

# ONE SMALL-RUN FOR CPOs, ONE GIANT LEAP FOR PHARMA!

*Pascal Keogh, MD of Millmount Healthcare, explains how utilising CMOs and CPOs as part of a long-term strategy can allow pharmaceutical manufacturers to adapt to the demands of the modern pharmaceutical industry, while helping to cut costs.*

**T**he Times They Are a-Changin' (Dylan, 1965): the theme song for Pharma in 2011? Never could a song capture the mood of the current state of affairs in the pharmaceutical industry like this one does.

The pharmaceutical landscape as we know it is changing. The industry's desire to reduce cost, innovate and commercialise value-added products demands new approaches to how it makes and delivers drugs. The once indomitable pharmaceutical giants have had to come to terms with the reality of no longer being able to rely on a pipeline of blockbuster brands to maintain their huge profits. The focus, it now seems, has switched to niche products, and the flexibility and capability to manufacture them.

What role, if any, can contract manufacturing organisations (CMOs) play in this 'Nouveau Pharma' landscape? John Bolla (GSK) recently remarked, "There is a significant opportunity for contract manufacturers to help us and rationalise our manufacturing networks". Indeed, for pharma companies big or small, outsourcing has always played a vital role – providing opportunities to lower scale-up and manufacturing costs, increase flexibility in terms of manufacturing capacity and eliminate capital costs associated with the launch of, and continued market demand for product.

If we agree that CMOs have a vital role to play in the new pharmaceutical environmental – what role, if any, for a more specified branch of the CMO – the contract packaging organisation (CPO)?

Pascal Keogh, MD of Millmount Healthcare, explains how his company's commercial business model is adapting to the demands of the modern pharma-



Pascal Keogh, Managing Director, Millmount Healthcare.



ceutical industry – small run / late-stage customisation.

**How would you assess the current plight faced by many organisations operating in the pharmaceutical industry?**

The pharmaceutical industry is faced with more challenges than ever before – strict legislation in the form of governmental price controls, an apparent lack of new blockbuster candidates, personalised medicine and patent expiry, with increased competition in the form of new generic entrants. As a result, the market share for the existing companies is drastically being reduced. There are increasing demands for smaller run sizes. Subsequently, there is a major focus on inventory control and wastage associated with short runs, regulatory change and short shelf-life products.

**What challenges, if any, do these changes in the landscape have on companies such as Millmount Healthcare?**

The contract manufacturing industry is one of constant change. It suffers or benefits from the stresses and strains of the pharmaceutical industry. Consequently, Millmount Healthcare must be flexible, and where possible, anticipate our partners' requirements in order to exceed all their expectations. This has meant us adapting several of our lines to facilitate short-run, quick turnarounds. We work with our customers to standardise on pack layouts, so that the cost of cutter profiles are kept to an absolute minimum. We are also working with our suppliers to ensure competitiveness on short-runs.

As a company, we have had to streamline our systems and procedures by introducing LEAN practices. Our definition of a small run is probably 25% of what



we would have considered a small run several years ago. Down-time reduction and rapid changeover times remain key factors for driving efficiencies in this model.

**With cost becoming a critical deciding factor when choosing a contract packer, are you finding customers increasingly moving to non-European service providers?**

We are actually finding that the trend is starting to reverse. Although companies are still open to the idea of purchasing tablets/capsules from outside the European Union, there is a drive towards small scale / late-stage customisation within Europe. This allows them to closer match country-wide demand with bulk availability, with a typical conversion time from bulk to specific market livery within three weeks. It also means that analytical testing is reduced to testing on the bulk batch, as opposed to sub-batch testing for each market.

**So what does this mean for generic manufacturing in Europe – are we seeing the beginning of a decline in this area?**

There are ample opportunities for growth in the generics market, despite the fact that it is an extremely cost-conscious area. The market dynamics here focus on being first-to-market, with fierce competition, and fast attrition in market share.

I believe that we are seeing the beginning of a trend, whereby large-scale manufacturers are focusing on core competencies, whilst realising that outsourcing has the potential to deliver excellent business value, beyond simple cost savings and operational flexibility. They are breaking down production runs to large and small series and on the whole, are focusing on tablet manufacturing and large series runs internally, giving them extremely competitive costs of goods, while outsourcing the small series runs to companies better geared for this type of work.

Millmount Healthcare has the necessary systems in place, along with compatible machinery and tooling, to form a seamless extension to our partners' current manufacturing practices. Our partners can typically expect to enjoy reduced cycle times, costs and resources associated with packaging, while maintaining control of information.

**What additional advice can you offer manufacturers to improve efficiencies and/or reduce cost?**

Despite specialising in packaging and warehousing solutions, we have on occasion been sought after for advice and counsel by our partner companies. We are happy to provide this service, and would look for a solution to their packaging problems on a case-by-case basis.

Pack lay-out is one area which can reduce the cost substantially. For example, 28 tablets in one blister typically cost half the price of two blisters of 14 tablets. Standardisation of pack design is another area which warrants further examination, with the potential to speed up changeover, both on packaging lines and component suppliers, leading to cost benefits.

### CONCLUSION

The pharmaceutical landscape is well and truly 'a-Changin', with manufacturers being forced to re-think their operations and as a result, transform their approach to outsourcing. Rather than meeting the changing landscape with fear and trepidation, they must embrace the challenge and learn how best to build alliances with both CMOs and CPOs as part of a long-term strategy to alleviate their cost and R&D woes.

### ABOUT MILLMOUNT HEALTHCARE



EXPERTS in contract packaging operations, Millmount Healthcare provides an effective outsourcing strategy from 3 cGMP compliant, Irish Medicines Board (IMB) approved manufacturing facilities. Major pharmaceutical and healthcare manufacturers use Millmount Healthcare for their blister packaging, bottling and warehousing requirements to achieve high-quality results with lower overheads. The company also acts as a European site of importation for non-EU products.

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