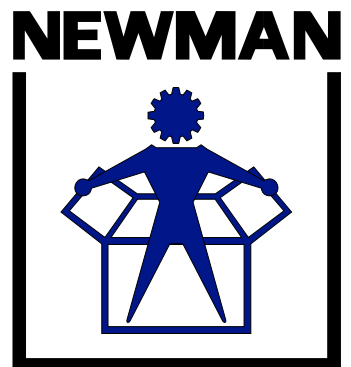



How Do You Ensure **Flexibility** in a Pharmaceutical Labelling Machine?



By

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In the world of pharmaceutical labelling, radical change has never really occurred, nor is it on the horizon; changes are predominantly incremental. However, change is most definitely afoot - not revolutionary, but definitely perceptible - directly linked to the development of therapeutic 'smart drugs'. Drug development has previously only really impacted the packaging line where new container types are introduced, but that's not the case with smart drugs. Bit by bit smart drugs, in conjunction with advancements in lean manufacturing, are actually altering the very nature of the pharmaceutical packaging and labelling industry.

Getting Smart but Small

Therapeutic smart drugs really made it onto the radar in the 1990s and early 2000s. These are targeted drugs that are tailored towards specific strains of disease and even to individual patients, taking into account knowledge of disease pathogenetics; essentially this is personalised medicine. Understandably, the outcome for patients has the potential to be superior to the outcome for those taking a traditional 'one size fits all' style of drugs that we have been used to. The technology to achieve this is now commonly available and the pharmaceutical industry is increasingly moving towards this new style of drugs.

For the pharmaceutical packaging line, this latest industry development has had more of an impact than you might think and it all stems from the smaller batch sizes that are inherent with producing smart drugs. Whereas ten - even five - years ago, a standard batch of a drug would often take a day or more to label, we are now looking at comparatively tiny batches of drugs produced for a single person. Setting up the labelling system for a very small batch can end up taking longer than the labelling itself. Shortcuts can't be made; all the same procedures, quality and validation remain essential and are required under strict regulatory control.

Unexpectedly, the labelling element has become a little more costly and a little more onerous than it had been previously.

Building in Flexibility

Pharmaceutical labelling manufacturers have been aware of this trend and accompanying predicament and a number, including Newman Labelling Systems, have risen to the challenge. Our key focus has been to build greater flexibility into our labelling systems to readily handle smaller drug batches and all the challenges this brings. These include the ability to accommodate a range of container and label types and sizes, different languages that might be required on a label and changes in labelling speed dependent on



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the type of container and batch size; all from a single labelling machine.

Not all labelling machines have been designed to be flexible – there was less need in the past. If you are finding batch sizes are getting smaller, whether from smart drugs or not, then you should consider investing in a labelling system that has been designed with flexibility in mind.

But what constitutes flexibility in a pharmaceutical labelling system?

There are a number of key aspects to consider. The first and arguably the most important of these is the labelling machine's efficiency of changeover between the different drug batches. The changeover must be quick and simple. Changing from labelling one container type to another often requires considerable down time for preparation. At the lower end of the scale, the more rudimentary labelling systems will require each setting on the machine to be manually adjusted by an operator which takes time and increases the potential for operator error; the more adjustments and tools that are required, the greater the possibility for mistakes. Mistakes in the pharmaceutical sector can often be considerably more expensive and potentially dangerous than those in comparable industries, such as food and beverage, as the product is often of high value and has the potential to cause harm if administered incorrectly.



Some labelling systems offer an alternative, more efficient approach by allowing you to change over entire fitments in one go, which is certainly faster and less prone to error. The changeable fitment could be a starwheel, an entire feeding system, or just the guidance for the container. This is certainly better than adjusting all the machine settings individually, but it's not an overly sophisticated solution and it still takes time and skill.

What we are instead seeing is a greater interest in labelling machines that are able to automate the changeover process. Such systems incorporate inline machine settings which enable the operator to



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auto synch all the machine's features and functions from one container type and the speed of labelling (referred to as containers per minute – cpm) to another, at the press of a button; it's a menu driven approach that is highly efficient and reliable. Newman Labelling's S150 is a prime example of this as it is compatible with a good range of container sizes and shapes, plus label sizes and types yet can be set up with minimum use of change parts. Adjustment for the container diameter through the whole of the machine is achieved through just one adjustment point.



Further benefits of this automated 'user friendly' method includes tool-less changeover which results in less potential damage to the product and production line, plus requires less operator skill.

The machine control system is clearly fundamentally important here. The control system has to be smart enough to ensure the correct language label is being applied, for example.

Manufacturing Standards Driving Change

But it's not just the change in batch sizes that are driving these developments. The industry at large continually looks across all sectors of its business for improved efficiency, and product labelling is no exception. Lean production is a phrase that everyone involved in manufacturing is more than familiar with, looking at methods for reducing waste within manufacturing processes. Single-Minute Exchange of Die (SMED) is one such lean production concepts that is driving change in the pharmaceutical sector and directly relates to labelling. SMED requires a fast (less than ten minutes) and efficient means of converting a manufacturing process from running one product to the next. This focus on rapid changeover is considered key to reducing production batch sizes and thereby improving flow, reducing production loss and output variability.

Increasingly pharmaceutical companies are measuring their machine efficiency against DIN 8743 which sets out time related criteria for packaging machines and packaging installations.



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Will Increased Flexibility Affect other Aspects of the Line?

More recently, the emphasis on flexibility has been extended further along the packaging line. Transfer on to and off of the labelling machine, from upstream / downstream systems, can now be done with a fitment produced on CNC machinery that can be changed from one size to another without adjustment. It's literally a case of putting one fitment on and one fitment off.

So taking a more flexible approach to labelling is already having positive follow through on other areas of the production line. However, building flexibility into your production line does come at a cost. Clearly there will be a greater capital cost – automated systems are more sophisticated and are priced accordingly. But there are other implications to consider.

The first of these is the quality of the materials you use, primarily the containers and labels. Both must be manufactured to strict tolerances which may see your material costs rise slightly.

There will also be a limit to the speed of the labelling. The maximum speed for labelling in-line with a free standing stable container is 300cpm, but more flexible systems are most likely run at 100 cpm. As the batch sizes are small, this really doesn't have that much impact though – certainly

the speed of changeover between different batches easily outweighs this.

Small batch sizes and more frequent changeovers will, logically, also mean an even greater emphasis on GMP design, especially in relation to line clearance. It is absolutely essential that the machinery can be cleaned quickly and easily and that no residue from the previous batch remains.

Choice is Good

As we see a key pattern taking shape in the pharmaceutical sector, with smaller – often highly valuable – batch sizes becoming ever more prevalent, investing in a labelling system that provides you with enhanced options and flexibility brings you greater choice and ultimately helps to future proof your business.

Newman Labelling Systems, established for over 70 years, is a leading supplier of specialist pharmaceutical labelling systems. Customers include major global pharmaceutical manufacturers as well as many smaller biotech companies and locally-based manufacturers throughout the world. For more information please go to www.newman.co.uk



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