Insight Technology
Statistical Guidance
http://www.fb2c.com

Cutting costs in medical device - and pharma - development
Simplifying Compliance to Expand the Design Space.

The key word characterizing today's medical device development environment is confusion. In addition to doing their jobs, people are being asked to implement confusing, complex, at times misleading procedures.

Pushed by the FDA to move controls up-stream, medical device companies - but also pharma companies due to new regulations on combination products - are struggling with confusing, cumbersome, time consuming Design Control, Risk Management, and FMECA processes. These range from incompliant procedures without reference to any recognized standard to overly complex compilations of procedures borrowed from finance, aerospace and automotive. I did not even mention statistical methods, where two different engineers, applying the proposed software tool find two different answers to the same process capability question. Like Deming would say, there is no substitute for knowledge.

The answer to the question of cost reduction is simplification. 91/273 is the same fraction as 1/3. The latter is simple. To reduce costs, device and pharma manufacturers must simplify their design control, risk management, and statistical procedures so while compliant, they become understandable by an average technician who will feel confident applying it to expand the design space. It is time to move from form to function.

Mark Shal is a PhD Statistician with 16 years of experience in QA/RA, and NPD of drug delivery devices. Since 2008, he manages the consulting firm Insight Technology. For additional information, please visit www.fb2c.com