

Five Ways to De-Risk New Product Launches

In an evolving world, virtual pharmaceutical companies must adopt different methods to bring products to market, despite the new challenges that come with straying from the path

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Out-licensing their product's journey to Big Pharma has become the most well-trodden route to market for innovation-led virtual pharmaceutical companies.

By necessity, these small and agile operations have traditionally relied on the resources and expertise of much bigger players to take their products beyond the science, through to marketing, supply chain design, sales, and distribution.

Increasingly, however, virtual pharma operations are exploring ways to take their specialty drugs, biopharmaceuticals, and drug/device combinations to market independently. It's possible, but it brings entirely new risks and challenges.

Chief among these challenges is getting their product through all the steps to a successful market launch, and establishing an entire supply chain with all the obligations that are pertinent to these activities. To do this, virtual pharma operations need access to a vast range of experienced and professional support in

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the core areas of scientific discovery, specific disease-domain knowledge, clinical trials, and regulatory affairs.

Beyond the drug itself, they need access to broader business knowledge spanning financials, tax, legal, intellectual property tactics, and commercial strategy, as well as practical elements like manufacturing, supply chain, marketing, sales, order-to-cash, distribution, and new demands introduced by the ongoing evolution of the supply chain.

Partnering with a complex range of external expert resources will be essential to this journey, as will an understanding of how to manage a complex and dynamic network



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of external experts effectively, and ensuring there are no gaps in terms of scope, timing, and risk.

With this in mind, and against the backdrop of ever-tightening regulations and requirements taking place throughout Europe and North America, how can virtual pharma companies mitigate some of these risks to give their product the best chance of successful launch and adoption?

Robust Project Planning

From an initial idea, drug development and Phase I clinical trials, right through to regulatory compliance, product distribution, and post-marketing surveillance trials, a comprehensive project plan is the critical starting point for any effective product launch.

Any project plan – including your go-to-market plan – must be fully comprehensive, and account for every requirement and outcome. It should also ensure that the appropriate timings and interdependencies are reflected, which presents a particular challenge in a market launch scenario with many moving parts and significant uncertainties.

We have sometimes seen pharma companies relying on previous project plans that worked for a different product 10 years ago, yet, these plans are unlikely to cover the many changes and regulatory requirements that have happened since that time, or the essential

tasks that virtual pharma companies may not have been made aware of.

Particularly critical is early identification of the steps that have a long lead time, and reflecting them in your launch plan. Experience shows that the serialisation and traceability swim lane, for example, which takes you from strategy to sustainability, will take an absolute minimum of nine months.

Therefore, it's essential that virtual pharma companies begin to think about the compliance aspects from a serialisation and traceability perspective during the early stages of Phase III, allowing 12-18 months to complete this process.

By mapping out key deadlines for when things need to happen at different phases of a project lifecycle, as well as an outline of all potential costs involved at every phase of the project, virtual pharma companies can plan effectively, measure progress, and mitigate the costly delays that can often occur without these factors in place.

De-Risking the 'Known Unknowns'

When it comes to getting a new product to market, you can't afford to have any unexpected surprises. That's one of the reasons a robust project plan is so important.

If this isn't in place, pharma companies may underestimate the costs involved in bringing in mission-critical partners, or meeting key requirements, without which they can't launch.

This is nothing new, of course; the risks involved in getting any new drug to market are well-documented. It may not prove to be safe or effective, or you

might have missed critical regulatory steps in your project plan because you didn't have the full picture, which is a challenge facing a lot of smaller companies in virtual pharma.

However, the practical steps of launching your new drug on the market involves numerous other steps that may risk tripping you up. When operating in a regulated environment, it is especially critical that your implementation and go-to-market plan enables quality processes; particularly in terms of the systems you need to implement and the partners you must engage with.

This includes vendor selection and audit, quality agreements, change controls, document management, validation, roles and responsibilities, a training programme and role-based curriculum, and comprehensive SOPs, including exceptions handling.

Forming Solid Partnerships

Forming partnerships with industry experts and key suppliers is a vital part of preparing a new product for launch, particularly for virtual pharma companies running smaller, leaner operations.

In the short term, you'll need consultants who can help you choose the right long-term partners, and in the long term, these partners will become a critical part of your business.

The cost of bringing in outside expertise can be significant, but without this expertise, products are unlikely to ever reach commercialisation – and investing in external consultancy to fill in the gaps now remains minimal compared with the potential cost of a major setback further along.

It is critical to choose a partner who has the full vision and can offer expertise and skills that are at the leading edge of developments.

With the advent of serialisation and traceability requirements, compliance regulations have become even more

complicated, and consultants who specialised in this area years ago may not now understand more recent developments at the required level of detail.

Ultimately, without meeting all these requirements, companies simply cannot launch – whether they're looking to commercialise one product or one hundred – so having the right partnerships in place is essential.

Effective Systems Integration

The integration of partners and processes across a multitude of business areas is essential to achieving effective commercialisation. From your contract manufacturer and compliance partner to the government systems needed for reporting, companies will need to set up and operate fully functional and highly responsive systems and processes.

One of the most important elements of integration is having a traceability system that's able to communicate efficiently, effectively, and without interruption to and from each of your partners. Since all these elements are contracted out by virtual pharma companies, it is even more vital that every system is connected.

Your serialisation database must be able to talk seamlessly to the upstream contract manufacturers and downstream partners, such as third-party logistics providers and distributors. Given the nature of advanced therapeutic products, these often involve specialised supply chains and add-on services that will require the support of partners with the right expertise and capabilities.

Meeting Market-Specific Compliance Requirements

Finally, no product can reach market without fully complying with the applicable regulatory requirements. Compliance is a vastly general term because pharma manufacture and distribution are so heavily regulated,

and there are globally accepted best practice standards and national legislation requirements that differ by region.

The most recent expansion in compliance obligations has occurred around medicines traceability requirements; in particular, the two main markets of Europe, regulated by the EU-FMD, and the US, regulated by US-DSCSA.

Achieving a state of compliance presents a challenge, not least due to the number of hidden complexities between these markets. Yet compliance doesn't end at product launch. Pharma companies will still be subject to regular inspections, even after going into full production.

Robust serialisation compliance systems will enable traceability, transparency, and visibility of the product throughout the entire supply chain – not only with the initial requirements, but also in terms of the changing rules as they continue to evolve.

Working with the right partner in each of these areas will give virtual pharma companies every chance of a successful market launch.



Christoph Krähenbühl, Senior Director at **Excellis Europe**, has been involved in serialisation projects since 2006. He has acted as Global Serialisation Project Manager and Product Security Manager at AstraZeneca and as a leading consultant for a breadth of pharma customers. Christoph brings vast practical experience gained from working with clients in all areas of the industry, including leading global pharma companies to contract packers and niche specialised manufacturers, parallel distributors, wholesalers, and industry organisations.