MEDICAL ENGINEERING TECHNOLOGIES

1997-2022
25 YEARS
OF EXCELLENCE IN MEDICAL DEVICE TESTING

Global Excellence in Medical Device Testing

Medical Engineering Technologies has been supporting medical device manufacturers and developers since 1997

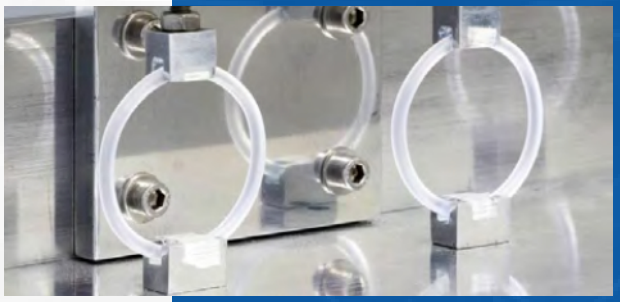
Analytical Chemistry | Medical Device Testing | Biocompatibility | Transit Validation | Human Factors Studies

Breathing Gas Pathway | Validation Testing | Packaging Testing | Combination Device Testing

Our Services

Medical device testing is the process of demonstrating the safety and performance in the laboratory, ready for clinical use. It forms a crucial part of the Design Validation for active and non-active devices, combination products, and drug delivery devices.

Careful protocol development and implementation can ensure an effective and efficient delivery of the test programme. An ISO/IEC Accredited 17025 Quality Management System, combined with good training and logic, ensures accurate results and reporting.



Medical Device Function and Performance Testing

Meeting regulatory requirements in the varied world of medical devices requires deft project management. This can be a difficult and complex job. You have to balance the needs of a lot of different parties whilst staying within budget and holding to tight deadlines. The clinical needs and safety of the device are paramount and must be demonstrated. Partnering with Medical Engineering Technologies will ensure that this part of your project runs efficiently and smoothly. Our technicians are frequently devising sophisticated protocols under pressure, and they are fully resourced to ensure rapid delivery of test work. We cannot guarantee what the results will be or shorten the dwell time in a test, but we can ensure accuracy and efficiency.

When you work with Medical Engineering Technologies you get:

- A partner that operates globally and has 25 years of experience in device testing
- A team that understands the urgency of your projects
- The benefit of our experience with and knowledge of a wide variety of devices

Whether you have a new product development, want to work with the recent changes to ISO 10993, or need to comply with regulations (FDA or MDR) we will understand your product, conduct a risk analysis and execute the study with aplomb.

Testing includes: initial consultancy, biological evaluation plans, human factors studies, packaging validation, physical testing, chemical characterisation and biocompatibility studies, and toxicity risk analysis.

We work to international standards ensuring your compliance where ever you are. This includes the MDR, EMA Guidelines, FDA Guidance, ICH, ISO standards, pharmacopoeias and any national requirements.

We Know Medical Devices

You benefit from this inside knowledge, which is informed by extensive testing experience with all classes of device and in many applications.

Performance Testing: Our laboratory has vast experience dealing with a wide variety of medical devices, from surface contact to permanent implants as well as with drug delivery products from auto-injectors to sprays and creams.

Materials Testing: Material characterisation has many applications in medical device development and production. It is the chemical analysis of materials to identify a 'finger print'. This information is then used to minimise toxicological testing of new designs as well as for production and design changes. Chemical identification should also be applied to incoming raw materials and on lot to lot production. MET has a wide range of chemical analysis equipment at its disposal for the knowledgeable application of characterisation. The methods are equally applicable to studying cleaning residues and the transfer of leachable materials from packaging and labelling.

Extractables and Leachables: Extractables and Leachables Testing is an analysis of potentially harmful materials that could be administered to a patient with a drug or device. Pharmaceutical manufacturers use laboratories to assess whether chemicals are transferring into the drug from packaging or production. Medical device companies use it to show that materials of concern are not transferred from the device to the patient. MET delivers a complete biocompatibility package from the Biological Evalaustion Plan, through the chemical characterisation and biological testing to the Biological Evaluation Report.

Packaging Validation: MET offers comprehensive medical device packaging testing to support engineers with the validation of pharmaceutical containers, medical pouches and blisters, including shelf-life claims for all classes of devices. Our facilities include an ISO/IEC 17025 accredited laboratory, dedicated accelerated ageing chambers, and sophisticated burst, leak and tensile testing equipment. We also undertake transit simulation studies to assess the suitability of shipping cartons or single boxes to protect the products within

MET provides complete confidence from a single source with experience of medical device testing since 1997. Testing includes: initial consultancy, packaging validation, physical testing, toxicity studies, and toxicity risk analysis.

»MET are a Fantastic company and a great supplier, We have a fantastic relationship with them and long may it continue«

Microbiology Manager, Sterilisation Company

»MET played a very supportive role in helping us in the qualification and validation of devices. MET experience and expertise in maintaining quality standards as per ISO guidelines is commendable«

Clinical Research Leader, Top 5 Pharmaceutical Company, India

»MET were professional and helpful in all aspects«

QA Manager, International component manufacturer

About MET

25
Employees

ISO 17025
accredited

Dover (UK)
Headquarters

Hundreds of satisfied medical device and pharma customers

25 years of excellence in medical device testing

Part of the Wickham Micro Group

Global Excellence in Medical Device Testing

Medical Engineering Technologies (MET) is the destination for medical and combination device batch release and design validation testing. Clients from across the globe have found our laboratory services to be rapid, precise, and extremely effective. MET has successfully delivered testing to medical device and pharmaceutical companies in over 20 countries across Africa, Asia, Australasia, Europe, and the USA. We knowledgeably, reliably, and effectively deliver medical device and packaging validation, and are a world leading CRO for combination device and pre-filled syringe testing.

Our services include: biocompatibility and chemical characterisation; dose delivery accuracy; formulation stability; mechanical performance; reference listed drug comparisons; sterile barrier verification; and lots of good advice. With accreditation to ISO 17025 for validation testing, and GMP for batch release testing, you can have complete confidence in the quality and accuracy of our results.

Find out why Medical Engineering Technologies are at the forefront of medical device testing, and why we are the best partner for you when it comes to product claims and regulatory submissions.

Contact

Get in contact with MET, we will make sure that your project moves forward rapidly and in the right direction.

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