

Making scalability on schedule

Wolfgang Emmerich, CEO of **Zuhlke Engineering UK**, discusses how medical device manufacturers are developing products through projects that are scalable and can be executed efficiently and on schedule, through a systematic development process

Medical device manufacturers are continuously faced with the issues of providing innovative high quality products, while at the same time addressing increasing pressure for cost reductions in the health care system. The demand for ever higher performance, more complex and more economical products, as well as stricter product liability laws force manufacturers to perform increasingly comprehensive product tests.

Medical products must be developed according to strict international regulations. EU and US directives and liability legislation place tough requirements on medical products and the companies that bring them to market.

Manufacturers need to utilise a structured product development process that complies with safety and quality regulations, such as those prescribed by ISO 13485 or the US FDA 21 CFR, to ensure that newly developed medical devices meet these requirements and at the same time address the business needs to get products to market as quickly as possible.

By ensuring that product development proceeds in phases divided into iterations, and by involving strategically co-ordinated, clear-cut intermediate objectives, the risk of a non-compliant or inferior product is reduced.

Product safety is often considered to be a separate development discipline, however it is of major importance in the medical product industry, so it is vital that it is addressed and monitored appropriately. Intended use, medical applications, technical solutions and usability needs culminate in an overall safety concept that forms an integral part of safe, stable system architecture.

Mechanics or electronics, firmware or software is developed according to proven methods for the given discipline. The overall process at system level makes it easier to coordinate product progress and control the interfaces between the sub-systems.

This will result in an efficient process that is scalable and more likely to adhere to the timing schedule, thus significantly reducing time to market.



Those who consider suitable quality assurance strategies and concepts during the development phase of a product also prevent expensive adjustments in production, or worse product recalls. In order for quality assurance to take place optimally and efficiently, it must be integrated into the development process from the outset.

Verification through static or dynamic analysis techniques, such as model-checking, SAT solving or theorem proving of safety-critical subsystems should be done in parallel with development. These techniques reduce latent defect rates beyond those that are achievable by testing.

Working out and implementing test cases with suitable test strategies is essential for medical device manufacturers to guarantee a successful project. During this time, all questions relating to the size of the tests, test conditions, specimen identification, degree of automation, inspection documentation, interfaces, data management and 'make or buy' concepts are clarified.

By implementing a suitable test strategy and providing requirements for test concepts as early as during the development phase, manufacturers are able to take into consideration requirements for the production environment, consequently resulting in fewer risks.

In such a competitive, fast moving industry, medical device manufacturers are often faced with the problem of how best to manage the organisation of the future structure of their products.

The veritable explosion in model diversity and the complexity of medical product ranges has triggered a steady rise in the costs, times and risks involved in development.

Newly developed medical devices must meet strict regulation, test and safety requirements

In this environment, the multi-use of platform elements over different products and product generations is a feasible way to develop new products and models quickly, cost-effectively and in a manner that can be planned. Time to market costs and risk can be significantly reduced in the process.

Individually adapted platforms and module strategies expand the focus on innovative projects from individual products to entire product ranges.

By breaking down a product into functional entities it opens the way to an international division of labour, enabling manufacturers to concentrate on core skills and make more efficient use of their resources.

Optimising product design can also have significant time and cost saving benefits. Manufacturers can see cost reductions of between 20-80 percent through a thorough revision of the production process.

By making all costs transparent and continually evaluating the project risks, manufacturers of medical products are able to analyse where there is scope for further cost reductions. The continuous assessment of the development process ensures that the initial objectives are constantly referred to, and subsequently met.

For example, the development of a critical medical product such as a laser device for eye surgery requires major risks to be identified early on and numerous trials to take place throughout its development. By incorporating the results and taking into account FDA assigned safety systems, manufacturers are able to achieve the objectives of creating greater precision and shortening surgical time.

In such a demanding and fast paced industry, it is essential that medical device manufacturers implement a development process that produces the best possible product, while achieving optimal business results.

By adopting suitable quality assurance strategies and continuously monitoring the development process, manufacturers are able to reduce risk and facilitate ensured compliance with international regulations, as well as enjoy both time and cost savings.

This approach creates an environment that encourages flexibility and initiates faster responses to future market changes, enabling a product platform strategy that will yield long-term business benefits.

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