Genzyme and NiTech collaboration delivers the world’s largest patent protected continuous API manufacturing plant

Genzyme in collaboration with NiTech has created the world’s largest patent protected continuous API manufacturing plant. The new process is the result of 18 months innovative work involving a diverse range of skills. It is an excellent example of how innovation in manufacturing design can deliver demonstrable benefits in pharmaceutical production through lower capital investment, reduced energy consumption and faster processing from a significantly smaller asset.

The close working relationship and expertise built up on both sides of this collaboration has enabled the project to be completed quickly and efficiently - with excellent results.

Peter McDonnell Senior Technical Director of Genzyme’s Haverhill Operations said: “I think the way the joint work has gone is a model for how we would like to work with many of our technology partners”.

The NiTech reactor used in the application is a Tubular Baffled Reactor (TBR®) that creates uniform mixing throughout the reactor and works well with three phase systems (solid/liquid/gas). It has a significantly smaller footprint than traditional stirred tank reactors and offers predictable scale-up and plug flow conditions. This new innovation is NiTech’s first move into the pharmaceutical market.

Ian Laird, NiTech’s Managing Director said: “Working with a company like Genzyme has demonstrated that our technology can make significant impacts on even the most forward thinking of companies. I believe that projects like this demonstrate what can be achieved when companies embrace innovation in chemical processing”.

Although the reactor is manufacturing a pharmaceutical API, the scale is in the multi-hundred tonne per annum range, which puts the process more on a fine chemical manufacturing scale. Prior to collaborating on the project Genzyme were considering using 2 x 150m³ pressurised reactors. The photo shows the reactor which - at less than 3 meters high - demonstrates well how new technology can revolutionise chemical processing, using significantly less construction materials, space and energy.

The initial work carried out on the project saw NiTech testing the chemistry within one of their batch OBR reactors. The next step was to move the process to a continuous pilot plant. This was initially used to prove the concept and after the optimisation, the pilot plant was used for phase trials. During the optimisation process the reaction was speeded up by more than a factor of 30.

Genzyme is one of the world’s leading biotechnology companies, dedicated to making a positive impact on the lives of people with serious diseases. Started up in 1981, it now has more than 10,000 employees worldwide and revenues of more than $3.8 billion (2007). Its products and services are available to patients in more than 90 countries worldwide. It is a leader in developing and applying the most advanced technologies in the life sciences sector. It has a strong commitment to innovation and this commitment is as strong today as it was in 1981 when it started.

NiTech is an innovative service and equipment provider assisting companies in moving from batch to continuous processing and scaling up from gram to multi-tonne scale. It has a variety of continuous reactors exhibiting excellent mixing and linear scale-up offering a range of technical benefits over traditional technology. Since its formation, NiTech has worked on a diverse range of chemistries and applications including pharmaceutical API’s, crystallisations, fermentations, hydrogenations, polymerisations and general organic synthesis. NiTech spun out of Herriot Watt University and is helping many companies blue chip to SME’s improve their competitiveness through more efficient processing. These include Fujifilm, Bunge and AstraZeneca; they also work with Universities such as St Andrews, Leeds and Glasgow.

NiTech is a key member of Chemistry Innovation’s strategy board (ISB) and is actively engaged in its technology platforms.