MET News – April 2016
Global Excellence in Medical Device Testing

Meet MET in Stuttgart

Do you want to discuss your design validation requirements?
Visit MET's stand at the Stuttgart show. Our engineers with personal experience of developing medical devices and in-vitro diagnostics will be available to discuss your projects. Mark Turner was a designer, developer and project manager at Smiths Medical for over 10 years prior to joining MET. Mark and our team have assembled standard Design Validation Plans for a number of devices and can rapidly develop a programme specific to your needs.

A Variety of Consultancy Services are Available from MET.

Our experienced device developers and regulatory advisors can help you to develop your design verification strategy with a comprehensive programme of performance and safety tests. Areas of knowledge include: Toxicological Risk Analysis, 510k and PMA applications, quality system development and auditing, product design and development, gap analyses, project management and more. Whether you are a new start up or an established team looking for extra support, MET has the resources to help drive your projects. Further details can be found here.

Safety Testing for Infant Products

Chemical analysis at MET now includes child safety tests from EN71.

EN 71-3: Specification for migration of certain elements
EN 71-9: Organic chemical compounds – Requirement

These tests are applicable for baby and infant transport products and other items the infant can contact.

Updates to ISO 13485

The new version of ISO 13485:2016, *Medical devices - Quality management systems – Requirements for regulatory purposes*, is now live. The new standard has increased the emphasis on risk analysis and post-market surveillance. MET has a dedicated complaint handling service for medical device suppliers which has been successfully operating since the year 2000. Customer complaints are sent directly from the end user to MET where they are decontaminated and analysed. We provide simple paperwork and there is no need to have soiled product on your premises. Details of *First Line QA* are here.

Pen Injector Standard Under Review

ISO 11608-4 *Pen-injectors for medical use -- Part 4: Requirements and test methods for electronic and electromechanical pen-injectors* is one of a number of medical device standards currently under review for possible revision at ISO. These include: ISO 10555-1:2013/prA1, and prEN ISO 10993-16

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