supply chains will be integrated in time but until that happens, there is FDD in the form of location and capability overlap and duplication.

Accidental FDD occurs where it becomes apparent that the long-term footprint design is flawed. This can happen slowly as the business evolves and measures taken to future-proof the design prove inadequate. Or this can happen suddenly where there is a fundamental shift in what the business requires of the footprint. In cases such as this, it may be necessary to undertake a more significant refactoring of the footprint design. A recent example that continues to impact the entire industry is global supply chains disrupted by COVID-19. Many organisations are reviewing their footprints with a focus on improving supply chain resilience.

Finally, footprints are complex systems with a tendency for complexity to grow over time leading to FDD. This commonly occurs where a footprint designed long ago has been abused and that original design philosophy is no longer clear or understood by those implementing incremental changes.

FDD requires close and structured management to maintain a footprint that is both performant and able to adapt quickly in support of the business strategy. FDD, particularly where it is deliberate, should be logged (Kanbans) so that it can be cleaned up at an appropriate time in the future. Changes required for FDD clean-up need to be planned for and prioritised alongside other business driven changes in a way that is analogous to software releases that typically combine new features with bug fixes.

Conclusion

Pharmaceutical companies can take concepts common in high-growth technology companies and apply them to continuously optimise their footprint. Companies that apply a product mindset and establish an operating model that supports a permanent strategic footprint capability have the upper hand over those that must repeatedly stand-up one-time programmes to adapt to shifts in company strategy and the external environment. In contrast to such multi-year programmes that typically follow a waterfall approach, the concepts of flow, continual feedback and close management of footprint design debt enable companies to establish a rhythm to make changes little and often thus accelerating change while continually focusing on paying down FDD and increasing value delivered to the business.

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