New tool for 'right first time' drug manufacture

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A technology which provides high quality images of the crystallisation process marks the next step towards a 'right first time' approach to drug manufacture, according to engineers at the University of Leeds.

Developed in collaboration with industrial scientists at Perdix and Malvern Instruments, the new process analytical technology (PAT) tool characterises particle shapes using a probe which collects images of the crystallization process. The tool will enable pharmaceutical companies to monitor and optimise these processes.

"Essentially we're filming inside the reactor so you can see exactly what's happening as crystals are forming – and we've shown that we can do this on a large scale," says Professor Kevin Roberts of the University's Institutes of Process R&D (iPRD) and Particle Science and Engineering (IPSE). "I believe we can help the manufacturing process become faster and more efficient, which will cut waste and save money - and shorten the time it takes drugs to get to market."

Crystallisation of drug compounds from solution is a fundamental part of the lengthy pharmaceutical processing chain. The size and shape of drug compound crystals has a significant effect on product purity and quality. It also impacts on other parts of the process, where crystals are sifted, milled and blended with other chemicals before being made into tablets or suspensions.

The Leeds technology uses a probe called the In-Situ Particle Viewer

(ISPV) designed and built by Perdix, in combination with Morphologi®, a commercial image analysis software developed by Malvern Instruments.

Until now there has been little research into how crystal formation can be monitored and controlled. Optimising crystal formation at the beginning of the manufacturing process could significantly affect the efficiency of the production chain, says Professor Roberts.

He believes that technologies such as those being developed at Leeds have the potential to revolutionise the pharmaceutical manufacturing sector. "The development of new technologies and processes to ensure that drug manufacture is lean and efficient is crucial. Getting it right first time requires an in depth understanding of each of the component parts of the manufacturing chain," he says.

"Essentially we're working towards developing high quality 'Six Sigma' manufacturing processes for the pharma sector - very much mirroring the approaches already adopted by high-tech sectors such as microelectronics."

Source: University of Leeds