MET News – November 2016
Global Excellence in Medical Device Testing

All Round Support from MET

Our global excellence programme is delighting clients in Africa, the Americas, Asia, Australasia, and Europe with studies including packaging validation, materials analysis, and device performance.

Whether you have a Class 1, 2 or 3 device a drug delivery / combination device or diagnostic product MET's services include comprehensive support for medical device developers. These services include: Project Management, Regulatory Consultancy, Design, Equipment, Lab Testing and Validation, Early Stage Production, and even Human Factors Studies. Contact us to find out how we can accelerate your projects.

New Analytical Chemists

Luminita Moraru and Leslie Philip have joined our team to reinforce our provision of material characterization services, extractables and leachables testing, cleaning validation studies, and chemical stability testing. Luminita has a master's degree in analytical chemistry with experience in monitoring environmental pollution. Leslie has had a long career in research and development and quality assurance in a leading pharmaceutical company.

ISO 11608-1 Revised

ISO 11608-*Pen-injectors for medical use – Requirements and Test Methods,* has been updated. The new version (2015/16) is easier to understand and presents the testing requirements more logically. Dose accuracy assessment is still required on new products and following pre-conditioning including fatigue testing and various atmospheric conditions. MET's test programme has been adapted to comply with this new version.

Did You Know That MET has an ISO 13485 Clean Room?

MET's clean room is available for trial batch quantity production. We provide assembly and packaging of medical devices in a class 10,000 environment. Clean air cabinets within the clean room provide an even more tightly controlled environment. We also use the cabinets for particulate contamination testing.

FDA Guidance on Biological Evaluation Published

FDA Guidance on biocompatibility is now published, it has been available for approximately 3 years in a draft format. It follows the newer version of ISO 10993-1 (2009) in requiring consideration of the risks associated with a device, the uniqueness of the products and materials, and their end uses. It is emphasised that testing is required on the finished clinical product which has undergone all manufacturing processes. The Guidance offers a modified version of the ISO 10993 test matrix, increased emphasis on risk analysis and chemical testing.

Call 08454 588924 or E-mail solutions@met.uk.com,
at MET we know about medical devices. www.met.uk.com

Medical Engineering Technologies Ltd • Unit 16, Holmestone Road, Dover, Kent CT17 0UF, UK
t +44 (0)845 458 8924 e solutions@met.uk.com www.met.uk.com

Registered No. 3295099 VAT No. GB 6838559 76