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SIIR offering expertise in Safety Evaluation of Medical Devices to meet Legal Compliance Requirement

All Hospitals and nursing homes must ensure that their medical devices must ensure that their devices are in compliance with regulatory requirements to avoid legal implications. Non-compliance can be a negative point in medico-legal cases and may go against hospitals and insurance companies may refuse claims.

What is a Medical Device?

WHO defines medical devices as any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by manufacturer to be used, alone or in combination, for human beings. It promotes the formation of normal healthy tissue as well as the integration of the device into adjacent tissue.

(Acute Systemic Toxicity in Mouse)

Requirement of Biocompatibility studies on Medical Devices

Medical devices are composed of biomaterial, which are non viable materials with claims of non pyrogenic, non inflammatory, and non allergic to host tissues. Therefore to understand the host response to biomaterial, biocompatibility studies are performed. It serves its purpose of treatment, monitoring, or diagnosis by interacting with the biological system. The ability of a biomaterial to perform its intended in vivo function is ultimately dependent upon the structural and biophysical properties, surface topography, molecular landscape and ability to resist infection. A designed biomaterial should serve its purpose in the environment of the living body without affecting other organs. Hence biocompatibility studies are mandatory in order to ensure the safety from any possible toxicants from the medical devices interactions.

Role of SIIR in ensuring the safety of bio-medical devices?

The GLP certified Toxicology Center of SIIR is assessing compatibility of medical devices with biological systems and is providing a comprehensive range of medical devices testing solutions as per ISO 10993-1 required by relevant regulatory framework worldwide. It is offering a complete biocompatibility panel for medical devices through

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our laboratories, high standard data and quality reporting for addressing the testing requirement of small as well large scale manufacturers.

Types of Medical devices which can be tested at SIIR:

A. **Non – Contacting Medical Devices:** Non – Contacting Medical Devices are medical devices or their components that have neither direct contact nor indirect contact with the body. Diagnostic softwares, *in-vitro* Diagnostic devices, Blood collection tube etc.

B. Surface - Contacting Medical Devices

a. Skin Contacting devices::
Electrodes, External Prostheses, Fixation tapes, Compression bandages, Monitors of various types, Computer Keyboards, Dials, Buttons, Touch Screens, SD cards, USB sticks, Cell Phones, Tablets, Catheter Handles used in hospitals/Operation Theaters.

b. Mucosal Membrane :
Contact lenses, Urinary Catheters, Intra-Vaginal and Intra- Intestinal devices (Stomach tubes, Sigmodoscopes, Gastroscopes), Endotracheal tubes, Bronchoscopes, Ortho Dental Prostheses, orthodontic devices

c. Breached or compromised Surface Medical Devices:
Medical Devices that contact breached or otherwise compromised breached surfaces e.g. Dressings or Healing devices or Occlusive Patches for Ulcers, Burns and Granulation tissues.

C. Externally communicating Medical Device are categorized as per their contact with application sites

a. Blood Path indirect:
These medical devices do not directly contact with blood path, but serve as conduits to deliver vascular fluid into the bloodstream e.g. Solution Administration sets, Extension sets and Blood Administration sets.

b. Tissue /Bone/Dentin :
Medical Device that contact tissues, bone, pulp/dentin system i.e. Laparoscopes, Arthroscopes, dental filling material, skin staples, tubing used for irrigation & medical device components have fluid contact with patients.

c. Circulating Blood Medical Device:
Medical devices that contact circulating blood i.e. Intravascular Catheters, Temporary Pacemaker Electrodes, Oxygenators, Extracorporeal Oxygenator tubings and accessories, Dialysers, Dialysis tubing & accessories, Haemoadsorbents and Immunoadsorbents.

D. Implant Medical Device

a. Tissue/Bone Medical Devices e.g. Orthopedic pins, Plates, Replacement joints, Bone Prostheses and Bone cement and Intra-osseous devices, Pacemaker devices, Drug supply devices, Neuromuscular sensors & Simulators, Replacement Tendons, Breast implants, Artificial larynxes, Subperiosteal implants, Ligation clips, Intrauterine devices that do not achieve their primarily function by chemical activity.

b. Blood Medical devices are contacting circulating blood into the cardiovascular system e.g. Pacemaker electrodes, Artificial Arteriovenous Fistulae, Heart valves, Vascular grafts, Internal Drug Delivery Catheter and Ventricular assist devices.

Microscopic examinations of Tissues

Medical devices shall be categorized according to the anticipated duration of contact as follows:

a) Limited Exposure (A) – devices whose cumulative single, multiple or repeated use or contact is up to 24 hours.

b) Prolonged Exposure (B) – devices whose cumulative single, multiple or repeated long-term use or contact is likely to exceed 24 hours but not more than 30 days.

c) Permanent Contact (C) – devices whose cumulative single, multiple or repeated long-term use or contact exceeds 30 days or more

If a material or device can be placed in more than one duration category, the more rigorous testing / evaluation considerations shall apply. With multiple exposures to the device, the decision into which category a device is placed shall take into account the potential cumulative effect, bearing in mind the period of time over which these exposures occur.

Upcoming opportunity in Medical Devices Testing

Apart from biocompatibility testing of medical devices, qualitative and quantitative data generation after chemical characterization is an upcoming requirement of the regulatory body. It is therefore necessary to collect data on the composition and potential extractability from medical devices to identify and quantify the soluble and insoluble elements. ISO 10993-18 lays the foundation for the characterization, identification and quantification of all medical devices. It is enabling us to obtain AET (Analytical Evaluation Threshold), which is intended to harmonize chemical characterization and subsequent toxicological risk assessment across the medical devices. For chemical characterization, exhaustive methods need to be adopted with simulation solvent with thermal stress application.

With availability of various physical, chemical and instrumental techniques, we may initiate the chemical characterization studies of medical devices at Drug and Pharma Lab along with biocompatibility studies.

The way forward

- Please visit our facilities and witness the infrastructure developed at SIIR to solve this problem.
- SIIR will be happy to have a partnership with affected trade bodies to solve this problem.

Research in new medical devices:

SIIR also undertakes joint research activities in collaboration with existing companies and start-ups. Many start-ups are working with us at SIIR. You are also invited to join this mission.