

CHEMICAL CHARACTERISATION OF **MEDICAL DEVICES**

Chemical Characterization is a crucial first step in biological evaluation of medical devices (ISO 10993-1). This can be done by 'information gathering' or by 'information generation'. Qualitative and Quantitative analytical studies can be performed to ensure that a medical device is safe with respect to its chemical constituents/components and does not have a safety impact on the patient.

WHY **GVS Cibatech**

Chemical Characterization is an extremely complex process and requires understanding of the application of the device and also the manufacturing process and materials that make up the device. It is a multi-step process right from defining toxicological hazards associated with the device, sample selection, extraction, multiple analytical techniques and finally interpretation and toxicological risk assessment.

GVS Cibatech Analytical leverages experience and expertise of its founders who have been performing chemical characterisation studies and toxicological risk assessment of medical devices for several years.

Our extended expertise in polymer and material science places us in a unique position to offer effective solutions.

Our science-based approach to risk assessment will be complemented by a state-of-the-art analytical laboratory.

End to end solutions right from study design, toxicological risk assessment, consulting, and training support.

OUR **DELIVERABLES**

- Chemical Characterisation studies for all types/classes of Medical Devices as per ISO 10993-18.
- Decisive identification of extractable compounds including degradation products.
- Toxicological risk assessment of extractable compounds.
- Analytical and desktop studies for material selection.
- Comparison of devices based on their chemical (extractable) profile.
- Consulting and training support.



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