Biological Evaluation of Medical Devices

Biological Evaluation is performed to measure the potential risk arising from the use of medical devices in Humans. It's a step by step process where, possible biological risk from material or device is evaluated and demonstrated that the device is safe to use in humans. Biological Evaluation is a risk management activity as part of ISO 14971.

A systematic Biological Evaluation has following steps

- **Biological Evaluation Plan (BEP)**
- **Performance of Tests**
- **Biological Evaluation Report (BER)**

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Biological Evaluation Plan

A **Biological Evaluation Plan** is a thorough review of device information, checking the compliance to the corresponding standards, analysing and evaluating the biological risk associated with the device, identifying gaps and proposing the tests if required to demonstrate the safety of the device.

The **Biological Evaluation Plan** should be written by a knowledgeable and experienced individual/team. A well-drawn biological evaluation plan will help to wave off many testing requirements with proper justification. Avoiding unnecessary testing of the device can save cost and time of the organisation

The **Biological evaluation** starts with the characterisation of Medical Devices. This involves

Categorisation of Medical device for Biological Evaluation

A. **Nature of body contact:**

- Surface contacting device
- Externally communicating device
- Implant device
- Non contacting device

B. Duration of contact

- Limited exposure
- Prolonged exposure
- Long-term exposure

- **Gathering and reviewing information on configuration/design of Medical device**
- **Material characterisation**
- **Chemical characterisation**
- **Extractable**
- **Leachable**
- **Degradation products**
- **Evaluation of Toxicological Data Packaging and Sterilisation**

Recommendations: Identification and recommendation of tests are based on the gaps if observed and the Endpoints as per Annex A of ISO 10993 Part 1.

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Biological Evaluation Report

The Biological Evaluation Report is a document which summarises all the reviews performed, chemical and biological tests conducted, toxicological risks assessments, collective summary of all biological tests performed and justifications provided for not performing the tests wherever the tests are waved off.

The Report consists of all the points discussed in the biological evaluation plan including

- Summaries of literature survey,
- Gap analysis, device configuration,
- Material characterisation,
- Chemical characterisation,
- Biocompatibility tests,
- Toxicological risk assessments,

Reviews and analysis to demonstrate that, the medical device will not cause any potential risks to patients and intended users during the course of its use.

Contact us for:
Biological Evaluation Plan/Report

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