Outsourcing: *The Key to Navigating Fill-Finish in Pharmaceutical Manufacturing*

The fill-finish phase in the pharmaceutical manufacturing industry is undergoing a significant transformation. Once primarily focused on the aseptic filling of vials and syringes, it has now evolved into a multi-faceted process requiring a high degree of technical precision, regulatory awareness and strategic foresight. This change is not incidental, it reflects the broader transformation in pharmaceutical development itself, as the industry moves toward more intricate, sensitive, and personalised medicines.

Against this backdrop, the fill-finish process presents both operational challenges and strategic advantages and, as such, third-party outsourcing companies have become central partners for pharmaceutical brands. For the BCMPA, the UK's trade association for contract manufacturing, packing, fulfilment & logistics, many of its members are at the centre of this evolution. The capabilities of Contract Development and Manufacturing Organisations (CDMOs) spans formulation, aseptic fill-finish, advanced packaging, and logistics, and are critical in scaling up production for new biologics, gene therapies, and other high-value treatments. And as these therapies become increasingly sophisticated, so too must the infrastructure and expertise required to prepare them for patient use.

Post-Pandemic Pressures

At its core, fill-finish involves taking a bulk pharmaceutical product – whether a vaccine, biologic, or small molecule – and precisely filling it into its final container for distribution. For some products, such as biologics, the complexity is amplified due to their sensitive nature. These treatments require highly specialised, sterile environments and precise handling to maintain their potency and safety. The demand for biologics, gene therapies, and cell therapies has rapidly accelerated, and so has the need for innovative solutions in fill-finish packaging and manufacturing.

The COVID-19 pandemic served as a major catalyst, prompting a global effort to produce and deliver billions of vaccine doses, which placed unprecedented pressure on fill-finish infrastructure. While the urgency for COVID-specific treatments has eased, the vaccine market was already on a growth trajectory prior to the pandemic, and with the increased focus on other diseases, there is now a global shortage of capacity in the development, manufacture and further commercialisation of these much-needed new therapies.

Growth has been seen in several other areas, including oncology and specialty drugs for rarer conditions, as well as the continued expansion of interest in "digital health" to enhance remote patient care. In addition, the rapid growth of GLP-1-based therapies for diabetes and obesity management has seen a new wave of demand take hold. These products have increased the need for advanced, high-capacity fill-finish operations to keep pace with an expanding market and meet both clinical and commercial demands.

BCMPA member Flexible Medical Packaging (FMP) has responded to this shift by offering a turnkey approach that includes formulation, fluid blending, and bespoke packaging. With over 30 years of experience, FMP supports clients from feasibility consultation through to manufacturing and delivery, reflecting the sector's move toward complete, customer-focused solutions.

A New Age of Patient-Centric Packaging

In parallel with more complicated medicines, there is also a growing expectation that treatments should be easier to use – particularly for patients who self-administer in domestic settings. This has pushed the industry toward more intuitive packaging designs, including prefilled syringes, autoinjectors, and devices that simplify the treatment process. These innovations can play a pivotal role in ensuring that the final product meets practical usability standards.

One packaging trend gaining ground is topload packaging, which organises components such as syringes, instructions, and safety caps, so that everything is clear and accessible. This not only improves the patient experience but can also reduce errors and support better treatment adherence. Packaging is no longer just a matter of protecting the product, but is also part of the treatment itself. As a result, pharmaceutical manufacturers are increasingly seeking packaging partners who understand the full picture: regulatory requirements, usability, materials sustainability, and international logistics.

Regulatory Compliance and Operational Effectiveness

Of course, compliance to regulatory standards is vital, especially in fill-finish operations where sterility and precision are non-negotiable. The 2023 revision of the EU Good Manufacturing Practice (GMP) Annex 1 has introduced comprehensive updates to improve aseptic processing and contamination control. Key changes include the implementation of a robust Contamination Control Strategy (CCS), expanded guidance on the use of isolators and Restricted Access Barrier Systems (RABS), and stricter monitoring requirements.

The evolving regulatory landscape underscores the necessity for pharmaceutical companies to partner with fill-finish providers and CDMOs that not only meet but exceed compliance standards. Such collaborations are crucial for maintaining market credibility and ensuring the safe and efficient delivery of next-generation therapies.

Technology, Automation, and Risk Mitigation

To meet these rising demands, many companies are investing in technologies that improve reliability, reduce errors, and increase production. The integration of automation and robotics has allowed contract manufacturers to improve agility, scale operations flexibly, and maintain consistently high standards of quality. These developments are especially important as the industry balances the need to produce large quantities of high-demand drugs while also accommodating the smaller, tailored batches required for precision therapies.

Automated systems and robotic handling have also helped reduce human intervention, significantly lowering the potential for contamination – a key priority

in the production of sterile injectables. In addition, the widespread use of RABS has improved the industry's ability to maintain aseptic conditions, ensuring compliance with increasingly rigorous global regulations.

But meeting industry demands isn't just about having the latest equipment – it's equally about collaboration. For pharmaceutical companies, working closely with experienced co-packers and manufacturers creates effective partnerships that bring together technical knowledge, compliance expertise, and scalable infrastructure, enabling faster routes to market and more reliable supply chains.

Moreover, packaging must now deal with additional layers of complexity: cold-chain logistics, cross-border regulatory nuances, and, increasingly, sustainability. Smart packaging featuring live tracking, tamper-evidence, or thermal condition monitoring, is gaining purchase.

As a result, outsourcing fill-finish operations has become a strategic choice for many pharmaceutical brands. With products coming to market quicker than ever before, few companies have the internal capacity to manage every aspect of fill-finish operations in-house. Outsourcing to third-party specialists with experience in sterile processing, is increasingly seen as a strategic imperative. It enables them to concentrate on core research and development efforts while leveraging the specialised capabilities of contract partners to manage the complex demands of sterile production and packaging. In today's competitive market, the value lies not only in execution but in expertise – particularly when CDMOs can offer end-to-end solutions that integrate technical precision with deep regulatory understanding.

BCMPA members such as Central Pharma have highlighted the need for early-stage partnerships to optimise packaging designs and ensure regulatory alignment before commercialisation. This proactive engagement helps avoid costly delays and supports faster, more efficient product launches.

Outsourcing in an Intricate Market

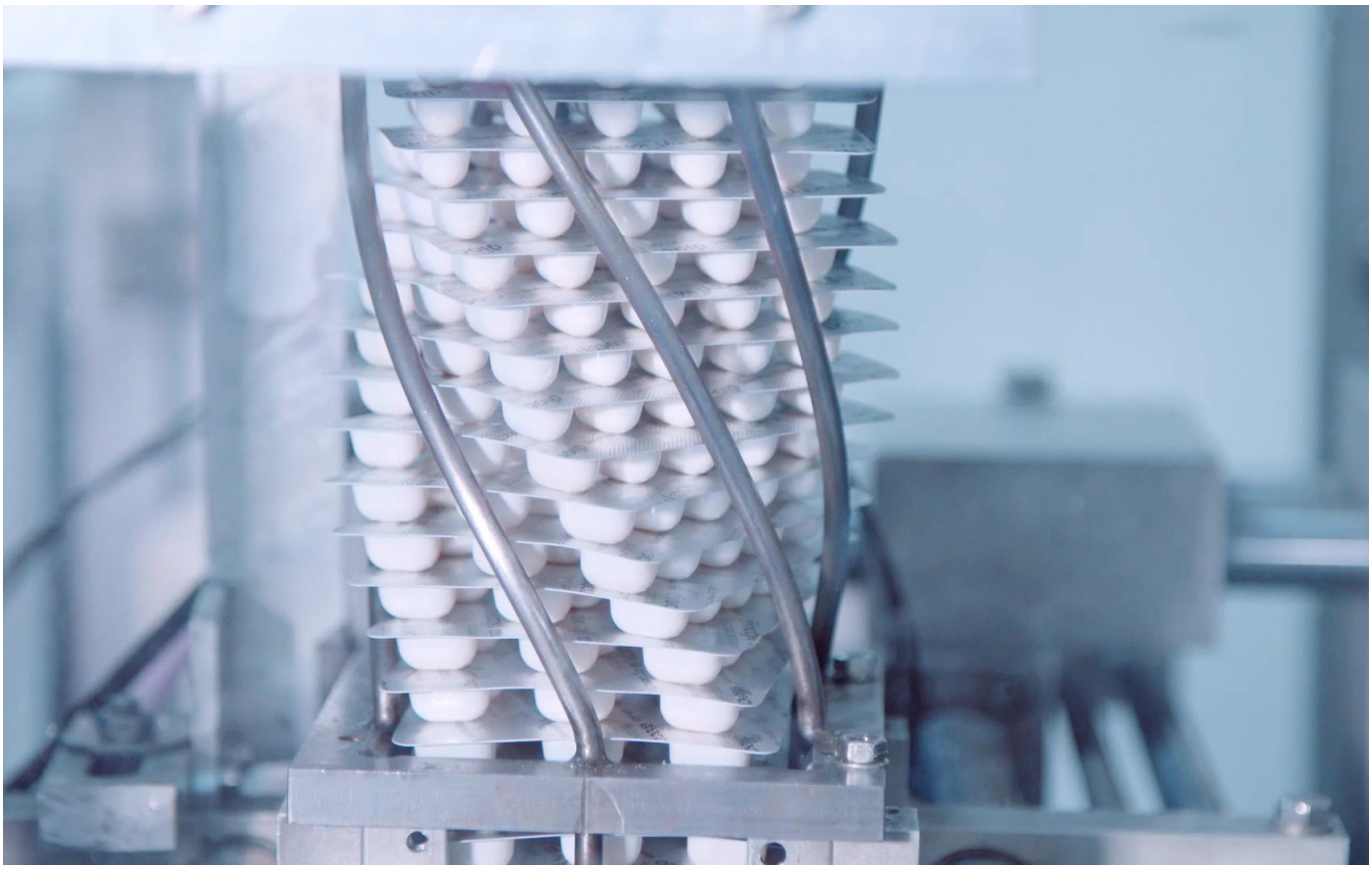
Indeed, outsourcing is no longer a transactional decision. It is a long-term partnership that must account for shared risk, collaborative quality oversight, and geographic alignment. According to Roots Analysis, the global biologics fill-finish outsourcing market is expected to continue its upward path, driven by the need for agility, capacity, and technical depth. For contract packers and manufacturers, this means investing not only in resources but also in talent, digital infrastructure, and regulatory affairs.

BCMPA members are increasingly embedding themselves earlier in the product lifecycle, offering consultative input on packaging design, container closure systems and extractables and leachable testing. This comprehensive approach ensures that downstream fill-finish considerations are integrated from the outset, which reduces the risk of costly delays or rework at the commercialisation stage.

Embracing Strategic Partnerships

In today's fast-evolving life sciences landscape, forming strong and strategic outsourcing partnerships is also a critical driver of innovation and long-term success. As companies seek to bring products to market faster and navigate increasing complexity, trusted outsourcing collaborations offer the agility, expertise, specialised capabilities, and scalability needed to stay ahead and mitigate risk.

By aligning with the right co-pack and manufacturing partners early and throughout the development lifecycle, organisations can streamline operations, access specialised capabilities, and better manage risk. These alliances not only enhance operational efficiency but also



foster innovation by leveraging external talent and infrastructure.

For BCMPA members, and the wider outsourcing sector, this means staying at the forefront of both capability and compliance. By building fast-response operations, maintaining high standards of safety and quality, and working in close alignment with clients, the UK's contract manufacturing and packaging sector is well positioned to help bring the next generation of medicines to market safely, efficiently, and with patients in mind.

And as demand continues to rise – driven by ageing populations, an increase in R&D, and a steady stream of breakthrough therapies – the fill-finish process will be more than just a final thought. It will be a foundation of pharmaceutical success in the years to come.

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Emma Verkaik is the CEO of the BCMPA – The Association for Contract Manufacturing, Packing, Fulfilment & Logistics. With a career that began in advertising and marketing for blue-chip companies, Emma transitioned into a leadership role within the contract manufacturing and packing industry. Her deep understanding of third-party outsourcing and extensive industry knowledge have been instrumental in driving membership development and strategic marketing for the BCMPA. Appointed CEO in June 2023, Emma is passionate about connecting brands and retailers with the right outsourcing partners and championing the capabilities of BCMPA members across the supply chain sector.