

## pharmaceuticals



The patient information booklet, the two blisters and a branded outer carton remain connected at all times and therefore aids compliance

# Compliance issues bring new pack opportunities

With a number of major acquisitions and mergers in the last number of years and the manufacturing asset rationalisation that accompanies such activities, the UK pharmaceutical manufacturing base has seen a significant reduction in both the number of sites and personnel involved in both primary and secondary production. None the less, the UK pharmaceutical sector still remains a significant net exporter and leads the ranking of UK manufacturing sectors in terms of net positive trade balance.

The Association of the British Pharmaceutical Industry (ABPI) is the trade association for more than 90 companies in the UK producing prescription medicines for human use. Its member companies research, develop, manufacture and supply more than 80 per cent of the medicines prescribed through the National Health Service (NHS). The ABPI says the pharmaceutical industry continues to provide outstanding value to the nation with total sales to the NHS for 2009 being £12bn. Indeed, the proportion of the NHS budget spent on medicines has remained at roughly the same level for many years.

According to the ABPI, the development of the Falsified Medicines Directive in Europe has been a significant issue in the last couple of years and the draft directive continues its path through the European Union's legislative process with adoption

hoped for towards the end of 2010. It is anticipated that the directive will lay down a number of new requirements which will tighten up the supply chain for medicinal products and active pharmaceutical ingredients in Europe. It will also require the addition of safety features to allow tamper evidence for medicinal product packs and also unique identification of individual packs to facilitate verification of the authenticity of a medicinal product by the pharmacist and other members of the supply chain.

As for future trends in pharmaceutical manufacturing, the ABPI talks of the development by the International Conference on Harmonisation of Quality Guidelines Q8, 9, and 10 on pharmaceutical development, quality risk management and pharmaceutical quality systems respectively.

This, says ABPI, will lead in the longer term to a life-cycle approach to the development, manufacture and quality assurance of medicines with progressively less reliance on end testing of products and a facilitation of adaptation to emerging innovative technologies during the life cycle of products.

Pharmaceutical manufacturers spend their lives jumping through regulatory hoops and this is often why any new product developments can take an age to reach the market. It is, by its very nature, a conservative industry but Bayer took the

plunge with a brand new pack format from Burgopak to launch its Rennie ICE OTC product last year. And this new pack format also tackles the important issue of patient compliance head on.

The blister packs patented sliding mechanism helps provide an innovative design that's easy to use. In a one-slide motion, the pack opens to reveal twelve ICE tablets in two separate blisters while the patient information booklet, the two blisters and a branded outer carton remain connected at all times.

The Burgopak is designed around this unique operating system that has been optimised for production on the company's Bosch Siggpack machinery. The pack's high structural integrity also extends its lifespan and ensures that the patient retains the entire pack intact at all times as well as discouraging counterfeiting and piracy.

Four basic designs can be adapted, each of which can be customised to accommodate nearly any pill, blister or leaflet size.

Patient compliance is a key issue in pharmaceuticals as well as differentiation according to Burgopak's ceo Tim Clarke. "Compliance improves effectiveness of products and can therefore increase sales," he tells *Machinery Update*.

Learn more about Burgopak (page 30-31) and other developments in pharmaceutical packaging in the next few pages.

pharmaceuticals

# Combining long term goals with short runs

*Four years ago, Brecon Pharmaceuticals was welcoming a new owner and doubling the size of its Hay-on-Wye site. Business development director Steve Kemp talks to Machinery Update about its needs both for capacity and flexibility on-site - and for greater flexibility from its machinery suppliers*

As far back as the mid-1990s, specialist contract packer and outsourced services company Brecon Pharmaceuticals was planning the expansion that would see it doubling its footprint to some 126,000 sq ft by 2006. That same year, it became part of the \$75 billion-turnover US-based AmerisourceBergen Corporation.

Business development director Steve Kemp wastes no time 'unpacking' these two key events, in terms of the implications for Brecon and the context they provide for its operation.

On the question of scale, he explains: "Effectively, as a contract packing company, our 'inventory' is capacity. Prospective customers must be able to have confidence that we will be able to supply."

## Low utilisation

So, while a brandowner would be looking for a very high percentage utilisation of equipment, the target for Brecon is surprisingly low (but also commercially sensitive, so not for publication). As Kemp puts it: "I'd rather not have idle people, but I don't mind having idle machines."



*Steve Kemp is business development director of Brecon Pharmaceuticals*



*This Bosch Sigpack machine, the only one of its kind in the UK, produces Burgopak patented blister packs*

Otherwise, you've got nowhere to go in terms of new business."

The issues of capacity and utilisation are inextricably linked to the question of run length. While co-packers peg their expectations low when it comes to equipment utilisation, efficiency-hungry pharmaceutical brandowners are pushing in the opposite direction. But at the same time, the trend in the sector is towards shorter – not longer – individual runs, meaning potentially lower line utilisation efficiencies.

This is partly to do with wider developments in the sector. "By 2012 or 2013, many of the 'blockbuster' drugs will be coming off-patent," says Kemp. "And there are few new big products on the horizon. The newer generation of products tend to be required in smaller quantities."

From Brecon's perspective, these latest tendencies only serve to exacerbate the fundamentally fragmented nature of its business. Kemp, who is an engineer by training, here cites the example of blister packing. "We have more than 100 customers and, even on something as basic

as a blister pack, they all have a slightly different configuration or varying requirements. We have around 700 sets of tooling just for blisters."

The new trend towards smaller batches and shorter runs emphasises this effect. "The smaller the batch, the higher the cost," he says. "So you try to reduce that cost, which clearly helps the pharmaceutical company, but also helps to make the product affordable, for example, for a given emerging market."

## Late Stage Customisation

One option here is Late Stage Customisation (LSC), the production philosophy which hinges on the idea that automated; high-volume lines can be used to pack a 'core' format. This can then be customised, once an order is called off for a particular market, with online printing, labels and leaflets appropriate to that market. Kemp stresses: "Total packing costs may actually be the same, but overall, supply chain costs will be reduced."

The HAPA online printing system for 'white' cartons is a prime example of the

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Dedicated feeders are used for difficult to handle or fragile products at Brecon

LSC approach in action. Brecon has one of these lines, but Kemp explains that the bulk of the customisation phase is carried out either manually or on semi-automatic equipment.

In fact, although LSC enjoys a high profile, and makes perfect supply-chain sense, it still accounts for only a small proportion of Brecon's output - over 95% of which consists of 'final' packs, says Kemp.

### Anti-counterfeiting

Famously, Brecon is also home to the world's first Bosch Sigpack Burgopak machine, although a second is currently being installed in the US. Here, quite apart from the convenience, compliance and branding benefits, the burning issue of anti-counterfeiting comes into play. "There's so much of this trade going on, with fake product in a genuine-looking pack," he says, predicting that this struggle will intensify over the coming years. "Something like Burgopak can help, since it's a difficult pack to do 'diversion' with."

Another major change in the international industry is the introduction of 2D matrix codes. France and Turkey are making them mandatory from the beginning of 2011, and other countries will follow. "We're already investing £300,000 to install the necessary printing equipment, readers, verification and IT on three of our lines, but we will need to convert a total of 17 lines over time," says Kemp.

Similarly, patient compliance - or 'adherence' as it tends to be called now - is

a growing issue, he says. And as vice-chair of the European Healthcare Compliance Packaging Council, Kemp knows what he is talking about. Brecon's parent company has an assortment of different pack options, all of which promote both child resistance and patient compliance.

As with anti-counterfeit features, this is one area where packaging - and the machinery systems that make it possible - can play a vital role.

But to return to the second pivotal change of four years ago, the change of ownership, Kemp highlights the security this "huge parent company" gives to the business. While the group is no spendthrift, this does mean that when it comes to investment budgets "we do all right", he says.

In some ways, of course, the realities of the US pharma co-packing market are very different. "They call a 'short run' anything less than 10 shifts!" he says. "On some days, exceptionally, some of our lines will

change four times a day, and twice a day is quite common."

In fact, the parent company understands Brecon's need for flexible equipment - typically medium-to-high speed, offering fast changeover. But getting some key messages through to its machinery suppliers can be more challenging, says Kemp.

### Suppliers should listen

"Even the larger machinery companies could listen more," he explains. "In the market space they're in, serving the pharma industry, they need to understand Good Manufacturing Practice (GMP) and what it is their customers are looking for."

The elimination of traps where product can accumulate and potentially contaminate subsequent runs is a particular headache, he says. "When our own customers audit us, they ask what we are going to do about it."

He adds: "We deal with some excellent equipment companies. But then, we often find ourselves having to modify the machines ourselves to make them more GMP-compliant."

For a company so adept at tailoring products for its customers, it must seem odd that some of its own suppliers can appear less than willing to customise the products that they provide.



Brecon services over 100 customers



The Hay-on-Wye sites houses a Noack 623 blister packer and Promatic PC 4200 cartoner

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# Blister line is integrated

The new C80HS-A96 from Ima Safe is an integrated blister line designed for the production of medium batches and frequent size changes while reaching production speeds of up to 700 blisters and 450/500 cartons a minute.

Ima says the compact design and its ergonomics allows maximum accessibility and cleanliness and due to its ease of use, only one operator is needed for the whole line. The machine concept is based on the

Ima philosophy of flexibility in operation and changeover combined with easy cleaning.

An integrated blister stacker together with the special transfer system to the cartoner, via a positive blister transport, is said to guarantee efficiency. Rejected blisters can be identified easily due to a difference in shape to the correct ones which avoids any mix ups during the production process.

At the same time, Ima Safe has developed a medium speed packaging line for topical drug products which is destined for the demanding Japanese market.

The new packaging cycle consists of the loading of small aluminium tubes containing 5, 10 and 30ml doses of the drug and an application cannula into each pack. The packs are then collected into a cardboard container with enough room for the information leaflet which is



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GMP



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placed either on top of or alongside the packs. A special tear-off opening transforms the container into a display box so that all ten packs can be seen from the outside and easily removed by the patient.

The packaging cycle is completed by an Ima Safe Dynamica SM cartoning machine followed by a checkweigher, a second Ima Safe Easy cartoner and finally a case packer integrated with the Ima Safe Line CP18 Miniflex palletiser.

The line also incorporates a series of quality checks, all integrated into each machine.  
01789 767330  
[www.ima.it](http://www.ima.it)

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# Traceability laws should counter pharma crime

*Impending legislation mandating full traceability in the pharmaceutical supply chain will require investment in print and verification capabilities while validation is also coming to the fore*

With Turkey having implemented a scheme earlier this year and France's CIP13 scheme scheduled for start up on January 1 2011, the issue of product authentication via serialisation at unit of sale level is certainly concentrating the minds of the global pharmaceutical community at the moment.



*Domino's G-Series can print on a variety of substrates*

Turkey and France are in the vanguard but proposals for other markets – including Brazil, China, Greece, Serbia, South Korea, Spain and some US states – are also under discussion, along with a pan-European scheme being championed by EFPIA (European Federation of Pharmaceutical Industry Associations).

This means that “producers will have to comply with traceability schemes of any market they're supplying to, irrespective of where they are based,” explains Trevor Nichols, market sector manager at Domino UK. Indeed, according to Domino, up to 80% of currently installed coding devices will eventually be rendered obsolete by traceability requirements, due either to incompatibility with the requirement to produce serialised numbers or inability to do so at acceptable speeds.

“Proposed schemes vary from market to market but virtually all will require a combination of a 2DMatrix code plus multiple lines of alphanumeric text incorporating product code, batch number and expiry date,” says Nichols.

These requirements have been pivotal to the development of Domino's offering for the pharmaceutical sector, in particular its G-Series range of thermal ink jet printers and D-Series plus range of industrial scribing lasers,

both of which have been designed to integrate easily into new or existing lines.

The pharmaceutical industry is rapidly embracing the benefits of full product traceability, and with the World Health Organisation reporting that drug counterfeiting is costing manufacturers some £50bn per annum, it's not hard to understand why.

It is expected that 2D Datamatrix barcodes to GS1 standards will become the common currency of pharmaceutical product ID, so high print quality is a prime requirement in the sourcing of new coding equipment. Markem-Imaje laser and SmartDate thermal transfer coders share this capability, and each has its place in specific pharmaceutical applications.

With its ability to print on a wide variety of materials and surfaces, it is continuous inkjet, however, that has proved the most versatile printing technology for the healthcare industries, says the company. The design of the Markem-Imaje 9000 series of printers includes a compact and robust printhead, allowing for easy installation on any production line.

At the same time, Codeway can provide a complete service for pharmaceutical EFPIA identification including printers, label applicators, automatic on-line identification machinery, data capture equipment, consumables and system software including integration with host packages and logging of EFPIA coding.

01954 782551  
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www.codeway.com



*Advanced Medical Solutions uses a 9040 printer*

## Validation increases

Pharmaceutical labelling supplier Newman Labelling Systems has seen increased levels of validation work and documentation in recent times. More specifically, it has seen an increased requirement for Functional Design Specifications (FDSs) from its North American and European customers as part of the scope of supply when purchasing a labelling machine.

Five or so years ago, FDSs were only requested by top tier customers for high end machines, but now a much wider range of clients expect this level of documented work, even on standard labelling systems. These in-depth documents detail the function and operation of the labelling machine while FDSs remove any misinterpretation of what is being sold/purchased making them a valuable commodity for end users looking for increased equipment efficiency.

To provide comprehensive validation documentation for a specific piece of machinery, Newman has invested in technology and also trained its staff to understand not only the machinery but also the regulations and standards.

Labelling company Norprint is another supplier that spends time keeping its staff up to speed on any legislative changes.

It offers a print and verification solution that checks the information is correct, serialises each product label and provides a full audit trail as well as having a 2D barcode generated. It also offers a braille labelling system which embeds braille on to product packaging via a label and special software. This system can also be used by pharmaceutical importers.

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## special feature

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*The new CF-622 builds on the technology of this CF425 machine, especially the new moving parts around the container handling*

# Tablets counted at faster speeds

Cremer is very excited about its new CF-622 tablet and capsule counter as it demonstrates new developments in every area of product contact, container handling, electronic control and product containment.

It has taken several years of development and it will be launched at PACK EXPO (see page 24) in Chicago this autumn.

For most tablet counters, the speed of the system usually depends on the feed rate of the product and containers so that a buffer of empty containers is needed and an over capacity of speed is designed in to suit the rest of the line. This new machine, however, is totally different as the customer can preset the precise output required and this is delivered to onward machines such as cappers or labellers.

“There have been radical innovations to achieve this at high speeds of up to 300 containers a minute,” explains Roger Wayte, sales engineer at Cremer.

Firstly, and to suit customer requirements, the counter is made up of smaller six channel modules similar to its predecessor, and each module counts at up to 40 discharges a minute with the possibility to have between 3 and ten modules. Each module is fully servo motor controlled and setting up one sets an identical parameter on the others.

Next, the products are mechanically dosed onto the vibratory transport platens so there is gentle handling, complete hopper evacuation and a very even distribution across the width of the channels.

And, says Wayte, this high speed is achieved within the footprint of a typical single head machine. “This gives massive savings in Clean Room production area costs.”

“We have also patented the new IMFS (In Motion Filling System) and it provides a very long filling time under each filling module with no extra space requirement,” explains Wayte.

01276 35053

www.cremer.com

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# Taking great care of woundcare dressings

Olmec has helped two woundcare dressings companies to enhance their quality control systems while installing two very different types of machinery. A seal inspection system has been installed at one while a 5 axis pick and place QC transfer system with integrated vision, quality control and reject facilities is at work at the other.

The seal inspection system has been integrated into an existing medical dressing line to ensure the integrity of four sided seals. It checks for products trapped in the seal like foreign objects, the correct product or any contaminated product and subsequently rejects any flawed dressings.

Integrated cleanly into a minimal footprint on the machine, the system operates at up to 150 products a minute which allows OEE standards to be maintained. The company's strength in lighting techniques allowed a reliable solution to be achieved for these multi material packs.

As well as enhancing the quality control process at the second medical device manufacturer, Olmec has increased production speeds through the installation of



Olmec's seal inspection system ensures the integrity of four sided seals for dressings

the second line which is described as meeting the current trend within the pharmaceutical and healthcare markets for low cost, high performance machines. The pick and place QC unit links together two existing manufacturing processes enabling precise product placement of up to 168 products a minute.

Not only are the products accurately placed faster than the previous labour intensive process but, due to its double layer conveyor feature, the entire system has a high speed product changeover capability of less than two minutes.

01652 631960  
www.olmec-uk.com

## Purpose designed accuracy

A multi national veterinary pharmaceutical company has installed a new filling and capping line from Adelphi Masterfil which comes complete with a Bizerba checkweighing machine to ensure optimum accuracy.

The filling machine is a four head, 5 litre in-line Multifil filling machine and is linked to a single head indexing capping machine. A

checkweigher is positioned at the outfeed of the capper with the entire line designed to fit into a purpose built factory in Scotland. "We are now using the filling line every day and can fill a 3,000 litre batch in under 50 minutes compared to the 3-4 hours which is a great improvement," says the production support leader for the site. "The fill volumes are also excellent with a variation of less than 0.2%."

The filling machine has diving nozzles which can be programmed to rise with the level of the liquid and come with an integral drip suck-back system fitted to each nozzle.

The Mastercap single head indexing capping machine provides a reliable capping operation at a maximum speed of up to 60 a minute, depending on the product, container and the cap style and type.

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A new filling and capping line has been installed at a veterinary pharmaceutical company

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## Fast topsert applicator

Sovereign Labelling Systems has developed a high speed topsert applicator using a servo driven pick and place unit to complement its range of pharmaceutical specification outsert applicators.

To facilitate continuous running, the topsert is held in a 2,500mm indexing magazine, adhesive is applied to the product cap using a Nordson hot melt glue system and the topserts are then placed.

Cameras and pharma code readers can be linked to the system for product security.

The outsert applicators from the company can be used on round and square containers.

01206 304182

[www.sovereignlabelling.com](http://www.sovereignlabelling.com)

# Coatings measured on line

Oyster Manesty has worked with TeraView and the Universities of Cambridge and Liverpool to demonstrate its ability to measure the real time coating thickness distribution of individual tablets on line within a production scale coating pan.

The proprietary terahertz sensor technology has been adapted to the Manesty coater design to provide continuous on line measurement of coating layer thickness including multiple layer coatings. The measurements do not require calibrating and are made on individual tablets which allow tablet to tablet and batch to batch variability to be assessed.

Existing techniques require calibrating prior to every process formulation or product change and also measure multiple tablets rather than each individual tablet. This means tablet to tablet variability within a batch during the process cannot be measured.

Knowing and managing thickness variability is a key quality attribute for products whose coating thickness is directly related to their performance. Controlled release drugs, for example. Assessing

quality just on an average thickness can lead to tablets being out of specification or excessively coated. Industry figures have indicated that new controlled release products have between 10-25% batch wastage in the first five years of launch.

The integrated Manesty/TeraView system can measure this variability on line.

Because the system is flexible and fast, it can be used in process development, scale up, technology transfer and manufacturing and is suited to work on all scales of Manesty coaters. The unit also complements TeraView's existing offline tablet imaging system, the TPI imaga 2000.

The TPI imaga 2000 was developed specifically to study coating variability within individual tablets and between tablets off line and as such is perfect for product design. The new system translates this data and allows the measurement, and ultimately the control, of the coatings on line.

The company says this development gives it the ability to offer customers complete control.

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3. **Check** that packaging substrates are stored in clean conditions and at room temperature. The combination of cold materials and hot print-head can result in faint or patchy codes, whilst grease and dust also affect print consistency.
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5. **Optimise** the coder settings. Your SmartDate® coder has adjustable darkness settings – select the lowest setting that gives the required print quality to help prolong print-head life and reduce element failure.
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# Automated diagnostics

Lab21 has installed two semi automatic Flexicon FF series tabletop filling machines from Watson-Marlow to improve accuracy and relieve repetitive manual operations at two of its diagnostics facilities in Suffolk.

“Previously our vial/bottle handling and filling/capping operations were predominantly manual,” explains Ian Christopher, operations director at Lab21. “However, we knew that by automating these operations we would improve accuracy and consistency, as well as ensure the ongoing health and safety of our employees.



The FF20 is a filling system for medium sized runs of up to 2000 units an hour

Christopher says that the company’s main criteria were price, compatibility and size as space is always an issue. The model selected, a Flexicon FF30 semi-automatic tabletop filling and capping machine can handle bottles between 12 and 50mm in diameter.

This modular bottle handling and tightening system is ideal for small scale production (up to 1200 units an hour) and product changeover can be completed in less than 10 minutes. A second unit, this

time an FF20, has a filling range from 0.1 to 150ml. 01326 370370 [www.wmpg.co.uk](http://www.wmpg.co.uk)

## Maxi cartons

Manufacturer of the Compact cartoning machine U-E-T has launched the Maxi, the latest model to the range. It can accommodate much larger pitch cartons up to 200 x 95 x 250mm and is available with semi automatic or automatic product loading options. Within the units small frame range, the machine can be fitted with leaflet inserter, leaflet and carton barcode readers, coding equipment vision inspection systems and special pharma finishings, says UK agent Springvale Equipment.

01420 542505 [www.springequip.co.uk](http://www.springequip.co.uk)

## Validatable

Flow wrapping equipment that conforms to FDA 21 CFR 11 validation requirements is available from Italian manufacturer PFM Packaging Machinery following an extensive programme of development and proving with a medical device manufacturer. PFM has adapted its established Scirocco flow wrapper.

0113 239 3401 [www.pfmuk.com](http://www.pfmuk.com)

## Palintest tests the water with tablet press

Water analysis technology company Palintest has turned to Isopak for a new tablet press machine for its dedicated research and development facility at its Gateshead site.

Accuracy, reliability, space and value for money were all key factors in Palintest’s decision to opt for a CPR-6 bench top single punch automatic tablet press.

Described as one of the smallest bench top table

press units in the world, the CPR-6 is designed for small batch runs while allowing the user to view exactly what is happening to the product during the pressing process. The machine also records all activities and measures the compression forces needed for transferring the product to larger, full scale production systems.

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