

**Breaking News on Pharmaceutical Technology**

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## Pfizer wins Microsoft accolade in drug manufacturing

**28/06/2006- Microsoft has awarded Pfizer with its Pharmaceutical and Life Sciences Innovation Award for its manufacturing management system which revolutionises the scaling up and monitoring of active pharmaceutical ingredient (API) production, saving time and money.**

The award, announced at the annual meeting of the Drug Information Association (DIA) in Philadelphia, went to Pfizer's Catalyst, a fully integrated suite of functionality that spans the API manufacturing process, including design, production planning, and analysis.

The system uses several Microsoft technologies, including .NET, BizTalk Server, SQL Server and SharePoint Portal Server.

It is currently being rolled out at Pfizer's Groton plant in Connecticut, which, although fairly automated in shop floor machines and enterprise-wide systems, saw until recently the highly creative tasks of designing API processes and planning their production done conventionally.

What is more, chemists and engineers were spending too much time hunting down information and preparing documents, which took away from more productive work.

Now Catalyst allows industry workers in the plant to design, schedule and analyse manufacturing processes using a graphical user interface in a fraction of the time required by existing electronic and manual systems.

The system calculates detailed design data such as material balances, time-cycle analysis and environmental emissions, as well as automatically configuring shop floor execution and reporting systems.

The solution therefore radically reduces the need for manual review of process data to support a real-time quality system.

Design Catalyst, the process-design component, takes into consideration all information about materials, reactions, and available plant equipment, calculates a production recipe in a matter of seconds and also validates the model, leading to huge timesavings.

If there was an error made in the assumptions or input, Catalyst flags it and a new model is recomputed in seconds.

Catalyst will also automatically adapt the recipe for other plants and their unique capabilities, which helps with the second phase, production planning.

Planning Catalyst can assess current production status at plants around the world, identify what equipment is available, and rank each piece of equipment based on its ability.

The system can determine whether a vessel is in use or fallow and note special characteristics, for example, if a vessel or tank is glass lined, which might be desirable when dealing with corrosive substances.

When Catalyst is fully deployed, engineers will be able to draw upon Pfizer resources around the world to split up production between plants while maintaining quality and consistency, so the system gives Pfizer, which operates a dozen API plants around the world, an unprecedented and efficient way of scheduling production and optimising capacity on a global scale.

That capability can greatly reduce the time it takes to get a drug to market once it is approved, a fascinating prospect for Pfizer which plans to submit 20 new drugs for US Food and Drug Administration (FDA) approval by the end of the year.

But perhaps the area where Catalyst can matter most is regulatory compliance. To comply with pharmaceutical industry regulations, not just good manufacturing practice (GMP) but also environmental and safety standards, companies must generate an endless stream of reports and

documentation.

In API manufacturing, any anomaly triggers an internal investigation and a "notice of event" to the FDA and, depending on the outcome of the investigation, the company can be fined.

If, for example a batch of API for Lipitor, Pfizer's cholesterol-reducing drug, exceeded the normal temperature, an investigation would be triggered, but before Catalyst, conducting an investigation typically required an employee to hunt down documentation and interview people to piece together the situation.

This is a time-consuming and manual task as the records are scattered in different places, often not in electronic form, and rarely linked together in any meaningful way.

Making matters worse, a week or more can go by before an employee has time to go back and review the situation and, in the meantime, more batches will be run and, chances are, the same problem will affect those batches as well.

With Catalyst on the other hand, all the information relating to production is collected and stored in a central database, so engineers have all of the data they need, in a rich context, at their fingertips.

Instead of taking weeks and hundreds of work hours, investigations can take days or merely hours.

*"I think the FDA is going to be very pleased with what they're seeing here,"* said Cathal Strain, senior director of API Automation & Information Management at Pfizer Global Manufacturing.

*"It should set a new paradigm for the industry."*

The FDA has lately been urging the pharmaceutical industry to modernise, publishing guidelines for Process Analytical Technology (PAT) as part of its 21st Century Initiative.

Pfizer will have, by the end of the year, rolled Catalyst out to three more plants in Puerto Rico, Ireland and Singapore, representing its most complex API manufacturing sites.

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