MEDICAL ENGINEERING TECHNOLOGIES

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Global Excellence in Medical Device Material Testing

Analytical Services

Medical devices and pharmaceutical packaging analytical services at MET include the identification and quantification of metals, and organic chemicals in the liquid and gas phases. This allows us to conduct cross contamination studies, cleaning validations and biocompatibility studies. In addition, analysis of supplied materials and the application of Toxicological Risk Analysis at MET minimises the need for extended investigations of supplier or process changes.

Implant Degradation Studies

MET's chemical laboratory delivers a complete range of degradation studies for implanted devices. This testing includes ISO 10993 Biological evaluation of medical devices sections: 9, 13, 14, 15, 17, and 19. As part of our extensive medical device biocompatibility programme testing covers identification and quantification, along with USP physico-chemical analysis. This range of safety testing services covers many materials including: polymeric and ceramic devices, metals and alloys, IVDs.

Our analytical department is supported by toxicologists who can calculate the allowable limits of materials found and conduct Toxicological Risk Assessments.

Extractable and Leachables

Pharmaceutical containers (including supply chain containers and production systems) and many medical devices should be analysed to quantify what chemical species might be available to a patient or migrate into the active compound or delivery components. MET provides this analysis by employing a number of standards including: ISO 10993 part 18, pharmacopeia tests such as USP <661>, <381> and EP 3.2.1 and FDA Guidance Document, "Container Closure Systems for Packaging Human Drugs and Biologics".

Materials Characterisation

Part 18 of ISO 10993 includes a decision making flow chart. This allows the toxicological assessment of materials according to their history of use and chemical materials characterisation.

This analysis is also employed when making product changes. MET's equipment and knowledge can be used to demonstrate whether small production changes will result in a change to the toxicological properties of a device.

Cleaning Validation

Trace contamination analysis reveals the effectiveness of in-process cleaning for implants and other components. Our detection methods will identify residual metals and cleaning agents.

Excellence in Materials Analysis from MET

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