**NEW PRODUCT INTRODUCTION (NPI)**

New Product Introduction (NPI) projects are complex and multifaceted. They generally require changes to production methods, equipment, analytical methods, labor requirements, and environmental and safety systems. New equipment is required for the development of cleanability, development, reproducibility, and scale-up for drug substance and drug product. For more details on this project and how we can assist you in design and project delivering contact John O’Reilly on joreilly@biopharma.ie.

**BRIEF INTRODUCTION TO CONTINUOUS GRANULATION PROCESS**

BioPharma Engineering delivered our first Continuous Wet Granulation processing suite for Pfizer in 2008, the suite was designed to produce up to 400 kg of powder per hour to operate continuously for up to 28 Days between changeovers and can continuously formulate up to 4 excipients and 1 API through milling. Blending, continuous wet granulation, continuous fluid bed drying feeding into 3000 Litre IBCs for downstream Tableting and Coating.

As mentioned above we are currently working on the BOD phase for a new Continuous Processing Facility which will leverage our previous experience in the delivery of the Continuous Wet Granulation with the delivery of 2 large scale wet granulation trains - 400 kgph and 1000 kgph along with a Continuous Dry Granulation process using Roller Compactor operating at up to 300 kgph.

The customised equipment trains detailed above will also be complemented with a number of Off the Shelf fully Continuous Granulation, Tableting and Coating units operating at 100, 150 and 200 kgph ranges.

At BioPharma Engineering we have unrivalled practical experience in design, delivery and qualification of Continuous Manufacturing for OSD production. With the right design, Continuous Manufacturing will let you stay ahead of the reduce costs and increase throughput. We have set out a number of challenges and benefits in moving from batch to continuous processing which we would be delighted to discuss with you in further detail.

1. **Equipment Selection**

   Equipment selection is critical to the successful introduction of a Continuous Granulation process. The selection of the equipment is decided by several factors – campaign duration, product throughput, product formulation, scalability and cleaning frequency.

   Availability of raw materials and delivery of the materials to the Continuous Facility is another factor to be taken into account in deciding an approach to Continuous Manufacturing. The utilization of Big Bag automated dispensing can dramatically reduce the amount of manual handling associated with traditional batch dispensing and lead to reduced manual handling and labour costs. Availability of raw material in FIBCs may be a challenge in the current supply chain particularly from API suppliers and is an area to be considered early in the Continuous Train.

   In addition, a fit with product development / R&D equipment selection may be considered in the longer term for new product introductions. It is crucial in the long term to keep a link between product development and your manufacturing system if you are to attract new products to your site.

2. **Decreased Production Time & Costs**

   Removal of the manual interventions associated with batch production will lead to improved product quality due to the removal of batch to batch variation. It will also allow for reduced costs due to increased batch size, less head count to staff the equipment and reduced costs of raw material due to savings incurred in packaging.

   Reduction in plant service costs i.e. steam, compressed air, electrical services and cleaning materials in relation to running one processing train versus multiple batch processing trains can also add considerable cost savings to an existing facility.

   Improved efficiencies in compression due to increased batch size - where IBC fill capacity can be increased as the granulate is continuously blended and fully loaded in the granulator, thus making the follow on step / start up easier.

3. **Facility & Capital Costs**

   Capital costs to construct new solid dosage facilities that incorporate continuous manufacturing systems will be significantly reduced allowing for more efficient pharmaceutical revenue to be dedicated to shareholder value.

   With smaller and more energy efficient buildings requiring less footprint, new facilities will be the less challenging parts of an overall capital expenditure program. New facilities will undoubtedly be leaner and greener when using continuous processing as its manufacturing system.

   Current estimates of between 20-35% savings on facility build costs are achievable where a reduced facility footprint is driven in use of relatively small continuous equipment instead of the batch equivalents. In continuous processing, multiple unit operations are directly coupled together. This means that the process has inherent containment attributes, thereby reducing manufacturing material movements and work-in-progress storage requirements.

4. **Benefits of Continuous Processing**

   The decision to adopt continuous processing should ideally be based on process understanding and business requirement. Continuous wet and dry granulation processing may not be a suitable technology when a process relies on back mixing as a control mechanism, or is an inherently slow process.

   Several studies have demonstrated the benefits for this type of process, as follows:
   - Unattended and lightly attended operations.
   - Increased process efficiency with regard to output and yield.
   - Reduced manufacturing cost due to low manpower and energy requirements.
   - Reduced cycle time due to the inherent efficiencies of batch processing.
   - Reduced space and capital requirements due to the generally smaller size compared to batch equipment.
   - Extension of working hours from 8 hours day to a 24/7 operation.
   - Better quality attributes due to improved potential for process control.

   For more information contact John O’Reilly on joreilly@biopharma.ie.

We would like to welcome the following new team members to BioPharma Engineering

**Dermot O’Driscoll** – Lead Building Services Engineer

Dermot is a mechanical and building services engineer with more than 20 years experience in the design, construction and commissioning of HVAC and building services systems. He has worked on a wide range of industrial and commercial projects but mainly for the pharmaceutical industry including sterile fill-finish facilities (project engineer with MSD Biologics), API facilities (Eli Lilly and Pfizer) and Oral Solid Dosage facilities (Pfizer Loughbeg). He has had a particular emphasis on energy reduction projects in recent years, including airflow and demand reduction for API and Sterile Fill Finish facilities and CHP projects for both pharmaceutical and food industry clients.

**Ben Corbett** – Senior Piping Designer

Ben is a senior piping designer with more than 30 years experience in 2D and 3D process and utility piping design including co-ordination, commissioning and construction supervision in API and Bio Pharmaceutical Industry. He has worked on green field and brown field projects for various pharmaceutical plants (Pfizer, Eli Lilly, ROCHE,MSD) amongst others. Ben’s vast experience covers all areas of Pharma piping design from high purity bio systems to carbon steel systems and he will be a valuable member of the team and effective team member with a strong client background and appreciation of site requirements for successful project delivery.

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Our Capabilities

We design, manage & deliver projects for a broad spectrum of clients in the following Industries

PHARMACEUTICAL

BIOTECHNOLOGY

MEDICAL DEVICES

To find out how we can tailor our service to meet your business goals give us a call or visit our website.

- BioPharma’s First China Project
- New Product Introduction (NPI)
- Brief Introduction to Continuous Granulation Process
- New BPE Team Members