

Matthew Tulley

Single Use Surgical, UK

Medical Devices: From the idea to a sterile product

Keywords: sterile products, prototypes, product testing, cleanroom

For over 10 years Single Use Surgical have been taking ideas and transforming them to sterile products used in the operating theatre. Many aspects of problem definition and development are common to any product development, but there are particular challenges relating to the operating theatre environment and the regulatory framework. This seminar details some of the practical issues encountered in this journey.

Often the problem and potential solution has arisen in theatres, and so interest and access is facilitated. There are guidelines and protocol for these theatre visits and involving the correct people can ensure fewer blocks later on. Sometimes it is possible to produce proof of concept non-sterile prototypes that can be used in a non-clinical situation but still in theatres (eg at end of case). These visits result in much higher quality feedback than meetings with the same people in an office environment.

A sterile prototype is actually medical device, and requires full CE marking, together with technical file, risk analysis, sterilisation validation and product liability insurance. This can be less of a challenge where reference can be made to similar product families. Production of the prototype has to be in the same controlled environment as volume production, and so we invested in a cleanroom for prototypes at SUS. (This cleanroom is also available for daily hire at £100/day). Final feedback from prototypes can give confidence for final tooling and volume production.

Selling a finished surgical product generally takes around 10 times the effort and cost of developing it. SUS now sell to over 450 UK hospitals and export 30% to over 20 countries. Understanding the challenges of the different mar-

kets also influences product design. Post market surveillance and customer feedback provide further opportunities for product improvements, sometimes many years after initial launch.

www.susl.co.uk