

Predictive design

Optimal product reliability and performance demands vigorous test and quality control procedures during manufacture. In the healthcare industry, where safety is paramount and safety critical devices are prevalent, this has long been the case.

While product testing to ensure compliance with specification will always be a manufacturing fact of life, there is a move underway likely to have a profound effect on the way product performance is viewed, especially in the healthcare industry but also in industries including automotive and aerospace.

Known as Quality by Design (QbD), the initiative is being championed by the American Food and Drugs Administration (FDA). QbD contends that product testing should no longer be considered as the only means of determining product performance. Instead it shifts the emphasis from testing final product to building quality deep into the design and manufacturing process.

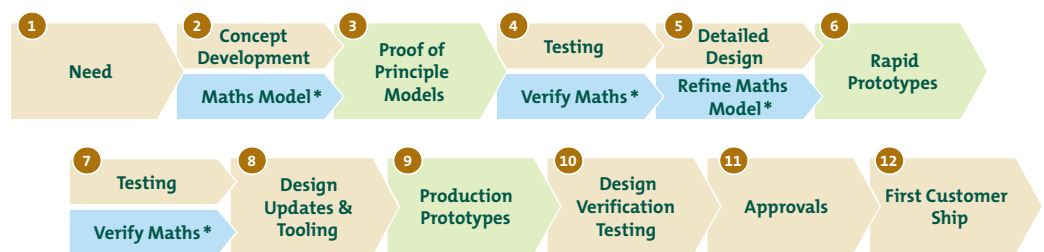
Sagentia has been actively involved in this area for some years through the development of its predictive design offering. While the FDA's approach does not currently call for such a process, it is the only way to demonstrate a full knowledge of the design. As such, there is a strong expectation that it will

eventually be incorporated into the overall QbD approach.

Our approach is based on mathematical modelling and statistical analysis and has grown out of Sagentia's work in the medical device area. It has become a very powerful extension of the design process.

As Alastair Willoughby, Consultant at Sagentia, observes: 'Predictive design is all about risk mitigation. For high volume, safety critical products, it's essential that the issues of performance, reliability and fitness for purpose are considered and acted upon at the design and manufacturing

How predictive design fits in the development process



*stages where predictive design is embedded

stages, and not left to chance when they are launched and used for real by the public. We do this by applying our understanding of design, specifically the variables that may occur in manufacturing and in use. We can then go on to predict how design variations will influence performance.

'Just recently we've undertaken work for a pharmaceutical company involved in drug delivery. We used a number of mathematical models to verify the failure rates of different concept designs for a device and used the results to determine the best way forward at the detailed design stage.'

Predictive design uses mathematical modelling and statistical analysis techniques to introduce variants to the design at key points throughout the design and manufacturing process. The diagram below shows where predictive design is embedded in a conventional design process:

The evolution of predictive design at Sagentia grew from our involvement in the medical device sector, specifically our work with inhalers. However, we are now witnessing the embedding of the process into all design work involving mechanisms that are safety critical. It is also being applied in instances where space is critical, ie highly evolved designs, and those that are inherently difficult from a design, manufacturing, assembly or functional perspective.

Predictive design has come of age. Developments such as QbD and a growing awareness

of product safety by the general public will ensure that it takes its place as an integral part of the design process. Manufacturers and brand owners will demand this of their product development partners and Sagentia is well placed to deliver it.