PERSPECTIVE

Delivering service on a quality platform: Case of medical device testing services from a research institution of national importance

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Designing and Analysing the Service Concept

A parallel operations design happens when an organisation not necessarily in the service business enters a new service development process. The development of the service process is tuned in such a way that the organisation's strategic objective, the unmet customer need and the operational excellence which benefits the customer are considered. The Biomedical Technology Wing of SCTIMST aims to promote research and development in biomedical engineering and technology. The technology thus developed is transferred to the medical device industry for commercialisation. Hence the target customer group is the medical device industry.

The medical devices used for /diagnosis/ treatment/ mitigation/ prevention of a disease or disorder are to be ensured as safe to be used in human beings. Following the philosophy of risk assessment, management and ensuring safety in the use of medical devices, in vitro and in vivo evaluations are carried out. Medical Devices are made up of different kinds of materials like polymers, metals, ceramics, alloys, biodegradable materials, fabric etc., which, when in contact with the skin, tissue, blood or bone, may cause adverse reactions that may be risky to human life. These materials and the devices made with them must be compatible with tissue or blood. If not compatible, the body may reject the material causing adverse reactions. Hence to assure that the product intended for diagnosis/ treatment/ mitigation/ prevention of a disease or disorder is not to cause any adverse effects, the Regulatory Authorities maintain strict regulations, and the manufacturer of a medical device has to comply with them and ascertain the safety and efficacy of the medical device before it is used in human beings. So medical device testing could be called a "must availed service".

The testing requirement for medical devices & biomaterials was an unmet need in India during early 2000, and the industry had to send their devices to foreign countries for testing. Moreover, for a service like medical device testing, the customer might have only bits and pieces of information on the tests needed and the regulatory requirements for the medical device under development. Even internet searches on the subject give incomplete indications of some standards or clauses that are difficult to scrutinise and analyse. The industry is stuck here, and the search words change from "tests for medical devices" to "testing services for medical devices". Under such circumstances, introducing new testing services to the medical device industry was a thought to support this unmet need.

Identifying this unmet need was easy as the Institute already had alliances with Medical Devices Industries in the form of Technology Partners. The products developed at the Institute had to pass through preclinical testing on/before the Technology transfer stage. The Institute was already involved in the testing of in-house developed medical devices/ biomaterials, and the testing phase of the New Service Development could be successfully carried out in-house and the internal customer's feedback and inputs improved the system.

Development/Operation

The operational activities of testing services started in a low-key mode around the year 2000. To ensure the global acceptability of test reports and support customers, the Institute established the Quality System in testing procedures in 2002. The establishment of a quality system was resource-demanding, and the service process was to be structured so that all the resources were adequately used to deliver efficient service. The 'structured' and 'systematic' operations thus gave an impetus to implement a Quality Management System which would evolve procedures for the functioning of the service system. Thus the Quality Management System for testing services conforming to the international standard ISO/IEC 17025: "General requirements for the competence of testing and calibration laboratories" was implemented in 2002. The Quality Management System had to be accredited by an accreditation agency that is well acceptable t the Regulatory Authorities. The accreditation of Testing Services was thus done by Le Comite Francais d'Acreditation (COFRAC) of France. The Quality Management System brought a structured operational format, as every aspect of the service system was well-defined in the Quality Manual. Definite system procedures and work procedures were made for each of the activities involved in the service system.

Medical Device Industry on the Customer Role

Testing and evaluation of medical devices and biomaterials being a technical service the customer is not exposed to the operational procedures inside the laboratories. The final output (the test report) is traceable through all the procedures involved in testing. The awareness of medical device testing in India is appreciably increasing compared to the early 2000 period. The establishment of the medical device regulatory system in India has helped the medical device industry confirm to the testing and evaluation requirements. The presence of an Accredited Quality Management System also provides a perception to the customer that the test procedures are well audited and based on international standards ensuring global acceptance of results.

The Institute has been in the testing service for more than a decade now and is familiar with the Regulatory scenario, and the test reports confirm to the standards and formats of Regulatory needs.

Medical device testing involves the proportional mixing of knowledge from various disciplines like material science, chemistry, physical sciences, mechanics, biochemistry, toxicology, histopathology, microbiology, veterinary science, engineering etc. The implementation of the quality system based on ISO 17025 takes care of all the procedures right from the review and acceptance of test requests to the issue of reports. There are procedures for the handling of every parameter of the management requirements for testing, such as:

- Document control – document approval and issue, document changes
- Review of requests, tenders and contracts
- Purchasing services and suppliers
- Service to the customer
- Complaints
- Control of non-conforming testing and calibration work

- Improvement
- Corrective action
- Preventive action
- Control of records
- Internal audits

The various technical requirements that are dealt with in the standard are:

- Personnel
- Accommodation and environmental conditions
- Test and calibration methods and method validation
- Equipment
- Measurement traceability
- Sampling
- Handling of test and calibration items
- Assuring the quality of test and calibration results
- Reporting the results

External Stakeholders

In the medical device testing service, the external stakeholders' role is vital as many of the procedures are highly dependent on the policy/procedural changes these stakeholders bring about. The primary external stakeholders in the medical device testing scenario are:

Standards-making organisation: The tests are carried out through structured procedures, and in most cases, international standards are followed in conducting the tests. Thus the test house is bound to move along with the revisions, amendments and additions implemented by this stakeholder. The prominent standards organisation in medical device testing are the International Organization for Standardization (ISO), American Society for Testing & Materials (ASTM), American National Standards Institute (ANSI), United States Pharmacopoeia Convention (USP), etc.

When following a quality system, the medical device testing services must be accredited by a suitable Accreditation agency, a certification specialist in issuing official certificates of compliance with established technical standards. Thus the test house which offers medical device testing service is bound to undergo surveillance audits of the accreditation agency to verify the compliance maintained with the standards, regulatory requirements and the customer. The accreditation agency thus forms another player in the ecosystem. There are different accreditation agencies in this field of testing, of which DAkkS GmbH, AAALAC, COFRAC, A2LA, UKAS, NABL etc, are the prominent ones. COFRAC of France accredits the medical device testing services of the Institute.

The preclinical phase of medical device testing involves the use of animals (both small & large animals). The quality maintenance and use of experimental animals are regulated by the guidelines or policies laid down by different government laws to ensure humane care in the use of the animals. When FDA follows the Animal Welfare Act, and the Public Health Service Policy of Humane Care and Use of Laboratory Animals, the use of animals for preclinical testing in India is regulated through the guidelines by the Committee for the purpose of control and supervision of experiments on animals (CPCSEA). The regulatory mechanism for animal testing, thus, has its own role in medical device testing.

The medical device testing ecosystem will be incomplete if the final regulatory authority of medical devices involved in the pre-market regulatory control is not discussed. Even though the medical device testing service is not directly responsible to the pre-market regulatory authorities (the regulatory control is region specific) and it is regulated by the laws prevailing under this. The beneficiaries of the medical device testing service finally submit the test reports to these regulatory authorities, which helps them deliver their product to the medical device market. In India, it is the Central Drugs Standard Control Organization(CDSCO); in the US, it is the United States Food and Drug Administration

(FDA or US FDA); in Australia, it is Therapeutic Drugs Administration (TGA), the European Medicines Agency for the European Union etc.

Participation in interlaboratory comparison or Proficiency testing programs is an effective method of assuring the competency of testing personnel and the quality of the test results. In this case, the organisation, performance and evaluation of test results between two or more laboratories happen under a predetermined condition. Hence the laboratories participating in the Interlaboratory comparison program become another stakeholder in the ecosystem.

Two decades of testing services

Through the analogy of the Biomedical Technology Wing of Sree Chitra Tirunal Institute offering testing services for medical devices & biomaterials, one of the findings put forward by Abbie Griffin (1997) through his survey is emphasised that: "the dominant differentiating factor for achieving service success was having a market driven process". The testing services for medical devices and biomaterials of the Institute have attained expertise and experience in almost all major evaluation parameters required under the medical device preclinical phase. This, includes physicochemical characterisation, biocompatibility evaluation including cytotoxicity, hemocompatibility, toxicology and histopathology, microbiological testing, and preclinical small and large animal evaluation for safety and efficacy. The Institute also has the expertise for blood bag evaluations, accelerated ageing studies, drug release studies, toxicokinetic studies, cellular uptake studies, in vitro hepatotoxicity studies etc.

The Institute has a very dynamic approach to the testing service as it is one of the prime requirements in promoting the Institute's vision of supporting the medical device industry in India. The Institute has a policy and mechanism to keep itself abreast of the regulatory requirements for medical devices, IVDs (in vitro diagnostics) and biomaterials development trying to introduce more and more tests/ studies to cater to the needs of the medical device industry in the evaluation of medical devices and biomaterials. The Institute's testing services welcome the medical device industry for all their regulatory needs.

For any further information or assistance on testing and evaluation of medical devices requirements at SCTIMST, please contact us at:

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