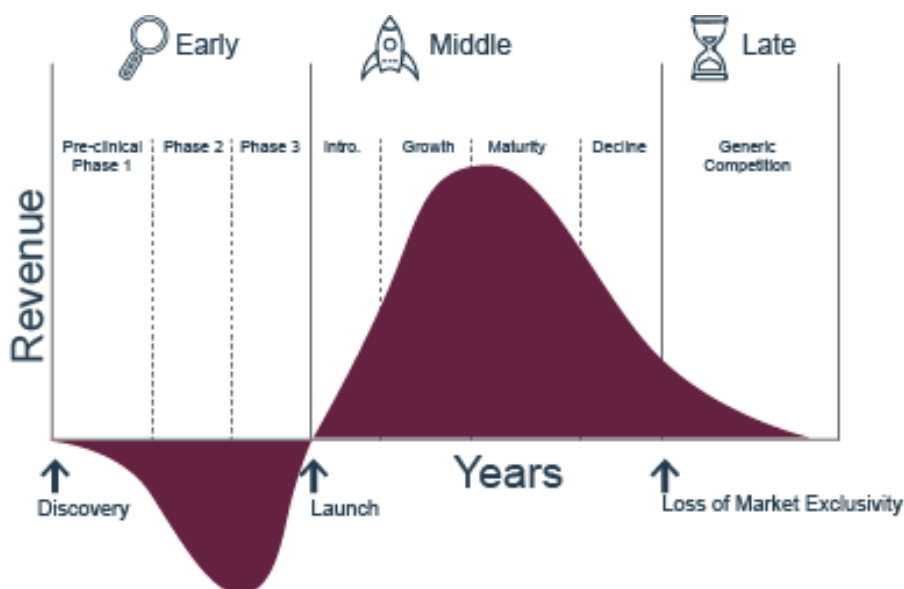


The New Age in Strategic Outsourcing Lies in the Mature Portfolio

Companies must safeguard their mature portfolios while continuously innovating and developing new products. But in-house resources are stretched and often lack the broader knowledge needed to ensure best practice for ongoing maintenance activities. As a result, traditional models of outsourcing – the low-cost, “lift and shift” approach of the past – are giving way to a more nuanced, strategic approach, one that leverages external expertise globally and delivers more efficient methods for supporting the product lifecycle. Dr. Constanze Burkhardt, Vice President, Head of Program Management, explores why outsourcing the mature portfolio has become an industry priority.



Mature products are integral to a pharmaceutical company's financial bottom line and to its reputation. Consider one of the best-known products on the market, Aspirin, which established Bayer as a leader in pain relief and stroke prevention. Companies build a reputation in a particular therapeutic category (Novo Nordisk and Lilly in diabetes, Genentech in oncology, AbbVie in rheumatoid arthritis, GSK in vaccines) and strive to protect their mature portfolio, while continuously innovating.

Yet mature products require ongoing maintenance activities, such as pharmacovigilance, maintaining regulatory dossiers and labels, and conducting ongoing benefit-risk analyses in order to maintain licenses. Drug companies must comply with fast-evolving regulatory requirements to avoid critical actions from the healthcare authorities and the enormous cost this implies, both financially and to a company's reputation. Adding to this complexity is the fact that regulatory authorities across different countries and regions often have divergent expectations – even within the EU, despite strong and ongoing efforts by the European Medicines Agency to harmonise processes.

These challenges, combined with the need to keep internal resources focused on product innovation, are leading to a new

trend in outsourcing, where companies seek to outsource the maintenance and strategic management of their mature product portfolios.

A New Era in Outsourcing

Pharmaceutical outsourcing has changed significantly since its early days 40 years ago when companies began turning to external partners to reduce their costs and enhance their flexibility. What started out as a “lift and shift” model, with transactional outsourcing to low-cost, offshore locations, has changed over the years. In recent years,

companies began seeking partners that could provide specialised domain expertise in key geographic regions and local knowledge in countries where they didn't have presence.

Increasingly, there has been a need for a more nuanced approach to outsourcing, where expertise and regulatory intelligence are combined with efficiency and cost containment. Equally, companies have sought to find new ways to strengthen their pipelines and develop more efficient methods to support the product lifecycle. This has led companies to build relationship-



based models to manage their established, marketed products in a more strategic way through partners that offer a tailored, blended model of in-country, near-shore, and offshore resources. Importantly, there is also an emphasis on partners that not only have demonstrated expertise in global regulatory requirements but have also adopted innovative, best-practice approaches.

To make the most out of this more strategic outsourcing approach, pharmaceutical companies need to assess their existing operating models for the maintenance of their mature products and consider how they might benefit from an integrated safety, quality, and regulatory model available through trusted third-party partners that can provide tailored services where required. There is more to a tailored approach than delivering integrated services. At its best, a partnership is about a trusted relationship that brings regulatory intelligence and insights, as well as ongoing back-up, stability and security for all processes. This end-to-end relationship is only made possible when trust is built between all parties involved.

It's not enough, however, just to have that central expertise. Rather, any mature product portfolio strategy must also provide local support through teams of compliance experts, particularly for routine functions.

Aside from the obvious cost benefits that outsourcing provides, removing the burden of maintaining compliance for established products enables companies to focus on innovations and other strategic business. As importantly, it also provides ready access to a large pool of external industry expertise and knowledge, which may be limited in-house. Moreover, this expertise brings together best practice and knowledge gained from working across many different companies – large and small – in multiple markets, which in turn leads to greater innovation and efficiency.

Strategic and Tailored

There should never be a one-size-fits-all approach to strategic outsourcing, since success is about far more than short-term cost savings.

To determine the right outsourcing approach, companies should first consider their geographic markets – both current and intended – to determine whether they have the necessary resources to manage mature products in those regions. Even if there are teams in place in those markets, do they have capacity to manage mature products as well



as support new launches or does it make more sense to leverage the local expertise that a partner can provide as part of a tailored outsourcing model?

This also applies at a global level, where companies often have resource constraints and need to focus on products under development. Having an external global strategist oversee maintenance of the mature portfolio allows internal employees to focus their attention on new developments. Companies need to decide where best to focus internal resources and whether having in-house teams spend their time maintaining mature products makes strategic sense.

Managing established products can be even more challenging given the varied organisational structures that many companies are working with. A company with 100 or more operating companies or affiliates worldwide needs to understand the structural constraints facing many of those affiliates, many of which will have tiny offices and perhaps only one full-time staff member to manage all regulatory activities.

To allow these affiliates to focus on core activities – including helping to launch innovative new products to market – pharmaceutical companies should consider tailored models that introduce greater efficiencies to lift the burden local affiliates face. A flexible and strategic approach will also be important when managing new technical requirements from the health authorities.

There are any number of different operating models – from headquarters being responsible for determining technology and processes and coordinating regional efforts; to a collaborative approach between headquarters and the affiliates; to a model where affiliates hold responsibility for maintaining products in their region. Irrespective of the model, however, local teams may struggle with the workload demands of managing mature products or they may lack the expertise to navigate complex safety and quality requirements. Technology and process limitations also represent a challenge for affiliate offices; for example, while automation is increasingly being leveraged to streamline many repetitive processes, affiliates may not have the technology or expertise needed.

Global strategic outsourcing of the mature portfolio can alleviate those issues, ensuring local requirements are met and allowing the overall organisation to take advantage of digital and other innovations to improve the product maintenance process.

Cross-functional Collaboration

By outsourcing the maintenance and strategic management of mature portfolios, pharmaceutical companies can achieve better collaboration across cross-functional teams and elevate the organisation so there is better coordination and further optimisation of business processes. One way this is achieved is through models that are built around task rather than function, which facilitates collaboration across functions,

locations and regions, enabling companies to pivot faster as priorities change and evolve.

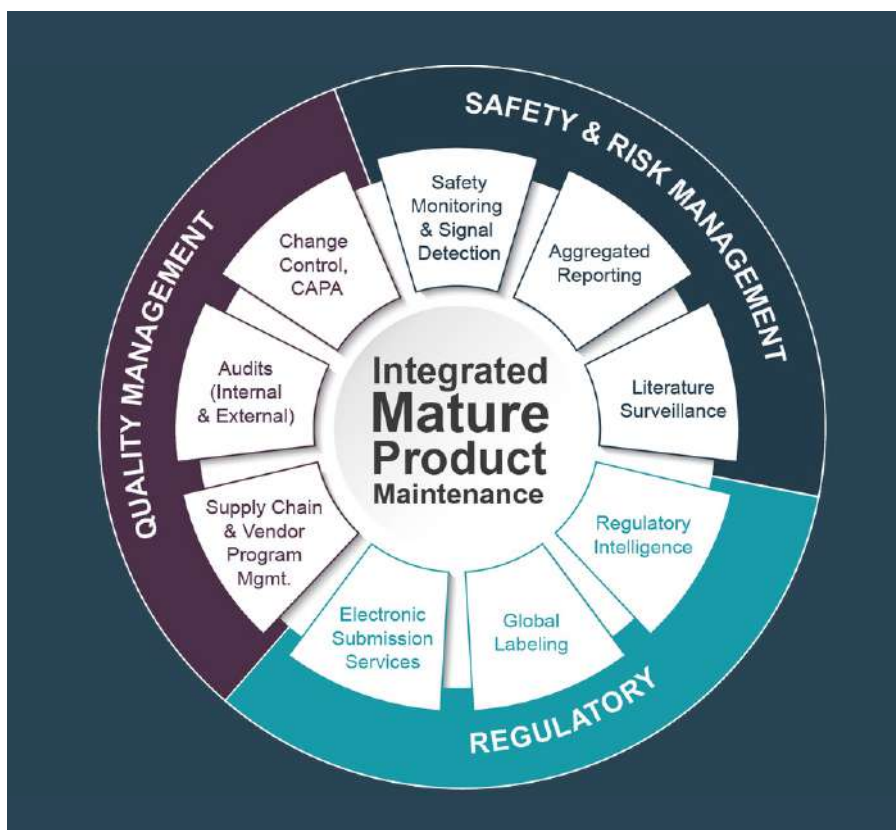
The ability to be agile and innovative is important when preparing for changing regulatory requirements. As an example, the EMA is moving away from documents and toward data and digital systems. What that means is that, going forward, when submitting variations to a marketed product, companies will need to ensure the product datasets in the SPOR database (Substance, product, organisation and referential) are correct and complete. Such changes will require operational agility to ensure quality and compliance requirements are met to safeguard products on the market; it will require knowledge of the shifting regulatory environment; and it will require digital know-how.

The challenge is exacerbated where companies have a decentralised approach to portfolio maintenance. Here there is a very real risk of disparate functions and teams managing their activities in an uncoordinated manner, resulting in fragmented data and documentation at different locations.

Having partners that bring specialised expertise and a blended, tailored model, lets companies take advantage of new and emerging technologies, better manage regulatory information, adapt to evolving global regulations, mitigate risk at the local and global level and respond quickly to data and documentation requirements. Such a model ensures information is centrally available and managed by the outsourcing partner, which is better able to adapt to new ways of working regionally and globally to meet changing regulatory requirements.

From the 1980s to 2022

As has been observed, the trend that began more than 40 years ago amid efforts to cut spiralling development and regulatory costs has evolved into a highly specialised field, where outsourcing partners have gained extensive knowledge and process expertise. So, while cost savings and flexibility remain factors for outsourcing, the bigger focus is on knowledge wealth. Today's more strategic outsourcing models allow companies to tap into a network of specialists and gain efficiencies that wouldn't be possible in-house, given the outdated and inefficient processes most pharma companies have acquired over the years.



Through strategic and tailored outsourcing of the mature portfolio, companies can modernize their processes and safeguard compliance and quality while staying ahead in a rapidly evolving regulation landscape. A further advantage is the ability to leverage organisational information across the regulatory, safety and quality continuum to achieve productivity gains and a more holistic view of the portfolio.

The new wave of outsourcing also leads to a more coordinated multi-functional approach to portfolio maintenance, which helps to overcome a common challenge of fragmented data and documentation at different locations. Furthermore, outsourcing allows companies to take advantage of technology advances, such as automation, without the need to invest in infrastructure or deal with quality management testing and validation.

This new wave of outsourcing, when carefully planned and prepared, can bring huge advantages to organisations, allowing them to improve processes and remain compliant while allowing in-house teams to focus on innovation and value-added activities. Across the board, this more tailored, strategic approach gives companies access to innovative perspective and more efficient ways of managing regulatory activities.



Dr. Constanze Burkhardt

Dr. Constanze Burkhardt is known for her innovative, solution-oriented approach to global program management strategies. With over 15 years experience in the pharmaceutical and biotech industry, she has an extensive track record and experience with building strong team environments in a matrix management setting, with high commitment to the drug development and LCM process. She is applying her analytical and conceptual thinking ability, international working experience and expertise in Program Management to build integrated Global E-2-E Delivery platforms, Outsourcing solutions, and Strategic Consultancy. Dr. Constanze Burkhardt is currently leading the Global Program Management department responsible for delivering large Global programs to clients. She and her team are driving operational excellence by implementing strategic program platforms designed to optimise efficiency and product compliance from drug development through commercialisation to product maintenance.