SELECTING RIGHT LABORAORY FOR MEDICAL DEVICE TESTING

Test reports plays very important role in getting CE certification and product registration with global registration agencies / authorities. So, manufacturers of medical devices must ensure that testing laboratories are complying to required quality systems.

The EU and USFDA recognizes ISO 10993-1:2018(E) for selection of Biocompatibility tests based on many criteria. However, USFDA issued a guidance document “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process” for Industry and Food and Drug Administration Staff " on: June 16, 2016. After issuing of FDA guidance document, manufacturers can submit same reports to EU for CE marking and FDA (with some additional tests required by FDA). For selection of biocompatibility tests for EU submission shall be selected based on ISO 10993-1:2018(E) recommendations and for USFDA submissions USFDA guidance document shall be referred. For other tests, USFDA recognizes consensus standards and list can be found in https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

Even though Japan is active in ISO standards framing, they framed a separate protocol for biocompatibility testing for submission to Japan. For selection of biocompatibility tests for submission to Japan can be referred to “Basic Principles of Biological Safety Evaluation Required for Application for Approval to Manufacture (Import) Medical Devices” from Director of Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labor and Welfare.

Selection of Laboratory for Medical Device testing:

Usually, manufacturers of medical devices select labs based on price, turnaround time and quality certifications. Request below information from Labs to ensure quality before placing tests:

- The quality certifications of laboratory (GLP certificate, ISO 17025, AAALAC and USFDA etc.,);
- Expertise in testing;
- Staff details with qualifications and Experience of Study Directors who is handling studies;
- USFDA audit history;
- Facilities and infrastructure;
- Complying to national and international guidelines and standards;
- Thorough understanding of selection tests and test method for devices;
- Careful selection of extraction solvents and extraction condition.

Importance of Selecting GLP certified Labs for Biocompatibility Testing:

To comply to EU, USFDA and other regulatory agencies it is always recommended to choose CRO certified for compliant to OECD GLP and also it is wise to choose labs audited by USFDA.

As mentioned under B.4.5.2 Good laboratory practice of ISO 10993-1:2018(E) “Quality systems controls applicable to non-clinical testing are known as Good Laboratory Practice (GLP). GLP studies are carried out to defined quality standards in laboratories that are accredited in line with an internationally implemented governmental scheme. Typically, studies will be conducted under a laboratory quality system compliant to ISO/IEC 17025 or an equivalent standard.

Conducting tests at labs accredited to ISO 17025 is accepted by CE notified bodies only and perhaps it will save little amount of money on testing. But testing at GLP certified and USFDA audited lab will ensure compliance to global regulatory requirements and also avoid repeat testing. As most of the biocompatibility tests are in long duration, accreditation boards like National Accreditation Board for Testing and Calibration Laboratories (NABL) is not recognizing tests with long duration under scope of accreditation. So, long duration tests will fall under scope of GLP.

Considering above, experts from Medvin Biosolutions with many years of experience in biocompatibility testing and regulatory compliance, thoroughly audits testing facilities to comply with required certifications like OECD GLP, ISO 17025, AAALAC international and USFDA.

We are glad to help further on your testing requirements and for any further information please write to us on sridhar@medvinbio.com