

BPE INSIGHT

Engineering Design and Project Delivery

TRANSFORMING FOR THE FUTURE

2018 is proving to be another evolving year for BPE and its clients.

Having recently completed four large capital investment and high profile projects over the last 3 years (including a €110M greenfield Biologics facility, two €30M secondary manufacturing facility upgrades, and a €35M Small Scale Continuous manufacturing project – which you can read about in this issue)we are now entering into a time when we are actively acquiring new clients, taking on new projects and growing our team.

We are confident in our brand, quality and team to deliver not only successful projects for our clients but projects that are seen as leading edge technology and at the forefront of Pharma 4.0.

In this issue we look at what trends we are seeing in the market, how BPE is adopting to service them and some of the exciting projects our clients are implementing to keep up with the future of pharma.

STATISTICS

+ €250 Million Euro Worth Of Projects Delivered in the last 3 Years



1.5 Million safe Manhours last 3 years



1 new Safety award - Eli Lilly



12 Years in Business - Cork Office



2 Years in Business - Dublin Office



75 In House Design Engineers



20% Process Engineers

CONTINUOUS MANUFACTURING WITH BIOPHARMA ENGINEERING

BioPharma Engineering are now the leaders in the market when it comes to delivering continuous manufacturing methods. Having delivered one of the first wet and dry continuous manufacturing projects in Ireland in 2008 we just recently finished a small volume continuous processing project for another client in 2016. This one proved to be very high profile, now amongst the world's first FDA approvals for this technology.

CASE STUDY

SMALL VOLUME CONTINUOUS PROCESSING API FACILITY



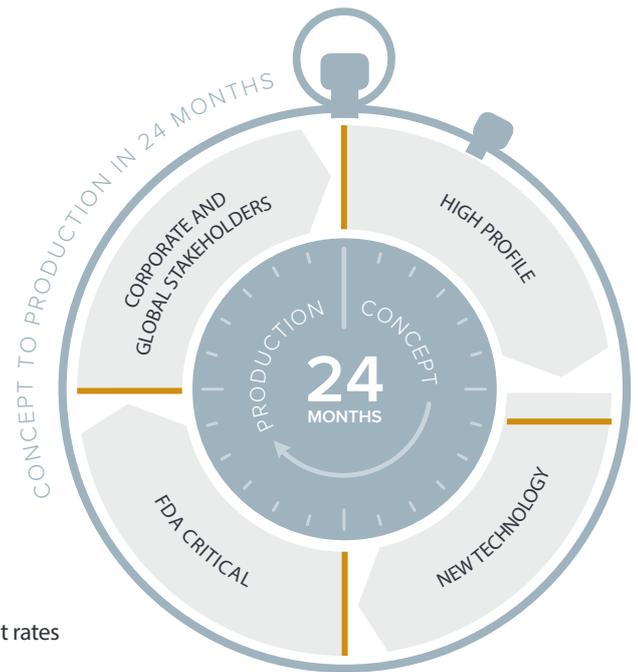
Client:
CONFIDENTIAL



Duration:
24 MONTHS

At the end of 2015 BioPharma Engineering were appointed by our client as the multi-disciplinary design and Project Management team for delivering the c. €30M new technology investment. This Small Scale API Continuous Processing (SVC) Project was developed from initial scope definition through to CQV completion by BioPharma Engineering.

Small Volume Continuous is the concept of fully continuous processes operating at rates of 3-10 kg/day to deliver material quantities less than 1500kgs/yr.



WHY CM?

- ▶ The clients Portfolio Trended to Lower Volume Products.
- ▶ >75% of the clients post FHD portfolio has a projected API volume of less than 1500 kgs/yr.

THE HIGH-LEVEL PROJECT SCOPE

The extension and remodelling of an existing pilot laboratory for the propose of small volume continuous processing projects.

- ▶ Extending and remodelling and existing facility (c. 400m²)

- ▶ Walk-in fume hoods.
- ▶ Small volume process equipment skids such as evaporators, pumps and instrumentation for a full 3 step continuous small molecule processing.
- ▶ Solvent room containing agitated and jacketed 50-200L glass lined steel vessels plus an arrangement of small volume pressurized transfer vessels.
- ▶ Provision of utilities such as hydrogen, nitrogen, vacuum and process vents to both the fume hoods and to the vessels.
- ▶ Provision of a solvent manifold station including purified water user points.

- ▶ Provision of ATEX capable fume hood infrastructure.
- ▶ Provision of a dry end room for batch isolation (crystallization, filtration, drying and bagging)
- ▶ Provision of a technical space adjoining the Dry End for associated utilities.

DRIVE TO DELIVER

The BPE team delivered this project which was not only highly complex and used some of the most advance technologies and techniques but it also required the dedication and drive to deliver the full project in under 24 months.

HOW TO IMPLEMENT CM?

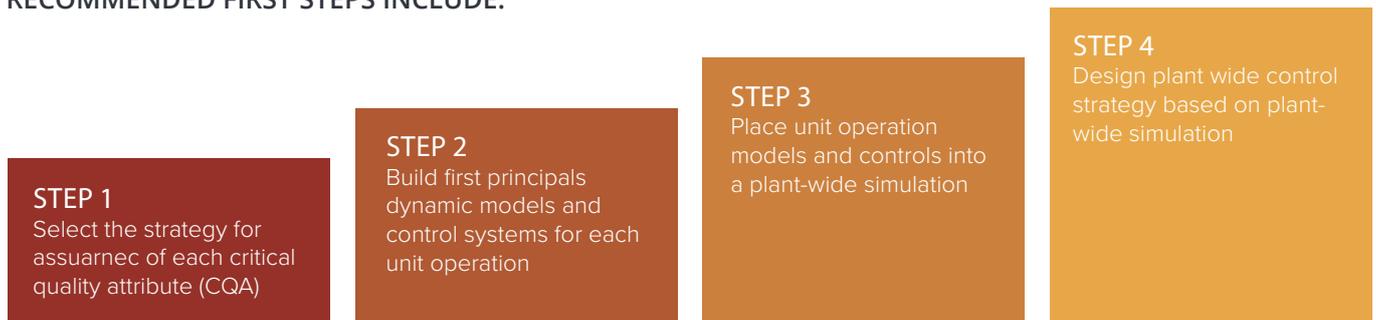
A very successful outcome for us and our client but also for the industry as a whole. The ROI for the lean delivery model is substantial when you look at reduced cleaning cycles, reduced down time, increased automation, increased quality and output as well as efficiency in overall process. Although the benefits of CM seem obvious and significant, large scale deployment is still in its infancy. Many companies are still in the exploratory or wait-and-see stages for adoption.

BENEFITS

Improved Speed	Lower Cost	Improved Quality	Improved HSE
<ul style="list-style-type: none"> Automated DOE's Eliminate Units Ops Streamline Tech Transfer Rapid Prototyping 	<ul style="list-style-type: none"> Better Synthetic Routes New Capabilities Added Capacity Deferred Capital Investment Increased Throughput 	<ul style="list-style-type: none"> Real-time Analytical Steady State Equipment is Engineered to Process Less Material at Risk 	<ul style="list-style-type: none"> Reduced Waste Containment Smaller Volumes Lower Reagent Amounts Neat Reactions

Part of the success of the project was the clients commitment to CM and the overall site and stakeholder engagement to execute the project.

ACCORDING TO RECENT ISPE PUBLICATIONS – RECOMMENDED FIRST STEPS INCLUDE:



cGMP FOR CM:



To discuss your Continuous Manufacturing needs talk to BioPharma Engineering today. Please contact us on **021-2307145**.

CLIENT SPOTLIGHT



BPE have been awarded the extended BOD and Project Management on design and build project

Our client is a clinical-stage pharmaceutical company dedicated to developing significantly differentiated anti-infectives aimed at combatting the global crisis of multi-drug resistant (MDR) pathogens. A VC backed company, pre IPO and have chosen to locate their new OSD manufacturing facility in Dublin. The new facility will look to manufacture sulopenem – an antibiotic drug for treatments for urinary tract and intra-abdominal infections. The drug is at late stage clinical trials. BPE have been awarded the extended BOD and Project Management on this Design & Build project.



BPE completes contract for concept, front end study and detailed design for a new purification suite

BioPharma Engineering have recently completed the contract for the Concept, Front End & Detail Design for a new Purification Suite at a Dublin Facility. A fallow space within a recently constructed building is allocated to the new Purification suite. The new Purification Suite is to be routinely used for the manufacture of peptides.

New Services and Team Update

In order to better serve our clients and our expanding offices, we recently split our business into Internal Operations and External Businesses. This new delivery model, ensures constant focus on our continuous improvements and customer satisfaction as we grow. CEO, John O'Reilly will now head up the external business division, concentrating on strategic client support and BPE commercial development. While COO, Richard Holohan will lead our internal operations ensuring quality of delivery and project designs.

Following the recent changes and requests from our clients, BPE are delighted to officially offer our new support services. Over the past few months we have helped a number of our clients with resources and support for site. Through our offerings we now provide, short-term and long-term staffing solutions through secondments and site placements. Additionally, we also provide Peer Reviews, Client Teams, Managed Services and Independent C&Q services.

To discuss your needs please contact Aisling Crowley, Client Relationship Manager +353857441155

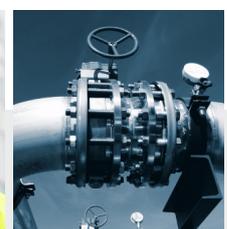


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