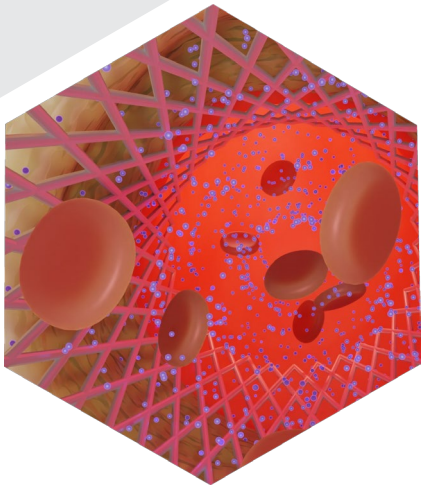
Cambridge Polymer Group

Biological Evaluation of Medical Devices



Summary

ISO 10993-1:2018 places an emphasis on conducting the biological evaluation of medical devices within the risk management process, i.e., the biological evaluation of a medical device via ISO 10993-1 must also meet the requirement of ISO 14971:2019.

How Do I Address Biological Risk?

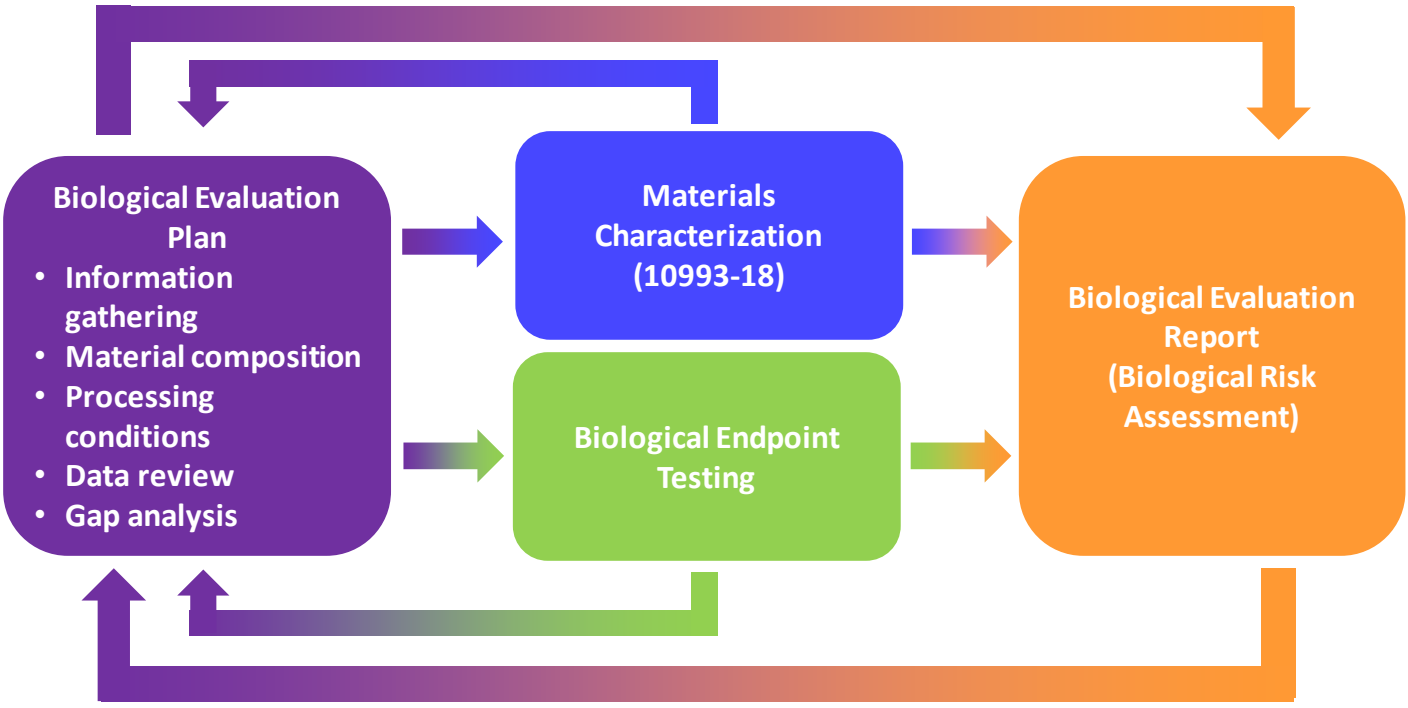
As a risk management activity, the biological evaluation of medical devices, with reference to ISO 10993-1 and ISO 14971, requires a biological evaluation plan (BEP) and a biological evaluation report (BER), The BEP is tailored to each medical device and determines the most suitable strategy towards biological endpoint testing and/or chemical/materials characterization to further evaluate risks to the patient during the intended use of the device. The BEP serves as the framework for a subsequent BER, in which a benefit/risk assessment is made to draw a conclusion with regards to the biological safety of the medical device

Do I Need To Redo My Biocompatibility Evaluation After Manufacturing Changes?

In general, the biological evaluation process should be reconsidered if there is any design or manufacturing process change or if a risk is detected by post-market surveillance.

Should I Use a Consultant for the BEP?

CPG can provide the knowledge and expertise required to conduct the biological evaluation and is aware of the constantly changing regulatory environment. Additionally, CPG scientists are experts in material science and can assess if material changes or manufacturing changes are likely to impact product safety and efficacy.



When To Redo Your Biocompatibility Evaluation

Cambridge Polymer Group, Inc. is a contract research laboratory specializing in materials. We partner with our clients to solve the world's toughest polymer problems utilizing our multi-disciplinary research team and full service laboratory.

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