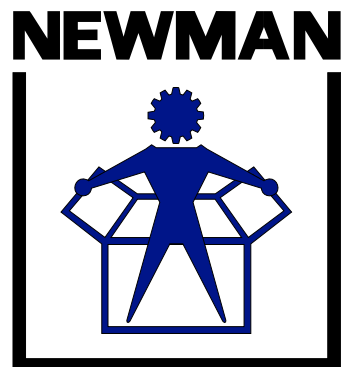



Speed is of the Essence... or is it?



By

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With ever increasing packaging production line speeds in the food and beverage sector, Mark McMahon, Managing Director, examines why the pharmaceutical industry isn't hurrying to follow suit.

On the roads speed may be judged by miles per hour but, on a pharmaceutical packaging line it's all about containers per minute (CPM); that's the number of containers processed every minute the line is in operation. When it comes to the specific part of the process where labels are applied to the container, CPM is increasing in other sectors - most notably the food and beverage markets - in a bid to get product to market faster, in larger batches and more cost-effectively than ever before. Where the food and drink markets go, the pharmaceutical market tends to follow. But not in this instance. So why hasn't the pharmaceutical industry embraced the need for speed?

Newman Labelling Systems has been in the business of producing automatic self adhesive labelling systems for the pharmaceutical market for 70 years and whilst we have certainly seen a number of changes in that time, one thing that has remained relatively constant is the speed of labelling. Certainly in the past decade or so there has been no significant change in CPM, which at first inspection seems at odds with industry trends in general. The maximum speed for labelling a free standing stable container remains at 300cpm.

There are some key physical aspects that impact the speed of labelling, which it is worth looking at first, including the container to be labelled and the label itself.

Container Type

There are a variety of containers used in the pharmaceutical sector, from glass vials to plastic bottles and card cartons, all of which come in different sizes with different capacities. The nature of the container has a direct impact on the speed of labelling; the larger the container the slower the speed. It is considerably faster to label a batch of 2ml glass ampoules for example than 500ml plastic bottles.

What might be less obvious is that the quality of the container also has an impact on speed of labelling. We have seen firsthand the effect of poorer quality materials used in containers and poorer quality container manufacturing processes. Not only is there a risk of potential breakage or damage to a poorer quality container, but the lack of uniformity can also be problematic as it can result in label skew. We saw this recently with a glass bottle container, where the mould and the overall container manufacturing process were substandard which directly affected the label application. It may seem tempting to reduce costs by using cheaper containers, but you may well run into difficulties at the production stage.

Another relatively new aspect which may have an impact on speed (and certainly has an impact on cost) is an increasing



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demand for preventing glass to glass container contact, or glass to metal, during the packaging process, particularly with glass vials, syringes and ampoules. It reduces the stress on the container so there is less breakage, which is important for health and safety considerations and also for profitability as some of the container contents are extremely valuable. This is difficult to achieve – although not impossible! – plus any additional requirement placed on a packaging line is bound to impact the speed of that line.

Label Type

The nature of the label most certainly has an impact on application speeds, very much in synch with those of containers, i.e. size and quality.

The longer, larger labels – typically used on larger containers - are slower to apply.

The quality of the label and label supplier is also important. Most self adhesive labels are die cut after printing. If the die cutting unit penetrates the label liner, it can lead to those liners breaking on the labelling machine. It is important to use a quality, experienced label supplier who understands the demands placed on the labels within the pharmaceutical market; thankfully there are plenty of excellent label suppliers out there.

One area that has helped speed up the labelling process has been the move over the past 20 years away from paper backed self adhesive labels to Polypropylene and PET liners. These are far stronger when



placed under tension so are better for labelling at higher speeds than paper lined labels.

Getting to the bottom of the issue

The vast majority of customers we work with use good quality containers and labels, but they still aren't increasing machine speeds. So what's really going on here?

In truth, there are a number of key reasons why CPM hasn't increased to any great degree in this market, but they may not be what you are expecting.

Regulatory demands

The food and drinks markets are highly regulated, but nothing in comparison to the pharmaceutical sector (as to be expected). Unlike the food and drinks sector, the pharmaceutical industry requires highly



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detailed documentation and validation, which directly impacts the speed at which a packaging line can run.

In theory, an inline Newman labelling machine could run at 600 CPM, but the third party equipment essential to meet regulatory requirements, most notably validation, cannot match these speeds and perform their task effectively.

In the European Union, the introduction of the Falsified Medicine's Directive will undoubtedly repress packaging speeds due to the coding requirements and the high quality printing and labelling required. Under the new Directive, every individual pack of medicine must be marked with a unique, non predictive serial number with information that can be read by people and machines; previously only data pertaining to the batch was required, but the onus has now changed to each and every individual container. The unique identifier must be placed in a 2D barcode and contain the product code, a serial number, the national reimbursement number (if requested by Member States), the batch number and the expiry date. Each serial number must be registered with a pan European database.

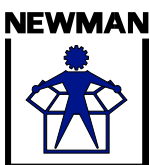
To achieve this, thermal transfer or inkjet printing technology is necessary, but these simply cannot operate fast enough to match the potential high speed a label applicator can accommodate. Vision systems are also a restricting factor although more recent models do operate well at higher speeds. The reality is

that these aspects of a labelling system – essential for regulatory compliance – have to run at a lower speed in order to provide the quality service they have been designed for. Very few such systems could run at 400 CPM or more and meet the quality required.

Batch sizes

In the food and drinks market batch sizes are often huge and packaging lines are operated round the clock, so the speed of labelling these items is important. Batch sizes have always been smaller in the pharmaceutical sector and, in recent years, have actually reduced. Whereas a batch would often take a day or more to label, the norm is now half a day. As the CPM speed hasn't increased, it's a clear indication that batch sizes have reduced.

This has changed the emphasis away from the speed of applying the label to the speed of changeover. Changing from labelling one container type to another often requires considerable down time for preparation. Lower quality labelling systems will normally require an operator to change the machine settings manually which not only takes time but also leaves it open to human error. This can be avoided, and the changeover time reduced, by opting for a labelling system that automates this process. Newman Labelling systems', for example, incorporate inline machine settings which enable the operator to auto synch all the machines features/functions from one container type and CPM to another, at the press of a button.



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Exception to the rule

The reality is that speed of labelling in the pharmaceutical sector isn't a key priority for most – line efficiency is. But as always there are exceptions to the rule. These exceptions tend to be with lower value items such as dental anaesthetic cartridges, containers of insulin, generic products and product destined for the veterinary market. Because of the low unit cost, there is a need to get these to market faster.

Whilst the majority of systems in use in pharmaceutical packaging are inline machines which operate below 300 CPM, to achieve higher speeds a different type of machine is required that is able to hold the container, rather than relying on the containers to hold each other in place. This generally involves a machine that operates with a starwheel or the less popular rotary carousel. Newman's VAL550, for example, is a starwheel based system that has

been specifically designed for high speed labelling up to 600 CPM. It uses a vibrating diamond shape to move containers forward gently into a starwheel via a simple gating blade to feed product. Such a design prevents the container from moving at the point of label application.

As you might expect, higher speed machines tend to come at a premium as they benefit from a more sophisticated mechanical design and are manufactured to a higher quality overall.

But this really is an exception to the rule. The pharmaceutical industry isn't driven by speed and, with the growth of the biotech industry, we are seeing higher value products produced in lower batches where line efficiency is the number one consideration, not speed. In fact, in some cases we have seen customers actually reduce speed with the successful outcome of increasing yield and overall output, as there is less damage to containers.

So it seems it is a case of the tortoise and the hare, with the slower tortoise winning the race!

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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