

pharmaceuticals, medical & healthcare



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- Two major studies on the pharmaceutical sector look at Supply Chain issues and current and future Trends, and Strategies and Issues surrounding the sector. Datamonitor's Supply Chain report covers an assessment of how big pharmaceutical companies are looking to cut distribution costs and improve overall supply chain management.
- Pharma producers want to take control of distribution of drugs, which is often 'circuitous' and involves many parties as well as increasing the potential for the introduction of counterfeit products. Pfizer, for example, has implemented direct distribution to pharmacies. Will others follow? How will this impact on production and packaging?
- A Strategic report, also from Datamonitor, looks at the impact of increasing competition in generic drugs, tougher regulations, clampdowns on healthcare spending and changing demographics.

The major drug makers are looking at different ways to cut costs and improve ROI. A swathe of job cuts could mean better business for machine suppliers, but machinery suppliers are also in the spotlight.
- According to Datamonitor the effective use of inhalers, regarded as the best means of delivering drugs for asthma and COPD sufferers, is being hampered by the plethora of delivery systems on the market and calls for better standardisation.

More information: www.datamonitor.com

Blister packaging continues to be the predominant pack style for solid dose forms in the pharmaceutical sector accounting for 75 per cent of global production, according to recent estimates.

However 'times they are a-changing'. The greatest developments in the pharmaceutical industry are in the field of bio-tech products with 45 per cent of new drug approvals incorporating bio-tech components.

With active ingredients in bio-tech products frequently being too unstable for solid dose forms, well over 90 per cent of products are packaged as liquids in syringes, ampoules and vials. This alone presents plenty of challenges for the machinery suppliers.

However the demand for sophisticated packaging solutions is driven by other factors as well as security and stability of the product: child resistance, senior friendliness and tamper evidence. Not to mention greater regulation from increasingly powerful health authorities and the threat from counterfeiting.

What of processing? With these more volatile products and much stricter production parameters, together with the need for new counterfeiting measures, spurring developments such as **Oyster Manesty's** Nano-Trust® single tablet code recognition system; levels of containment and validation for example are higher than ever before.

This would all seem to point to a booming

market for pharmaceutical processing and packaging machine builders and, indeed, at a recent press conference given by **Bosch Packaging Technology's** President Friedbert Klefenz, he announced the last two years as being highly successful for the group and cited pharmaceuticals as the strongest sector with 41 per cent of orders received of which 88 per cent was exported, half of them to countries outside the EU.

However, despite this and other up-beat assessments and some record results in 2007 for major pharmaceutical companies (AstraZeneca, for example, up 9 per cent and Shire also improving turnover by 36 per cent) there is a sense of gloom over the industry with GSK revenues flat, new drug approvals stalled for many companies and profits and share prices set to decline according to some forecasters.

A recent ABPI/CBI survey of 100 UK pharmaceutical companies found over one third expect to reduce R&D spending and half say the number of clinical trials will drop and, overall, 83 per cent were pessimistic about the future.

Klefenz sees this as a result of hardening competition, particularly in generic drugs, fierce regulatory issues, counterfeiting and capital markets expecting better returns from the pharmaceutical giants following another round of consolidations.

Cost pressures are mounting - what does this mean to the pharma sector? See pages 20-21.

pharmaceuticals, medical & healthcare



Goodbye to bells and whistles - low cost rules

What do mounting cost pressures within the pharmaceutical sector mean for the machinery sector? Andrew Manly examines the trends

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- Health Secretary Alan Johnson has approved new guidelines on drug prices which should cut the costs of many medicines. The Pharmaceutical Price Regulation System could see drug prices fall by an average of 5 per cent. The ABPI says this is causing uncertainty and pessimism in the industry.
- But a new report published recently by Business Monitor International (BMI) claims the pharmaceutical sector in the UK will continue to develop strongly, achieving a value of US\$35.2bn by 2012. BMI says the UK has one of the most technologically advanced drug markets in Europe.
www.businessmonitor.com
- A Health Compliance Packaging Council (HCPC) conference in Trieste, November 5 - 6, will explore ways that packaging can improve compliance with taking prescribed drugs. HCPC estimates that in Germany alone the overall cost of wasted drugs exceeds Euro10bn and is increasing by Euro500m annually. The EC and NHS will speak alongside Novartis and AstraZeneca.
www.hcpc-europe.org

A new culture of low cost sourcing for pharmaceutical equipment seems to be upon us. The days of pharmaceutical companies buying the best technology available with all the 'bells and whistles' is over.

Loyalty to a particular supplier has also "gone out of the window", according to many suppliers. Tendering is now fiercer than it has ever been and issues such as Total Cost of Ownership (TCO) are major factors in purchasing decisions.

In the past, lines packing patented drugs would often run at no more than 50-60 per cent capacity as the value of the product meant costs were not a critical factor. Today all the resources are expected to 'sweat' so machine flexibility, quick changeover, cleanability and efficiency are as important as in the food production industry.

But low cost sourcing can bring its own problems. Multi-national pharma companies can now look outside the traditional technology sources of Western Europe, USA and Japan for alternatives in India, China, Korea, Brazil, and other parts of the world.

Asian challenge

India, for example, has a burgeoning pharmaceutical machinery sector boasting about 800 companies. This has shadowed the development of India's huge pharma industry which now employs more than four million people and exports US\$6bn of its drugs annually. But because its machinery market has been artificially protected by high import tariffs the equipment is often made to local not international standards, and problems have arisen when it is rolled out to sites outside Indian and other Asian markets.

This has not prevented the major Western machinery companies responding to protect the 'entry level' markets in both their home territory and in the emerging 'E7' economies.

Both Oyster and Bosch have recently launched basic or intermediate blister machines. But Bosch's Friedbert Klefenz sees Asian competitors gaining strength and closing the gap each year.

He believes the answer is to offer scalable automation: a price/performance ratio improved by modular design and customised service packages.

The myriad of pharmaceutical products available further complicates the cost pressure equation. Alan Isaacs, until recently managing director of Doyen Medipharm, explains: "Short runs can mean as few as four packs and many batches are often a few hundreds or thousands. This can present enormous issues as companies must clean and validate the machine for each product."

He also believes that some machine companies merely pay lip service to validation and are more interested in the process than the integrity of the machine. "The quality and integrity of equipment must go up a level," he says.

Derek Moore of **Oyster IWK** thinks differently about validation. He feels most of the major machine suppliers do a good job in this area and have designed machines which can be cleaned, changed and ready for use both efficiently and effectively. "But what is the point of making a machine ready in an hour if the documentation takes two hours?" he asks.

Further he considers that there is less room for compromise on quality for processing machines. "The process has to be 100 per cent accurate and verifiable, not 99 per cent. So the compromise will be with the filler, blister machine or cartoner."

Andrew Longworth, managing director of the UK arm of **Körber Medipak**, agrees the average production run for non-generic pharmaceuticals is decreasing. "An average packaging lot size of less than 5,000 is not unusual. Increasingly segmented product ranges, simplified dosage regimes and minimised stock holdings all contribute to this



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The new Ultraclean System from OYSTAR Hüttlin and the Pilotlab fluid bed system which has the ability to open the metal filter during CIP cleaning

trend." He adds: "New pharmaceutical formulations may require novel delivery systems or specific systems may be required to ensure dosage compliance. Such systems directly influence the packaging needed. As a result equipment must have a high degree of flexibility and adaptability. Packaging material suppliers too must support these novel solutions, often for relatively short production runs."

This is where development of techniques such as Late Stage Customisation (LSC) help to accommodate requirements.

Even the traditional blister packaging system is having unusual demands placed upon it. Longworth explains: "The blister packaging of extremely friable oral dispersible tablets (ODT) brings very special challenges. So a new generation of blister machines must be capable of configuration to meet bespoke requirements as well as more traditional applications."

Process flexibility

For processors the challenges are the same although cost pressures may not be as high as for packaging equipment. But flexibility, adaptability and speed of cleaning and changeover are as familiar to processing as packaging.

Several developments, such as vacuum injection in mixers, computerised raw material dispensing, more efficient CIP systems and new coating technologies (for example the new

AccuSpray system from **Oystar Manesty**) are all geared towards improving productivity and versatility. Additionally the volatility and toxicity of more and more active ingredients means tighter health and safety regimes, hence advances in containment and transfer technologies.

How high up the agenda are environmental concerns in pharmaceutical packaging and processing? The truthful answer is probably: "Not as high as it is in other sectors." Where the prime concern is to deliver a complex, fragile and often very expensive product in the right formulation with the correct dispensing component, dosage information and storage capabilities, environmental considerations may be deemed secondary. However, reduced use of materials in packaging is not being ignored and several advances in the process area have the effect of better use of chemicals, energy and water, particularly in CIP systems.

All commentators agree that innovations such as 'Track & Trace' and on-line printing are positive developments and continued improvements in drives, controls and inspection are all helping to meet the demands of the pharmaceutical giants.

Another bright spot is that the development of nutraceuticals or 'Conf-Med' products is enabling companies like Bosch and Oystar, which have expertise in both the food and drugs sectors, to transfer technology used in one to the other.

But concerns exist that attempts to drive prices down and specifications up will lead to casualties and have the effect of inhibiting growth in the emerging markets where companies relatively new to pharmaceutical manufacture rely on the 'know-how' of established, specialist machinery manufacturers to improve their production regimes and quality of products. This expertise simply does not exist inside local machinery manufacturers.

As well as bio-tech products the sector is also being driven by demographic changes in the developed economies and rapid growth in the emerging ones. The last word goes to Friedbert Klefenz, of Bosch: "Companies are focusing on efficiency, output levels, multi-functional installations and optimisation of investments. In technology terms key components are barrier systems, precision checkweighing, auto cleaning and disposable filling systems."

One thing is certain. The rapid development of pharmaceutical products using bio-tech and nano technologies will place increasing demands on processing and packaging equipment suppliers to develop new technologies to bring to market safely, reliably and in repeatable formats by cost effective means.

■ India, China and Turkey are the fastest growing pharmaceutical markets and, overall, the E7 (largest emerging economies) will see their markets grow at a CAGR of 11.5 per cent between 2007 and 2012 to a value of \$116bn, compared with 4.95 per cent for the G7 economies.

Markets for drugs in India, China, Russia and Indonesia are dominated by generic products.

There is less penetration in Brazil, Mexico and Turkey. With generics, IPR and counterfeiting still remain significant issues in the E7. (Source: RNCOS)

■ By 2012 the E7 countries will account for half the world's population and demand for chronic therapies will grow more strongly than for acute therapies.

Cardiovascular, cancer and other chronic diseases have overtaken communicable diseases as the biggest killers in these countries. (Source: RNCOS)

FURTHER INFORMATION

Bosch Packaging Services
T: +44 (0) 1332 626262
E: ukenquiries@boschpackaging.com

Körber Medipak
UK & RoI
T: +44 (0) 1753 754865
E: andrew.longworth@uk.koerber-medipak.com

Oystar IWK
T: +44 (0) 1252 732210
E: info@oystar-iwk.co.uk

Oystar Manesty
T: +44 (0) 151 547 8000
E: info@oystar.manesty.com