



Partnering to Advance Human Health

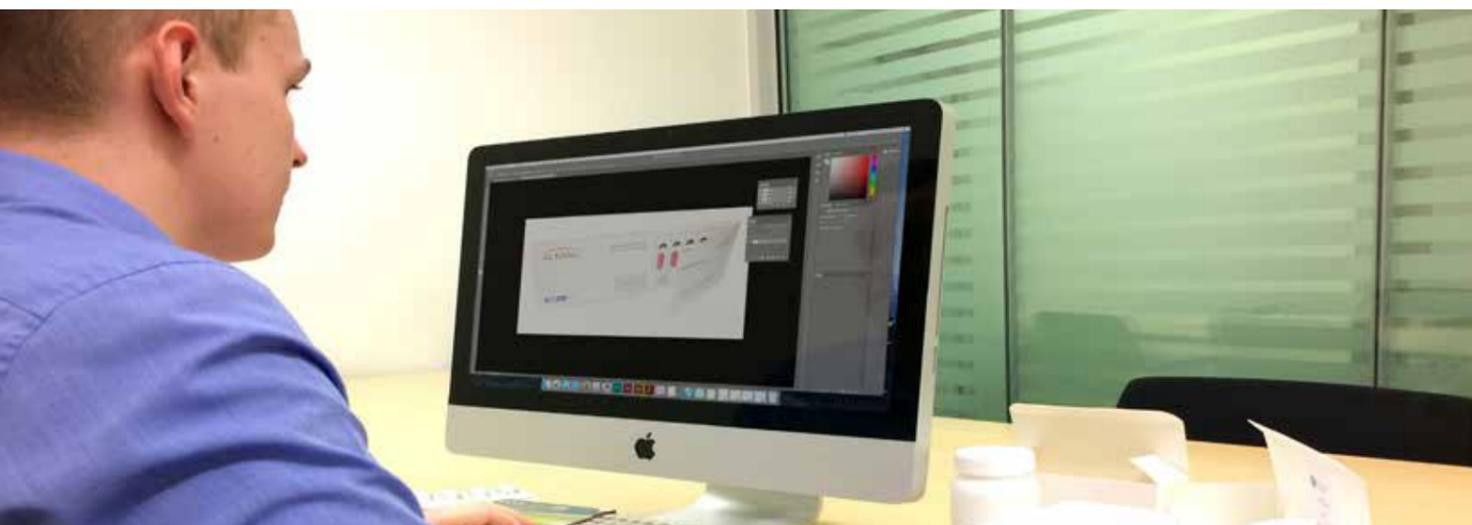
Case Study

Handle challenges and avoid common mistakes in drug product packaging

Outsourced Pharma / Life Science Leader



Handle challenges and avoid common mistakes



Michael Rooney, business support manager for Almac Group, has spent over 12 years working in the pharmaceutical industry. Prior to joining Almac, he spent time working as an associate scientist at ABC Laboratories and an analytical chemist at Nicobrand. In his current position, he assists clients with guidance and advice on packaging issues. I spoke with Rooney about the challenges companies in the pharmaceutical industry face with regard to packaging.



Outsourced Pharma: What are some of the most common packaging challenges?

Rooney: Some of the most common packaging challenges witnessed by Almac when working with client partners to launch their commercial product is the difficulty clients face in striking the right balance between the functions of packaging (protection, presentation, identification and communication of information) with market, compliance and sustainability concerns whilst meeting patient demands for user-friendly, age-specific dispensing solutions. The biggest challenge is addressing these requirements without unnecessarily increasing the complexity and cost of the pack presentation, while still providing a pack fit for purpose.

OP: What is one of the most common mistakes you have seen implemented by companies attempting to address these challenges?

Rooney: When client partners are launching their drug product, there are times when little thought has been given to the commercial packaging design. As a result, Almac is often presented with an unnecessarily complex and subsequently expensive pack prototype. Packaging should be kept as simple as possible without impacting the quality of the product. A complex pack not only increases costs in terms of materials, but also in terms of labor and processing. Both will impact your bottom line and increase lead-times.

The opposite can also be said for many of our non-European clients who are launching in the EU for the first time.

U.S. packaging and patient information leaflets are typically in a single language (English), whereas when launching drug product in the EU client partners are faced with complexities such as multi-lingual packs, bluebox labels and serialization requirements.

These complexities can sometimes take client partners by surprise and complicate or extend the critical path to launch.

OP: What are some best business practices for addressing these challenges to avoid making a costly mistake?

Rooney: First, choose a CMO partner that has experience with similar product launches. From the outset, define an experienced project launch team that will address such things as responsibilities, deliverables and timelines.

An integral part of any launch plan is a comprehensive packaging risk assessment. The risk assessment should review factors such as:

- Product Value vs. Material Cost
- Sustainability
- Environmental
- Physical
- Microbiological
- Regulatory
- End User & Compliance
- Timeline for Launch
- Target Markets & Cultural Precedents
- Equipment/Tooling Requirements

Once the packaging risk assessment has been completed, the lead packaging prototypes (usually two) will be identified, feasibility batches will be manufactured and a stability program initiated. After a set duration, usually six months, a lead packaging prototype should be identified. If for any reason a lead candidate cannot be clearly identified, the packaging risk assessment process should be widened and restarted.

OP: Explain the different challenges for clinical trials packaging versus commercial packaging?

Rooney: With the high number of drug products in clinical trials failing to reach the ultimate end point of commercialization, pharma companies typically shy away from investing heavily in clinical trial packaging design with the preference for flexible packaging to meet each individual clinical trial protocol. The most obvious difference between clinical and commercial packaging is batch size; clinical trial batches are smaller with commercial batches running into millions of blisters/bottles. However, just because batches are smaller doesn't make them any easier. Batches are a lot more varied with key challenges of dosage titrations, randomization, multiple country groups and of course supply chain pressures to meet 'first patient in' dates.

With regard to commercial packaging, a lot of the hard work is completed up front with packaging selection and design taking place for regulatory submission/ market approval.

Packaging design is paramount at this stage as you are essentially changing from a blank clinical pack to a commercial pack that requires not only product and prescribing information but company branding and design. Once the product is approved and launch strategy is implemented, the product's packaging remains the same with changes only being made when regulatory or product indication updates are required.

OP: How far in advance should you start planning for clinical trials packaging and commercial packaging and why?

Rooney: It is never too early to start the process. If you can have a pack format that closely resembles what you plan to go commercial with during your Phase III trials, it provides a good opportunity to receive feedback from physicians and patients, as well as your CMO.



OP: What steps should you take to ensure your packaging will be accepted by the FDA?

Rooney: The key steps to ensure that packaging will be successfully approved by the FDA are as follows:

- Ensure the packaging maintains drug safety and is effective in its proposed use.
- Ensure the drug's proposed labeling is appropriate.
- Ensure the packaging used in manufacturing the drug is adequate to preserve the drug's identity, strength, quality and purity.
- Ensure the packaging promotes accurate dosing and compliance and is child resistant and senior friendly.
- Ensure the packaging supports the supply-chain integrity of the medicine.

OP: What are some of the considerations companies should take into account regarding packaging of different classification drugs, (i.e. controlled substance or a potent compound)?

Rooney: One of the main considerations for packaging of controlled substances and potent compounds is the balancing of child resistance with accessibility for the patient. It is essential that the pack design is correct by enabling and restricting access to the drug product, making the packaging child resistant and/or senior friendly.

Another key consideration is patient compliance especially given the potency of the drug products and the increased risk of overdose/underdose. This issue can be addressed with compliance packaging such as blister cards that are marked with day/morning/ evening/week etc.

OP: How will serialization affect commercial packaging and what are some of the best business practices being implemented at your company to be prepared for 2015?

Rooney: Almac implemented a custom-built serialization solution in 2011 that meets all current global requirements. Direct experience has shown that serialization presents several challenges such as overcoming space constraints on existing printed packaging components and revising SOPs to provide additional controls during packing operations while ensuring throughput rates are maintained. Current business practices reflect the in-house knowledge; established processes such as packaging design, process validation and batch record design have been revised to ensure serialization requirements are considered during the initial commercialization stages and support an efficient pathway when applying serialization to existing products.



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