

The
PHARMA CHEM
reporter

Changes planned for PPMA Show

PPMA 2005 had 8600 visitors of which 5366 companies came to look for innovation in processing & packaging machinery and new sources of supply (an increase of 7 per cent on 2003 figures).

Mike Randall comments on the future of the show, "Whilst we are very pleased that the 2005 event delivered so well for members, we acknowledge that the UK environment remains challenging. We must remain very focused on delivering the event that gives our exhibitors increased return on their investment. In the light of this, Reed and the PPMA have agreed that some changes are required."

With Barbara Jackson's recent departure, Ian Crawford has been appointed as Show Director. Ian was UK Sales Director at Demag, a supplier of injection moulding machines and has been with Reed for 18 months during which time he has successfully revitalised the Interplas exhibition.

www.ppmashow.co.uk - 26-28th Sept '06



**Jerry Marden,
Export Director**



**Ian Crawford,
Show Director**



**Mike Warren,
Process Director**

PPMA's strategic plan focuses on Pharma

The first draft of the PPMA's 'new-era' Strategic Plan will be presented to the PPMA board in February by new CEO, Chris Buxton. Chris gives PharmaChem members the first glimpse of some of what the plan holds, "The PPMA Plan for 2006 is a comprehensive document and along with a wide range of initiatives that it has spawned, PharmaChem members will be interested to hear our focus upon the interests of the Process membership and in particular in the PharmaChem and Food sectors." Mike Warren of Niro Pharma Systems has been recruited as the Director responsible for Process and over the coming months aims to increase the Process membership from 75 (circa) as it currently stands. The increased focus in Process will be seen in all aspects of the PPMA service portfolio including the seminar programme and various PPMA Publications. Chris reiterates, "This initiative is not going to be at the expense of our packaging members for whom we also plan to provide a range of new and attractive services."

With most members reporting an increase in exports a range of initiatives to help members develop their overseas business will be developed. "The PPMA China office is a great opportunity in this respect and the new Plan seeks to realise the great potential that this facility offers. Jerry Marden of Marden Edwards has agreed to act as Director and Board champion for Export," commented Chris.

A new series of seminars aim to help members keep abreast of current Regulation, Technology and Business issues. Chris explains, "Our seminar series aims to help members tackle the current issues we all face in day-to-day business. Our series of Regulation seminars recognises that it's a critical year for Health & Safety, whilst our Technology seminars will look at how to survive the globalisation issue. Our Business seminars are designed to give members the opportunity to advance their own skills in a number of topical areas such as strategic market planning for small businesses and undertaking quality presentations."

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See page 6 for PPMA seminar details

Next Members' Meeting

Date	14th February 2006
Venue	KP Aerofill, Hayes, Middlesex Tel. 0208 848 4501 for directions
To book	Email john.cowdrey@ppma.co.uk

AGENDA

10.00 - Coffee	12.30 - ITCM Presentation; Challenges in the business
10.30 - Welcome to KP Aerofill site – H&S	13.00 - LUNCH
- Minutes of last meeting & agenda – Chairman	13.45 - Presentation on KP Aerofill's markets and factory tour
11.15 - Future direction of the PPMA & PharmaChem group – Chris Buxton, PPMA CEO	14.45 - Close
12.00 - Open discussion on Exhibitions	

Six months ago the Chancellor invited business to say where and how regulations could be simplified to reduce red-tape. In our October newsletter we asked members to use this opportunity to have their say. This 2 page report looks at how the PPMA, ABPI, and Procter & Gamble responded along with the latest news from the Cabinet Office.



Reducing Red-Tape - How did YOU respond?

PPMA's Response



The PPMA responded to the Chancellor's challenge in conjunction with Engineering & Machinery Alliance (EAMA) of which the PPMA is a member along with 6 other associations. This approach was to consolidate the views of not just PPMA members but also those of other 'sister' organisations that make up the alliance i.e. industry speaking with one voice. A combined survey of members was undertaken to seek the primary regulatory issues of concern.

For maximum effect and impact EAMA and the PPMA took advantage of every opportunity to submit their report to the Cabinet Office;

1. A presentation was made to the DTI Minister for Industry and the regions, Rt Hon. Alun Michael
2. A report summary was sent in a pre-budget letter to the Chancellor of the Exchequer Rt Hon. Gordon Brown
3. The proposal was submitted via the BRE (Better Regulation Executive) web portal

EAMA reports the facts

EAMA estimates that the UK's 13,000 mechanical engineering companies may be spending £430+ million a year on red-tape. On average this is £33,000 per company where the average turnover is £2.5 million.

EAMA comprises organisations representing over 1,000 SME manufacturers. PPMA and EAMA put forward the argument that in setting policy, it is easier for Government to obtain the views of more concentrated sectors such as aerospace or automotive than of a manufacturing sector dominated by SMEs such as mechanical engineering, where the culture, concerns and reactions to Government initiatives will not reflect those of larger company OEMs or first tier suppliers.

Survey Results

Companies highlighted four main areas where red tape and regulatory instances need addressing (note, some companies raised more than one issue):-



Companies ranked employment regulations as the most important area in need of simplification as they account for 80% of the costs. The report showed that employment regulations are now so complex that they are a positive disincentive for SMEs to take on new employees and pensions requirements have added approximately a quarter to these costs.

"UK firms are not anti-regulation per se. They see that regulations are needed and that they can be positive when they are clear and well targeted. But woolly, poorly conceived regulations that palpably have no direct impact on the ills that they are meant to address, give regulation and those associated with them a bad name. We should all want to do something about that."

Graham Hayes, EAMA Chairman

Suggested Solutions to Employment Regulations

When considering extending **Family Friendly Policies**, Government should also look at engineering SMEs' requirements for skilled workers to stand in for the absent mother or father. It was suggested that Government work with business to look at **retiree tax incentives** to foster a pool of skilled, trained personnel able and interested in taking on short-term work contracts (e.g. as parental leave cover).

To help **equip the unemployed with skills** that are needed in the workplace, the report recommends providing a simple **training credit against NI** or similar while a person acquires the skills an engineering SME can really use.

On **pensions**, companies would like to see the **regulator's requirements simplified**. The onus on trustees is now such that SMEs running schemes have difficulty recruiting employee representatives to serve.

To **cut bureaucracy and tax compliance costs** for both business and Government the report suggests **merging PAYE and National Insurance**. A joint business-Government simplification project could cut implementation costs and as a by-product show that the UK is intent on maintaining its position as the 'best place to do business in.'

Issues Concerning Environment and Statistics

In the environment and statistics areas, firms have identified procedures that cost the sector many millions of pounds and yet make no contribution to a better environment or Government policy or sectoral understanding.

ABPI's Response



The Cabinet Office has actively engaged with the ABPI to consolidate members' regulation improvement suggestions as well as to provide the greater picture for the pharmaceutical industry as a whole.

Over the next 6 months the ABPI will develop a consolidated landscape of regulations that effect the industry including the following key areas:-

- Clinical regulations
- Animal research
- Health and safety issues around laboratory environments
- Manufacturing regulation environment
- The administrative burdens on the commercial environment

Dr Philip Wright, ABPI Director of Science and Technology explains,

“Our objective is not about removing regulation, but creating better regulation. Working with government we aim to ensure that regulation are fit for purpose and that there is an appropriate level of administrative burden so reducing duplication of submission etc. This is going to take a bit of thinking out of the box for everybody involved and we welcome particular issues, ideas and new opportunities that companies feel should be addressed.”

Please contact Claire Bullen with your suggestions cbullen@abpi.org.uk

Procter & Gamble's Response



HSE Manager Ian Davies was asked to evaluate the cumulative impact of Safety, Health and Environmental Regulation on the UK industrial coatings, aerosols and speciality chemicals sectors and comments on the approach they were asked to take, “We were asked to put a cost against the compliance of safety, health and environmental regulations in our company to establish where the problems lie. It is impossible for us to do this. It is less a case of unnecessary costs that of failure to carry out risk-benefit assessments; do regulations bring sufficient improvements in HSE performance to justify their adoption? Currently, regulators are not receptive to risk/benefit discussions, only to the cost argument.”

Procter and Gamble believe that consistency in implementation / enforcement of regulation is a main concern for business. Ian explains, “At EU level, for example, the UK seeks to make regulations as pragmatic as possible and then to enforce them stringently. Other Member States prefer stringent regulations, which are enforced pragmatically. This can lead to a situation where the burden for business in the UK can be disproportionate.” Procter

and Gamble provided solutions to a number of regulations. The Machinery Directive was highlighted as one problematic area, “P&G

assembles packaging lines, for example, from different pieces of purchased equipment, each of which is CE marked and complies with the Directive. Under UK interpretation, however, the assembled packaging line counts as a new piece of machinery and must comply as a whole (e.g. a single ‘emergency stop’ button). This can cost around £20,000 per packaging line and makes a minimal

difference to safety. In France, provided the pieces of equipment are capable of being operated separately (which is the case,

Latest news from the Cabinet Office



New Bill to enable delivery of swift and efficient regulatory reform

On the 11th January 2006 Cabinet Office Minister Jim Murphy introduced The *Legislative & Regulatory Reform Bill* which aims to make it quicker and easier to tackle unnecessary or over-complicated regulation and help bring about a risk-based approach to regulation. The new Bill will allow the Government to deliver reform of outdated or over-complicated legislation more quickly and enable the mergers of those regulators not currently covered by separate legislation.

Pharma sector is under the spot light

Running in parallel with the better regulation initiative, a specific project group has been appointed to look at the Pharmaceutical sector and where to ease the burden of regulation. A progress report is due for publication shortly and will be summarised in the April issue of this newsletter.

It's not too late to get involved!

Contact the following organisations now:-

www.betterregulation.gov.uk

www.ppma.co.uk

www.abpi.org.uk



although it would not make sense to do so) this requirement would not apply” explained Ian.

“The main issue is not regulation as such, but the interaction between regulations.”

Ian Davies, HSE Manager

Ian concluded that ‘tinkering’ with the system is not the way forward, “The main issue is not regulation as such, but the interaction between different regulations. There is a need to step back and ask ‘what are we protecting?’ and to find a way of balancing different risks – environmental, worker health and safety, public safety etc. “

“Currently regulators are not receptive to risk/benefit discussions, only the cost argument.”

Ian Davies, HSE Manager



Insider's Guide to...

Pharma Liquid Dispensing pumps *Jim O'Neil, Hi-Tech Machinery*

When assessing liquid dispensers, the pharmaceutical industry primarily requires cleanliness, accuracy and speed. This 'Insider's Guide' provides an overview to peristaltic, time/pressure and volumetric liquid dispensing pumps.

Please send your 'Insider's guide' to kirsty.sharpe@ntlworld.com detailing a technical overview of your equipment or process.

1. Peristaltic

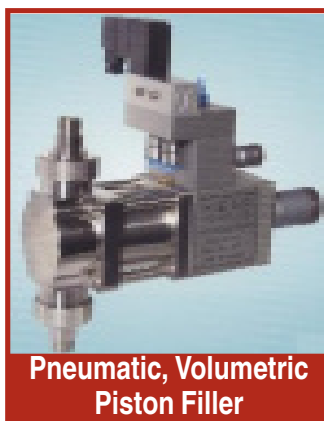
Peristaltic pumps provide a relatively slow fill and as long as the liquid is thin this system is a good method of simply moving liquid. The main element of the pump is flexible tubing which is squeezed by rollers to produce a pulsed fill. The tube wears and although it is cheap to replace, it limits the filling precision which is dependent on the tube returning to its original shape. The tube also defines the characteristics of the filling machine and this varies over time. As a result, adjustments are needed during batches to compensate for wear on the tubing. The "pulsed" fill can be minimised by increasing the number of rollers that squeeze the tube or by using multiple liquid paths. The liquid is dispensed as droplets which can cause splashing and there is also a tendency for a drop to be left at the end of a fill which not only affects accuracy but it could fall onto the outside of the container. Reversing the motor at the end of the fill to produce a "suck back" avoids this but increases wear on the tube.

2. Time/Pressure

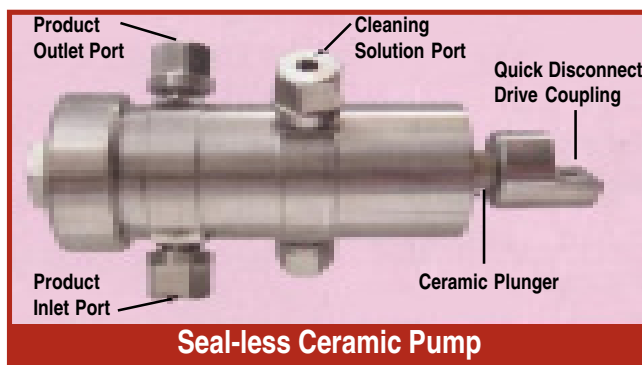
The volume dispensed by this system is determined by a pre-set time and constant pressure. It provides a smooth product flow. Devices can measure time very accurately, but pressure is much harder to control and accuracy is compromised. If the valve that stops the flow is a "pinch" type then the system can be designed with very few moving parts in contact with the liquid and is therefore easy to clean.

3a. Volumetric Piston - Pneumatically driven

The volume is dispensed in one continuous movement which results in a very smooth fill. Less turbulence equates to reduced splash and foaming. The speed of fill can be adjusted over a wide range. At the end of the fill the very rapid deceleration of the piston has a very good effect on stream "cut-off" at the nozzle tip. Recharge speed is adjustable independently. The piston and valve system usually require seals which will wear and add to the cleaning and assembly process. Accuracy is dependent on the piston moving a fixed distance, which is easy to maintain and not affected by the characteristics of the liquid.



Pneumatic, Volumetric Piston Filler



Seal-less Ceramic Pump

Latest Development

The newly available **Servo Driven Seal-less Ceramic** pump combines a positive displacement piston and valve. Along with the excellent wear properties that ceramic provides, this pump combines the speed, flow control and accuracy of a piston filler and moving parts in contact with the liquid have been reduced to one. Computer control means that setting time has been reduced in multi-head applications from hours to minutes. Filling speed, volume, fill profile, and recharge speed are all independently adjustable (and can be global in multi-pump systems). Tested with major pharmaceutical companies this new pump has been found to provide a process capability of one error in 1 billion doses on a 200mg target dose with a tolerance of +/-2% of nominal.

For further info please see www.fillers.co.uk

3b. Volumetric Piston - Seal-less - Stainless Steel - Hard Chromed

This system utilises a piston which rotates at the end of the fill to provide the valve action. These pumps are usually cam driven. The piston velocity profile is a sine wave which reduces the versatility of the pump because the speed profiles of the dispense and recharge strokes are fixed. Although hard, the surfaces wear with use and the "lost" material becomes part of the product being dispensed.

3c. Rotary Volumetric Piston - Seal-less - Ceramic

These pumps use the same valving method as the pumps in 3b, but the piston rotates continuously. An angle between the drive motor and the pump produces a linear displacement. The ceramic used is dense and is much harder wearing, more temperature stable and can be machined to closer tolerances than steel. The volume is adjusted mechanically and due to the geometry of the principle a small change in angle produces a relatively large change in volume. Adjustments to achieve the required volume are difficult and very time consuming in multi-head applications. Valving and dispensing operations cannot be adjusted in relation to each other. Dispense speed profile is half of a sine wave and cannot be varied.

ATEX Directive and Milling Equipment

Don Zorn, Quadro

*ATEX is important in many of today's pharmaceutical and chemical processing plants as a high proportion of process materials assume a powder stage on their journey to the end-product. The uncontrolled handling of these powders during this process period can lead to electrostatic or other ignition sources with the resultant risk of a fire or an explosion. The purpose of the ATEX Directives is to preserve the health and safety of the workers and in July 2006, Directive 99/92/EC (ATEX 137), the 'Worker Protection Directive' will become **mandatory** for all existing plant equipment.*



ATEX Directive Information:-

www.europa.eu.int/comm/enterprise/atex/index_en.htm

Milling Equipment Information:-

www.quadro.com



Directive 94/9/EC (ATEX 95) is commonly known as the ATEX 'Equipment Directive'. As of July 1, 2003, all new equipment installed in the European Community must conform to this directive if it is to be used in a hazardous "zoned" area or if it is to be used to process potentially explosive materials. Equipment that is manufactured to this Directive is marked with the "Ex" logo. There are two groups of equipment; Group I is for use in mines and Group II is for use on the surface. Pharmaceutical and chemical processing equipment falls into Group II. Directive 94/9/EC further sub-divides the equipment into three Categories as shown in the table:-

Zone		Equipment Category	Protection Level	Protection Method
Gas(G)	Dust (D)			
0	20	1	Very High	Two independent methods of protection are required which take into consideration ' rare malfunctions '. Safe with 2 faults.
1	21	2	High	One method of protection is required which takes into consideration ' frequently occurring disturbances '. Safe with 1 fault.
2	22	3	Normal	Method of protection suitable for ' normal ' operation.

Milling in an ATEX Environment

The first step is to establish the hazardous zone both inside and outside the mill. This is done by the purchaser of the mill. With this information, the mill manufacturer is able to take the special measures required to meet the ATEX Directive. The mill manufacturer is also responsible for advising the purchaser of any special procedures required to safely operate the mill.

In the case of Category 2GD and 3GD, the special features may include earth bonding cables, static dissipative brushes, casters and belts, screen temperature probes, level sensors and magnetic grates. Also, ATEX certified electrical motors, controls and interlock switches are used. For Category 1GD (internals), the mill must have all of the above features, plus be either inerted or designed to withstand an explosion. Two independent protection methods are required.

Displayed opposite are some approaches that may be employed to meet ATEX Category 1GD (internals) or if the product to be milled has a Minimum Ignition Energy (with inductance) [10 mJ.

Explosion Pressure-Resistant Design

An explosion pressure-resistant mill is designed to **withstand** the maximum explosion pressure, P_{max} of the product being milled, without any permanent deformation. A typical P_{max} is 10 bar, however, when "pressure piling" is taken into consideration, in some cases, this can rise to 16 bar. The mill is designed to meet Pressure Equipment Directive 97/23/EC or the ASME Pressure Vessel Code, Section VIII – Division 1.



Explosion Pressure Shock-Resistant Design

An explosion pressure shock-resistant mill is designed to **contain** the maximum explosion pressure, P_{max} of the product being milled, but may permanently deform during an explosion. Explosion pressure shock-resistant mills are often designed and manufactured to German guideline VDI2263, Part 3. An explosion pressure shock-resistant design is a more economical alternative to an explosion pressure-resistant design.



Inert Control Systems (ICS)

An inerted mill is designed to **prevent** an ignition from occurring. The inert gas, typically nitrogen, is injected inside the mill to reduce the oxygen concentration below the Limiting Oxygen Concentration (LOC) of the product to be milled. In order to inert the mill, it is necessary for the milling to occur in a 'closed system'. Inert control systems are available with oxygen monitoring and without oxygen monitoring.



Dear
PharmaChem
Editor...

In our 'Letters to the Editor' a major PharmaChem equipment manufacturer wrote with their comments on last year's PPMA show. They felt the show could be improved to relate more to the pharma sector and therefore increase the number of pharma visitors. What are your thoughts? If you have comments and feedback on how the show can be improved please join our Exhibition Debate at the next PharmaChem meeting on the 14th February (see page 1 for agenda and details).



Got something to say? Then write to our editor kirsty.sharpe@ntlworld.com

Argentina and Brazil join forces to produce AIDS drugs

Argentina's Health Ministry has announced that in partnership with the Brazilian government they plan to produce their own anti-AIDS drugs in an effort to lower the cost of treatment. The construction of a \$10 million jointly owned plant, possibly to be located in Argentina, will begin within a few months. At present Argentina

spends about \$60 million a year to treat some 30,000 patients while Brazil provides treatment for 160,000 people. The joint drug venture will also produce drugs to treat the deadly Chagas disease, transmitted by a blood-sucking parasite, and leishmaniasis, a skin disease also caused by an insect.

News from www.news-medical.net

Drug News

Technology Seminar Series

Full details on Regulation, Business and Technology seminars are available from Emma.Corney@ppma.co.uk

One Pot Pharmaceutical Processing Techniques

18th Oct 2006, Manesty Ltd (Liverpool)

This course will examine how recent changes to the design of processing equipment have provided improved standards of containment for pharmaceutical products. Topics presented by Manesty, Romaco Co LTD, Ima Swiftpack, Niro Pharma Systems include:

- >> one pot processors
- >> granulators
- >> tablet presses

PPMA Seminar Series

Shelf Ready Packaging Machinery

27th April 2006, TNA Ltd (Birmingham)

High Efficiency In-place Cleaning

20th June 2006, Campden and Chorleywood Research Association (Chipping Campden)

Future Uses of Robots in our Industry

2nd Nov 2006, Salford University (Greater Manchester)

It's your newsletter

If your contact details are incorrect or you would like others in your organisation to be added to the newsletter circulation list, please forward up-to-date details to the editor, kirsty.sharpe@ntlworld.com

Editorial Team

The editorial team committee members on this issue were Alan Isaacs and John Cowdrey. Editing the issue for publication in April are Stephen Holroyd and David Routley. Please send your comments on past or future issues of the newsletter directly to them.

PharmaChem Events

Members Meeting: 14th Feb - KP Aerofill

Passport Training: Contact John Cowdrey

Committee Contact Details...



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ISPE News

Roger Trew, ISPE

FDA Citation to ISPE

Dr Janet Woodcock, FDA Deputy Commissioner for Operations, presented ISPE with a Special Citation in recognition of the outstanding work ISPE have contributed to critical initiatives.

ISPE 2005 Annual Meeting Plenary Session

Dr Janet Woodcock spoke on the FDA Critical Path Initiative and the belief that the industry must "innovate or stagnate". With issues of critical drug shortages and potential pandemic threats speed to market must be improved.

More is invested in the Research and Development of new molecules than in manufacturing and to make improvements in quality and speed to the patient, the science of processing and manufacturing must be better financially supported. Progress will need co-operation and sharing of information within the industry.

The FDA believes that significant progress will be achieved if the concept of Quality by Design can be applied to all aspects of the industry, including equipment and facility suppliers. The final goal is to achieve the highest quality product with the minimum Regulatory input, and the Critical Path Initiative is seen as the catalyst to the integration of R&D, Manufacturing and Suppliers.

Pharmaceutical Professional Certification Programme

The terminology most likely to be used now is "Certified Pharmaceutical Professional" to avoid any concerns the UK Chartered Institutions have.

Forthcoming Publications

The Packaging Labelling and Warehouse Baseline Guide will be available soon.

For further information visit www.ispe.org