ASPHALION MedTech

A guide to demonstrate biocompatibility under Medical Device Regulation (EU) 2017/745

ASPHALION MedTech

What is biocompatibility?

• Biocompatibility of a medical device is an essential part of the technical documentation under Medical Device Regulation (EU) 2017/745.

• Ability of a medical device or material to perform with an appropriate host response in a specific application.

• Biocompatibility is one of the key criteria for the clinical success of a medical device, especially for implants.

• Biocompatibility and biological safety shall be considered during the whole life-cycle of the medical device.

Important aspects of Medical Device Regulation (EU) 2017/745:

• Critical substances CMR 1A and 1B, endocrine disruptors (GSPR 10.4).

• Impact of processing on materials and surface properties (GSPR 10.1).

• Absorption, distribution, metabolism and excretion (GSPR 10.1).

• Particles and nanomaterials (GSPR 10.4, GSPR 10.6).

Why is it so important?

• Assessment of the biocompatibility and biological safety of a medical device is a critical activity within the risk management process of the medical device.

• Potential biological hazards could include short-term effects as well as long-term or specific toxic effects, sensitization, genotoxicity, carcinogenicity and effects on reproduction.

• A deficient biocompatibility characterization strategy and biocompatibility testing of the device may result in compromised safety for patients in addition to an increased time and cost to market for manufacturers.

www.asphalion.com
medtech@asphalion.com | +34 93 238 59 45

ASPHALION MedTech

How to address biocompatibility?

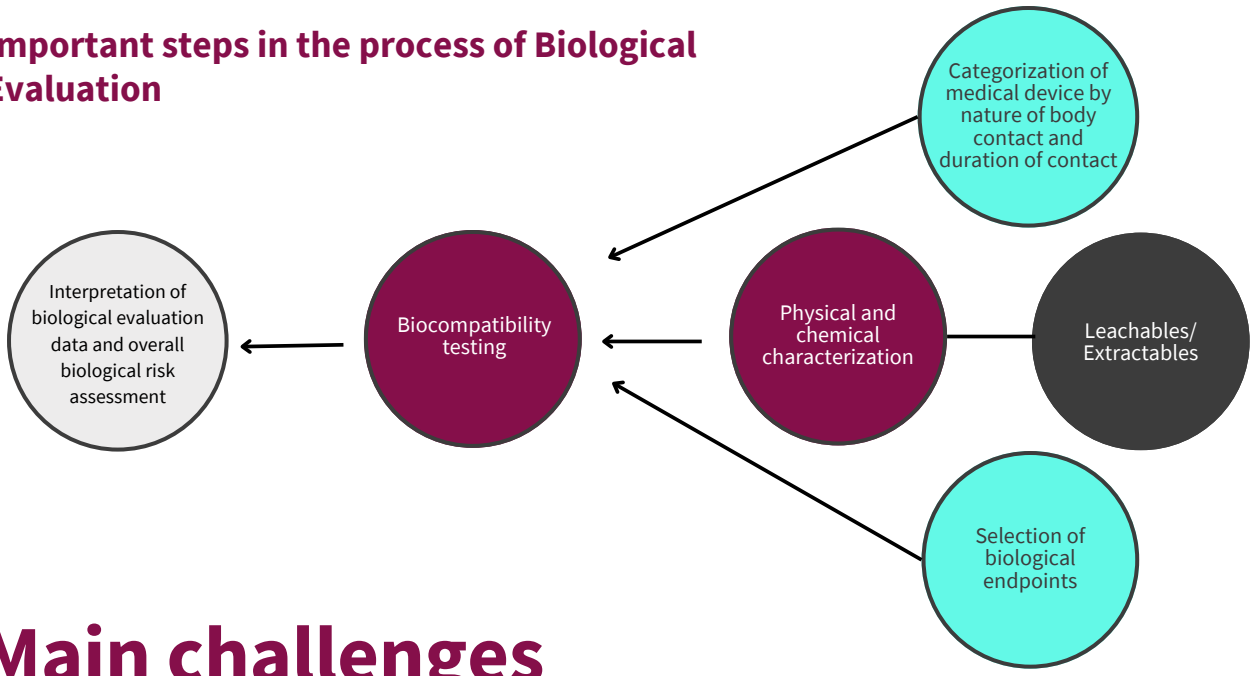
Each device should be released after a process of risk assessment, under the clinical conditions of use.

By addressing biological risks in a Biological Evaluation, we can aim at biocompatibility by assuring a safe device.

ISO 10993-1:2018 serves as a framework in which to plan a Biological Evaluation.

A Biological Evaluation Plan is an important document that should demonstrate risk management activity according to ISO 14971 and sets the strategy for biological testing .

Important steps in the process of Biological Evaluation



Main challenges

The biological plan should be drawn by a knowledgeable person/team. Do I have this expertise in my team?

Novel materials, how to address them?

What is the impact of manufacturing process? Can the processed material change its safety profile?

Gathering of relevant datasets for the biological evaluation. How to determine whether there is sufficient information or further biocompatibility testing is required?

www.asphalion.com
medtech@asphalion.com | +34 93 238 59 45

ASPHALION
MedTech

Need help? Contact us!

www.asphalion.com

medtech@asphalion.com

+34 93 238 59 45

Author

Patricia Marmol Carrasco
Medical Device Senior Officer