Managing Life Before a Product's Birth

Numerous design alterations can affect the lifecycle of a medical device before it even hits the shelves. Nicola Boyes looks at how the latest technology could manage this process.

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The age-old catchphrase "time is money" never rings truer than in the medical device business. In this rapidly growing industry, those who can bring their products to market first are often those who reap the financial rewards.

Constrained by an often highly restrictive regulatory environment, companies today face the added challenges of complex products, merged companies, internationally dispersed staff as well as outsourced development and manufacturing operations.

Due to high costs and long lead-in times, profitability depends on a medical device manufacturer's ability to design, develop and deliver products to the market while reducing costs and optimising profits. Pushing products through the development lifecycle is essential and can make the difference between taking home the gold and or blending in with the rest of the crowd.

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Winning armoury

To ensure they stay in the leading pack, companies are turning to innovations in product lifecycle management (PLM) software. These tools have the ability to manage issues and guide the manufacturer through regulatory pitfalls, which in turn can often speed up the rate of innovation and accelerate a device's time to market.

As global competition shrinks the opportunity for medical device companies to recoup their intellectual property investments gets smaller.

According to McKinsey and Co, companies lose up to a third of profit when they ship products six months late, compared with a meagre 3.5% when they overspend 50% on product development. The financial benefit of pumping money into a fast development process does, therefore, become starkly apparent.

"Time-to-market issues, cost of documentation, compliance and outsourcing complexities are all critical business issues," says Gisela Wilson, director of product lifecycle management solutions at analyst firm IDC.

"The medical device and instrumentation market depends on its ability to rapidly innovate its product offerings. At the same time, it must support rigorous legislative requirements."

PLM software allows companies to work together on creation and enables a flow of communication from computer-aided design and computer-aided engineering between departments. The software can support systems commonly used by medical device companies including customer relationship, supply-chain management, learning management systems and quality management systems, says Wilson.

Tough regulatory bodies like the FDA in the US or the Medicines and Healthcare Regulatory Association in the

UK require stringent documentation throughout the development of a device. Before PLM software became available for managing all the information from product design to operating procedures, drawings and documents could cause major issues.

The FDA even commented in a recent report there was growing concern that many of the basic science discoveries made in recent years may not benefit patients as quickly as hoped, because of the increasingly challenging product development path.

"We need superior product development science to address these challenges to ensure that basic discoveries turn into new and better medical treatments," it stated.

Evaluation and analysis

A product lifecycle management system allows medical device companies to manage product portfolios from research and prototype development to design changes. As designs alter and technology advances at a rapid speed, often plans need to be reviewed. In many instances, this can require the manufacturer to go back to the very first step and look again at the overall product design.

Because of this, storing all quality and product development data in a single place that integrates with the other business applications allows for the exchange of information and updates to models, says Wilson.

Today's global business environment dictates that very few medical device companies operate in a single location. But while the location of the product development centre and the manufacturer's headquarters can be countries apart, there is still a need for continuous improvements during a device's development.

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In addition, a growing trend towards outsourcing manufacturing operations has placed a serious strain on trying to implement continuous quality improvements, according to Chris Rehl,director of marketing at international lifecycle company CIMTEK.

"How many medical device companies with successful commercial products have a single location that is home to all product development and manufacturing activities?" he asks. Even small medical device manufacturers rely on design or manufacturing partners to develop and manufacture their devices.

Effective data collection methods and quality test systems are therefore critical elements in ensuring medical device design success.

"With the ability to access, organise and analyse test and quality data generated by production lifecycles quickly and efficiently, medical designers can stay ahead of their competition while increasing operational efficiencies and minimising risk," Rehl adds.

But despite this opportunity many organisations still have no coherent access to that data. "Large amounts of time and resources are spent developing custom solutions which are obsolete before even being deployed, as the data landscape is subject to frequently changing business and product demands," says Rehl. A single integrated information technology department is the answer.

Finding the answer

While PLM for the medical device industry is still developing and growing, companies like CIMTEK are providing some of the answers. Major players like Siemens have also jumped on board with its PLM software, Teamcentre for Medical Devices.

In addition, others such as Oracle have bought into the business following its purchase of Agile Software in January last year. The $495m deal was touted by analysts as a sign of the continuing evolution of the product lifecycle management, with manufacturers set to benefit from the technological developments.

With competition and globalisation cutting away profit margins the use of PML speeds up innovation, managing information from the research and development stage, through to engineering and manufacturing, production and supply. Even though it has been around for a number of years, it is only recently that design engineers and manufacturers are taking notice of the powerful technology.

The applications hold the promise of seamlessly flowing information, produced throughout the phases of a medical device's lifecycle, capturing design information and allowing for design tweaks.

While medical device companies have many options for responding to regulations and competitive pressures, as a single answer PLM appears to offer both.

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