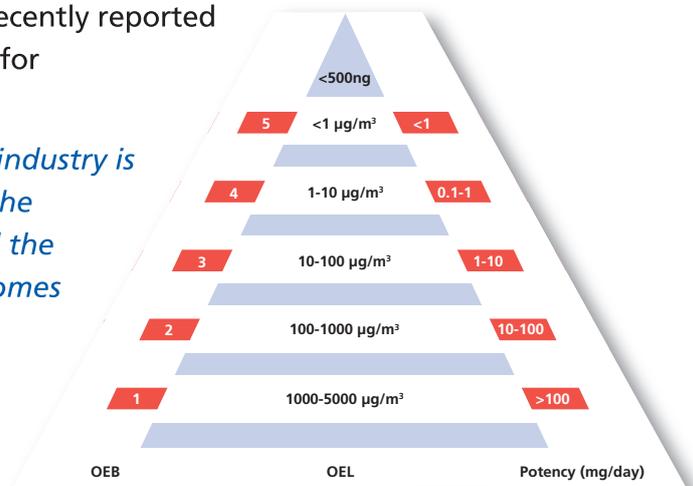


## Reducing the Costs of Pharmaceutical Manufacturing

### Hosokawa Micron Meets the Challenges

Leading trade journal Manufacturing Chemist Pharma recently reported how changes in the industry are transforming demands for manufacturing equipment.

*'The main driver influencing all aspects of the pharma industry is the growing downward pressure on costs. The end of the blockbuster era, government healthcare mandates and the linking of insurance reimbursement with medical outcomes are all affecting drug pricing. In response, pharma companies are taking a range of different actions to reduce their costs and increase efficiency and productivity...'* Manufacturing Chemist Pharma



#### Top Trends

- Outsourcing
- Continuous processes
- Online analysis
- Containment technology
- Used equipment market
- Single use technology



#### OEL Trends

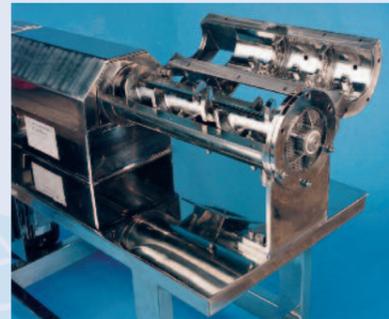
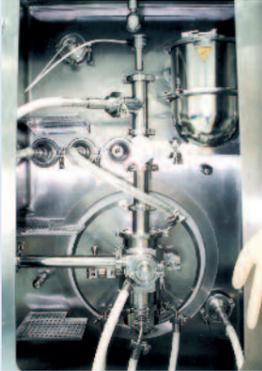
High potency active pharmaceutical ingredients (HPAPIs) represent the fastest growing segment in the pharmaceutical sector with processors searching for new and different ways to reduce the exposure of employees to harmful substances and minimise risks of cross contamination. To meet this change the containment trend is for lower OELs coupled with more rigorous OEL testing and documenting. Note the old 5 band OEL pyramid now has an additional <500ng level.

# Meeting the challenges of cost reduction in pharmaceutical manufacturing

Here we look at how Hosokawa Micron Ltd has anticipated and responded to these challenges with innovation combined with technical experience and exemplary engineering – to provide pharmaceutical manufacturers with solutions in key areas of change for their business.

## Outsourcing

We've recently completed three major milling projects for Contract Manufacturing Organisations (CMO's) for a European pharmaceutical company. Delivering a range of benefits that include the potential to increase productivity, reduce operational costs and access specialist production expertise, outsourcing to trusted partner companies offers a cost effective and efficient option.



## Continuous Processing

Manufacturers looking for higher production yields through deployment of equipment and technologies may benefit from Hosokawa

Micron's extensive experience in continuous processing. A continuous dispensary system installed for a pharmaceutical manufacturer in Puerto Rico and featuring a pharma Micron Extrudomix, mounted on a weigh scale demonstrates Hosokawa's capability.

*Read more: <http://hml.to/cdspd>*

## On-line Analysis

Continuous process analysis is crucial for maintaining optimum operating conditions and product quality attributes (PQA) at every step of production with significantly reduced waste, product loss and downtime also possible. Our on-line measuring system, the Optimizer/Pharmasizer, for continuous particle sizing during the production process, allows engineers to quickly identify out of specification product and take remedial action and assess the effects of any process change on the finished product. The Pharmasizer can also support Hosokawa Micron's Intellimill, intelligent diagnostics, control and optimisation system.



## Containment Technology

'Increasingly, HPAPI manufacturers are relying more on isolation and containment through equipment and facility design.' Manufacturing Chemist Pharma

## Pharmaceutical Isolators



Hosokawa Micron has pioneered the development of high containment pharmaceutical isolators including systems which are designed to achieve OELs down to 10 ng/m<sup>3</sup> (30ng/m<sup>3</sup> STEL) ( 8hr TWA). Working closely with customers we are continually developing unique advances in isolator design including:

Meeting increased demands for multifunctional designs incorporating:

- Interchangeable milling equipment for different particle size requirements
- Multi-feed options
- Flexible pack-off options for different sized bags, bottles, drums
- 3D modelling before final design for optimum ergonomic design, allowing for space constraints and operator task definition



## Single Use Technology

Interest in single use or disposable technology has gained interest in many bio-pharm areas, especially in the development of new drugs with the advantages of the greater flexibility and reduced cleaning and construction costs. Hosokawa Micron has been involved in the development of a plastic 50As Jet Mill, for the early development of HPAPIs. In this case the disposal of the mill after a single use avoided issues with cleaning validation.

- Clean/green filter options
- Upgrades of existing facilities to meet changing requirements, safety standards and options for automated operations
- Bespoke equipment, re-engineered for integration within a pharmaceutical isolator

*Read more: <http://hml.to/frandpdf>*

## Hybrid Flexible Containment Systems

Combining rigid walls and flexible enclosures our hybrid systems can be designed for multi-chamber, docked cell options and use within multi-use facilities where a higher level of containment is required to provide protection from cross contamination.



## Downflow Booth

Hosokawa Micron continue to pioneer developments in this product, extending containment levels at affordable costs.

- New wider/higher/deeper, modular design booths increase the actual 'protected work area' or 'safe working depth'
- Meeting the demand for lower OELs at a low cost our integrated 5 articulated containment screens are designed to deliver 1µg OELs whilst providing full access to workstations in the booth with excellent ergonomic movement for operators
- Latest software modelling services verify equipment spec before manufacture
- Save up to 30% on running costs with green booth design options on fans, lighting, filters

*Read more: <http://hml.to/mdbpdf>*

## Airflow Dynamics Modelling

- Early design stage proven designs
- Complements 3D ergonomic modelling
- Invaluable for complex, multi-use operations

With the latest airflow dynamics modelling package, customers can see for themselves, at early design stage, how the placement of objects, screens, equipment and operatives can affect airflow patterns in downflow booths and the impact this may have on achievement of critical OELs.

## Pack-Off Filling and Weighing System

Market demand escalates for single units or as part of a full processing system.

- Filling accuracies as low as +/- 10g
- Containment levels from 1000µg/m<sup>3</sup> down to nano
- Flexible systems to handle single/continuous liners, FIBCs, IBCs
- Wide range of sealing head designs
- Can be integrated into downflow or laminar flow booths



*Read more: <http://hml.to/dpfpdf>*



## Multi-process machine systems

Hosokawa has noticed an uplift in demand for systems with interchangeable machine units. This flexible option provides a long term, future proof processing capability. We have designed numerous

multi-powder size reduction systems:

- 315 UPZ milling system supplied to an a contract manufacturer, the UPZ mill is interchangeable with a 200 AFG
- A contained multi-purpose system with interchangeable 100AS and 100 AFG

*Read more: <http://hml.to/capipdf>*

# Highest Achievement Award for Alex



*Alex is pictured with her husband Michael, who also graduated from the Programme, together with Gillian Wright Fitzmaurice, Mentor Corporate Coaching.*

**A**lex Tamas has received the Highest Achievement Award on graduating from a Personal Excellence Leadership Programme. The award is determined by the votes of the other Programme participants.

The learning programme is based on 6 personal growth concepts designed to develop problem solving and inter-personal skills and intended to develop effective and inspirational leadership.

Alex says, 'During the 8 week programme, I learned how to handle difficult situations, especially acting outside my comfort zone and as a non-native speaker feel more confident now when speaking to customers, suppliers and others on the phone. We each had to consider how to improve our relationships with those we work with and other people too and focus on understanding what we want to achieve and how.'

During the programme we each had to stand and talk about various topics for 1 or 2 minutes. Topics could be a childhood incident, your attitude control plan, a visit to the dentist etc. On one occasion we were given the topic on the day so we really had to think on our feet in order to speak spontaneously in front of others but it has definitely improved my self-confidence.'

## Face Facts – Cut Costs

**C**onventional four step production of high quality face powders, requiring multiple machines is now being replaced by single machine mixing using the Hosokawa Micron Cyclomix. Unlike other cosmetic production processes no mill is required for dispersion of lumps. Lower investment costs, reduced cleaning and maintenance downtime and improved product quality are driving this change across the cosmetics industry.

**Application:** Intensive mixing of pigments and talcum and addition of oil for the production of face powders.

### **Objective:**

- Homogenous pigment dispersion without streaking
- Lump free incorporation of up to 25% of oil
- Damage free mixing of brittle and heat sensitive materials

### **Solution:**

The Cyclomix disperses the pigments completely. Oil is introduced from the top of the mixer with the position of the nozzle guaranteeing good distribution of the liquid in the powder. During introduction of the oil the mixer maintains mixing so there is no over-wetting of parts of the mix and no lumps are formed. Due to the ability in changing the rotor speed from 3-30m/s it is possible to introduce fragile materials or pearls at the end of the batch and mix them gently without destroying the product structure.

Due to this unique combination product losses are minimal and down time for cleaning minimised.



For further information on anything within this newsletter please visit  
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