

EU-system for identification

The European Federation of Pharmaceutical Industries and Associations (EFPIA) has called for measures to tackle the growing threat of counterfeit medicines, including a ban on repackaging medicines, a harmonised EU-system of identification, and heavier penalties for trafficking in counterfeit medicines.

Ten different systems coexist in Europe today (using different types of barcodes and with or without unique pack identification).

This fragmentation increases the difficulty to track and trace medicines effectively at a European level and constitutes a substantial cost for the pharmaceutical industry. EFPIA recommends the implementation of a standardised and unique coding system for medicines in Europe.

Proposals for tougher EU legislation are expected before the end of the year and EFPIA is recommending a ban on all forms of medicine repackaging as a prerequisite for an effective anti-counterfeiting strategy.

Additionally security features must be developed for packaging through unique identification codes to verify the origin of a medicine.

EFPIA is making plans to launch a pilot scheme of a unique bar code system, which will enable the pharmacist to verify each medicine pack before dispensing it to the patient.

This pilot will be launched before the end of 2008. The technology will use the 2 dimensional data matrix and could be used as an EU standard, says EFPIA.

www.efpia.org

Wind of change set to blow in from the East

While keeping more than one eye on competitive equipment from the East, established manufacturers of processing and packaging machines for pharmaceuticals must respond to new demand patterns in the sector. The development of bio-tech products is seeing an increase in liquid dose processing but solid dose forms still dominate the market, and tablet making and blister packing innovations are still of major importance. But batch sizes are coming down and cost pressures are going up, at the same time as regulations tighten, so the demands placed on machinery makers are high. How are they responding? In the following pages Machinery Update looks at some of the latest developments we have uncovered...

Integration is the magic ingredient

A maximum output of 1000 packs/minute can be achieved on its new, fully integrated processing and packaging line for pharmaceutical strip tablets, says Romaco.

StripTabs™ can now contain active pharmaceutical ingredients for use in the treatment of conditions such as migraines or even cancer, rather than simply for oral hygiene applications. The wafer thin strip tablets have a thickness of between 60 and 100 microns, are taken orally providing rapid distribution of the active ingredients through the body, claims the company.

Mixing of dry and liquid ingredients to form a homogeneous, dense solution is undertaken on a FrymaKoruma machine, which provides extremely accurate dosing of the active ingredients, says Romaco. Continuous circulation, recirculation and heating of the liquid keep the viscosity and concentration of the mixture constant during processing.

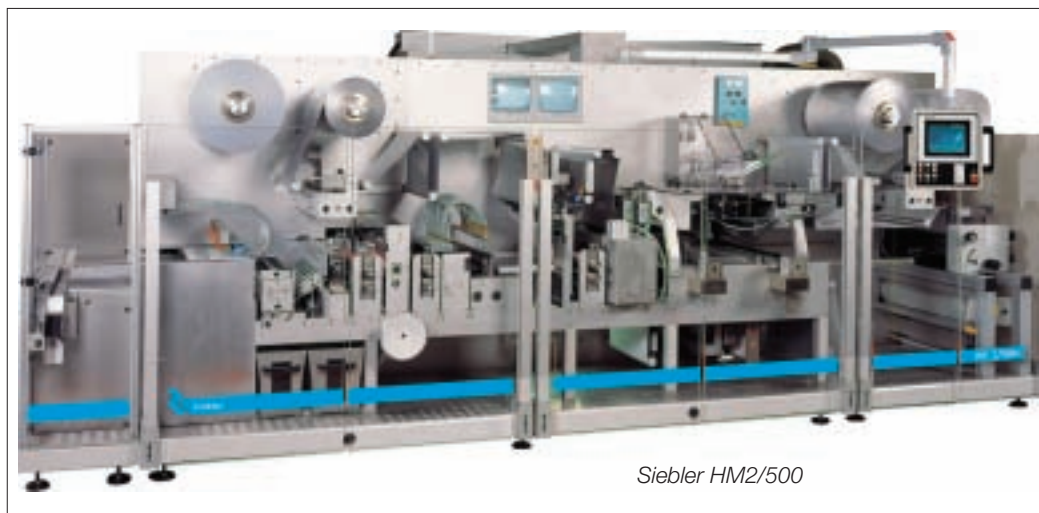
The solution, with a thickness tolerance of one micrometer, is then passed to a OPTIMAGS coating plant where it is applied to a carrier foil prior to being passed through several drying units, after which it is rolled up.

Cutting and packaging takes place on a Siebler HM2/500 hot-seal machine where the roll material is unwound and perforated into small rectangles (20x30mm). The StripTabs™ are then delaminated from the carrier foil and placed on the primary packaging foil via a shuttle system. They are then sealed in air-tight soft aluminium foil packages which can be peelable.

"The high dosing accuracy of StripTabs™ is achieved through the perfect interaction of different machine systems in a fully automated production sequence," according to Martin Grau, product manager at Romaco Siebler.

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Siebler HM2/500

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■ **Oystar IWK** has launched the BP5 flatbed blister machine for intermediate outputs. Key features are extremely fast changeover and format changes without tools, says the company. This machine complements the SC5 cartoning machine, also for low to intermediate outputs for both cycled and continuous operation, (up to 200 units/min). The modular design makes it extremely versatile, says the company.

Also from IWK the FeedCell is a new, flexibly configurable, universal feeder which can collect, group and transfer a wide range of different products. T: +44 (0) 1252 732210 E: info@oystar-iwk.co.uk

Giant is just in time

The Giant1 blister line from IMA is designed for larger pharmaceutical companies and contract packers where small to medium batches or just-in-time production is required, for outputs up to 350blisters/min and 175cartons/min.

By limiting the number of size parts and reducing their weight, changeover times have been reduced to 'unprecedented levels' claims the company. 'In the time it takes to changeover a super-high speed machine Giant1 will have completed 3 more batches'

The line is equipped with the new Touch & Change system, or Small Format Adjustment Drive developed by SICK-Stegmann in co-operation with IMA, for fully automated adjustments.

Also from IMA is a new rotary tablet press with wash-in-place, (WIP), capability, designed to meet the demand for automated cleaning and greater operator safety, says the company. With the Kilian Synthesis 700 WIP system the process area is completely isolated from the mechanical area through the use of Viton seals which separate the



die table from the cover segment and lower machine. A silicon band isolates the die fixing screws, while rubber bellows seals protect the punches. Spray nozzles are located in each part of the process area and also inside the aspiration system. Water use is limited to the process area to avoid moisture contamination on mechanical parts and enables reduced water usage.

Other recent developments are the Hermetica banding machine for tamper evident sealing of capsules and the Perfima 500 perforated pan for tablet coating.

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pharma - packaging

Dynamic motion for tube filler

The MT1000 rigid tube filler, launched by the Marchesini Group is claimed to be ergonomic, innovative and revolutionary.

Tubes are conveyed in holders using synchronised dynamic motion, while tablets are inserted using a positive pick and place system. A primary advantage is that both tube and tablet feed system are now more compact.

After orientation by screw feeder the tubes are picked, and loaded onto two parallel belts, each having its own independent motor. This synchronised dynamic motion, says Marchesini, cuts out unnecessary stops for the tubes between operations, making the process both smoother and continuous.

The tablets are picked up by suction cups in rows of 12 at a time and are then turned through 90° before being placed directly into the tube. This pick and place technique prevents the tablets being subjected to rubbing, friction and pressure, so preventing damage. Counting procedures are also facilitated by this method, says the company.

Marchesini also now offer a complete syringe line covering all operations from plunger application to palletising. It is comprised of a MP100 denester made by Co.Ri,M.A. which picks and checks the already filled and closed syringes. Handling is very precise, says the company, to avoid damage. Plungers are then applied, as well as labels and safety devices using an APS Combi, also from CoRi,M.A.. They are then sent to a



The MT1000 rigid tube filler

Farcon FBZ320 thermoformer for packing into trays. This machine uses eleven servo motors and is in full compliance with GMP standards.

Finally the trays of syringes are transferred to a MA302 cartoner, followed by a Neri BL 400VTE labeller prior to palletising on a MCP840 vertical case packer/palletiser.

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World's fastest line?

The blister packer B1660 MTI, with speeds up to 700 blisters/minute, is a newcomer to Uhlmann's range. In tandem with the C 2504 cartoner the company believes it is the world's fastest integrated line, packing up to 500 cartons/minute.

It can operate with all common types of forming material and controls the discharge of waste and heat to ensure a proper clean room atmosphere.

Among the claims made for the new blister packer, are: +20 per cent operating efficiency; +50 per cent cleanability; -50 per cent noise emissions; -40 per cent changeover times and -30 per cent life cycle costs.

A feature of the machine, says Uhlmann, is the blister transfer to the cartoner. Blisters are pushed in an upward direction and suction devices gently place them onto the vacuum conveyor where they

are moved to an intermediate position. The blister lanes are then centred before loading into the product chain. This new form of transfer means it is unnecessary to have an additional product chain in the cartoner, saving both space and money, it says.

The company also claims to make the world's fastest single lane packaging line – the Blister Express 500, an integrated blister machine and cartoner with production capability of batches between 30,000 and 150,000 pvc/aluminium blisters.

Also new from Uhlmann's VisioTec quality control division is the VisioNir in-line system for contact free monitoring of active substances.

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- **groninger** has several new developments for the pharmaceutical sector, including an enhanced method of dehydrogenising and silicone fixation in vial processing by means of single in-feed, hot air and cooling modules. Also available is the compact DFVN 1000 V nest filler featuring process steps, filling and stopper insertion identical to those used on a high speed line. With patented vacuum technology it is ideal for test runs or small batches up to 4800 syringes/hr, says the company. Two other machines, the MFCS 202 QL, capable of filling and closing up to 72,000 bottles/hr and the compact KVK 310 B fully automatic closer which can crimp caps at a maximum capacity of 36,000/hr are also new to the market.
www.groninger.de

- **Thermo Fisher Scientific Inc** and **Pharma Polymers** (part of Evonik Industries) are to co-operate to advance the hot melt extrusion process in the pharmaceutical industry by combining formulation and polymer expertise with equipment from Thermo Fisher Scientific.

The aim is to develop a solution that will overcome process challenges, such as solubility, and improve time to market. The teams will work together at the Pharma Polymers facility in Mumbai, India and will provide feasibility and trials for pharmaceutical manufacturers mainly in Asia.
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■ **Newman Labelling** has supplied a NV2 fully automatic self adhesive labelling system to Abbot's Mexico City plant.

The machine is being used in the tableting area for labelling plastic containers of vitamins at speeds up to 150cpm.

The NV2 was supplied on castors to facilitate moving between lines.

The machine can be used on cylindrical, flat and square containers from 10mm to 150mm.

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■ **Packaging Automation** has entered the medical market with a range of machines developed specifically for packing medical devices and surgical instruments including implants, diagnostic kits and wound dressings.

The machines incorporate special features, says the company, such as a direct pressure transducer to record that the seal force is within pre-set parameters and a thermal printer to provide data on seal force, seal time and other information for security and traceability.

The equipment also offers identification on the base sealing tool by the machine software, using RFID, to allow auto selection of process parameters.

The range meets the stringent requirements for hygiene, pack validation and seal security, according to PA, which offers its facilities for trials and testing of pack designs and materials.

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Blistering developments

The new CP500 blister machine from Körber Medipak has been developed specifically for packaging blisters with deep draw depths for ampoules, vials and syringes.

However the MediSeal machine is also suitable for the production of tablet blisters, especially products which require aluminium blisters with deep pockets and is ideal for small batch production, according to Körber.

A base storage bin has been incorporated which greatly reduces foil changeover times, says the company. The flexible pocket design, with an optional special forming depth of 35mm enables not only non-standard items to be packed, but also ampoules, vials, syringes or other medical devices. The CP500 can be switched from one format to another in less than 30 minutes.

Körber has also introduced a high performance stick pack machine to its MediSeal range. The fully GMP compliant LA600 SP can operate up to a maximum of 16 lanes and is capable of producing more than 1000 sticks/minute for both pharmaceutical granulates and liquids.

Its 6m2 footprint makes it extremely compact, while the machine also features a simple tube removal system and its modular design lends itself to expansion as production requirements increase.

Late Stage Customisation is now being offered on all Körber Medipak's MediSeal blister machines enabling serial processes such as packing, printing and cartoning to be run in



parallel achieving time saving and greater flexibility, says the company. Small, country specific, batches can be combined on one machine, it claims.

The heart of the concept is a logistics module, the BIB-BOB, which allows blisters to be taken from the packaging line and stacked in a bulk magazine. These blisters can then be transferred at a later stage back into the cartoning process. This says the company can improve line efficiency by up to 30 per cent.

The inline printing facility, which has been developed by Atlantic Zeiser, enables blisters to be coded immediately prior to being cartoned. A 2D matrix code can be applied as a unique ID for individual blisters, guaranteeing pharma security, says Körber, even when the production process is de-coupled. Other identity features such as an RSS code can also be applied in-line.

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Sliding into pharmaceuticals

Bosch Siggpack Systems has developed, in conjunction with its British designers, an automated line for the Burgopak style of carton,



particularly for use with pharmaceutical products such as OTC drugs packed in blisters.

Until now some 25 million Buropaks have been hand assembled for use with products such as DVDs and cell phones. The machine uses specially developed feeding-wheel technology.

The slide mechanism holds both the blister and information about dosing in position for each use. The carton is designed with open ends and access to the product is achieved by pulling on one side, causing the product carrier positioned opposite to extend and show usage instructions at the same time.

The pack is also tamper evident.

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- The patented Gentlewing mixing device from **Oystar Hüttlin** does away with the problem of products sticking to side panels and incomplete emptying, it claims.

It will produce excellent mixing quality even at slow speeds. The device has been incorporated into two new high-shear mixers, the lab-scale Mycromix, for batches between 0.5 and 2Kg and the Pilotmix, pilot-scale, granulator which features the same geometric container as the existing top-drive system. Both have bottom drive technology. www.oystar.huettlin.de

- The new Cyberfill aerosol filler from **Oystar Aerofill** can be configured as a single head machine for semi-automatic operation or as an in-line system for higher speed. It features a 'bottom up' filling technique. The company's new Flexipak machine features a patented change-part-free container handling system. www.oystar.aerofill-dawson.com

pharma - processing

Bosch gets clinical ...

The FX2050 syringe filling line for pre-sterilised syringes from Bosch Packaging Technology (BTP) has been developed for processing liquid pharmaceuticals during clinical trials.

The line replicates the same process parameters used in mass production, enabling producers to determine feasible parameters and optimum validation processes so avoiding risks when production is scaled up, says BPT.

The line is fully automated to reduce manual operation and keep the risk of contamination to a

minimum. It comprises automatic bag and tub opening systems, as well as an automated filling volume control. Rotary piston filling pumps are servo driven for accuracy. Sampling or removal of individual syringes for testing is also automated.

The FX2050 is designed with a small footprint to ensure mobility and can be operated under class A clean room conditions by integration into a Restricted Access Barrier System.

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... and highly protective

Bosch has extended its GKF series with the HiProTect, a fully integrated containment capsule filling system for processing potent substances. The design prevents contact between the operator and potent materials, eliminating the need for air suits, masks and other safety equipment, says the company.

The filling station processes powder, tablets, pellets, liquids and combination formats. Additional filling units are easy to install without extensive downtime, it claims.

The no-cap/no-fill function prevents product loss and contamination inside the machine.

GKF HiProTect fulfils various Process Analytical Technology requirements. A statistical gross and net weight control or 100 per cent control ensures improved end product quality. Even slight changes in product weight are reported to the filling station

so that errors are caught early and production downtime and product waste is minimised. An integrated wash-in-place or clean-in-place system comes as standard.

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pharma - processing

Eco-friendly and economical

Oystar division, Hüttlin, has recently completed an eight month installation of a fluid bed system to recover organic solvents at Ferring Pharmaceuticals of Switzerland.

The “environmentally-friendly” HKC 400 DJ is based on patented disk jet technology and, claims the supplier, has increased levels of automation, shortened process and cleaning times, decreased



Ferring Pharmaceuticals

wear and tear, enabled faster filling and discharging and reduced nitrogen consumption at the Ferring's plant. The plant makes products for reproductive medicine, urology, obstetrics, endocrinology and gastrointestinal inflammation.

The disk jet generates a specific Torodial current which distributes the gas evenly to ensure complete homogenisation. Depending on process gas conditioning the solids can be dried, heated, moistened, cooled or agglomerated by the injection of excipients. Particles can be spray coated.

A brine cooled condenser and low temperature condensation unit with liquid nitrogen in a closed loop enable the organic solvents to be almost completely recovered. This makes the installation both eco-friendly and economical says Hüttlin.

The spray nozzles are cleaned with pure organic solvent during the actual process enabling them to remain in operation for long periods.

www.oystar.huettlin.de

Pharma threesome from GEA

GEA Pharma Systems (Niro) says its latest Buck@Valve MC is a new concept in high containment valves, making the transfer of active pharmaceutical ingredients or chemicals between IBCs (Intermediate Bulk Containers) easier and less expensive.

The new system uses only passive valves (no drive units) which are compatible with valves fitted to most IBCs.

Up to now it has been necessary to use split valve technology to discharge products for IBC safety. This is suitable for process line situations but not between one IBC and another, says GEA Niro. And it is no longer necessary to use an active to active unit. Few moving parts and no lubrication are other claimed advantages, while product touching parts can be released manually, without tools.

The simpler method of transferring bulk chemicals allows docked, half passive valves to be driven from the shaft area giving smoother movement and eliminating the need for vacuum between the discs. Reducing the number of moving parts and standardising components enables Buck@Valve MC to reduce costs, says the company.

GEA Courtoy has introduced the

PERFORMA™ P tablet press, a single sided, high output machine featuring an exchangeable turret with an increased number of punch stations, ideal, says the company, for applications where long runs and few changeovers are required.

The turret incorporates a central die disc which is easily detachable from the upper and lower turret sections and so can be exchanged as a separate unit. The Exchangeable Die Disc (EDD) eliminates the need to duplicate the punch guiding modules and is an economic alternative to a completely exchangeable turret, says the company.

The EDD is available with conventional dies or Die Shells which are thin walled and allow an increased number of stations, leading to higher outputs, reduced tooling and less risk of tool damage, the company claims.

GEA Collette has developed the CONSIGMA™ high shear mixing and granulation system. Its small size, less than one quarter that of a conventional system, makes it ideal for R&D operations. Its modular construction means it can easily fit into an existing tablet production room, says the company.

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■ **Oystar Manesty** has continued its innovation surge with three new developments. The Xpress Wash-in-Place system will clean all substrates from the tablet press and is capable of using different water types, detergents or foams. Fully programmable, it can be linked to cleaning systems for ancillary equipment such as de-dusters. Productivity can be increased by 30 per cent, claims Manesty.

The XL™ Cota 350 is a new tablet coating machine with an improved system for inserting solutions into the drum. It is suitable for medium to large scale production with a standard drum capacity of 500 litres (95-440kg). A new 4 – 10 station tablet press, the XSpres enables the operator to study and adjust key compression data as the machine is not fixed to a compression cycle. It can produce single, bi-layer or tri-layer tablets, which is a first, according to Manesty. Mounted on wheels it can be moved to different production zones for small batch output.

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■ **Chronos Richardson's** CHRON-WEIGH™ E55 NXT precision weighing system is equipped with state-of-the-art loadcell technology and significantly improved cleaning access, says the company. The weigh hopper incorporates stainless steel contact parts as standard and is suitable for hygienic bulk weighing across all industries, it claims.

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