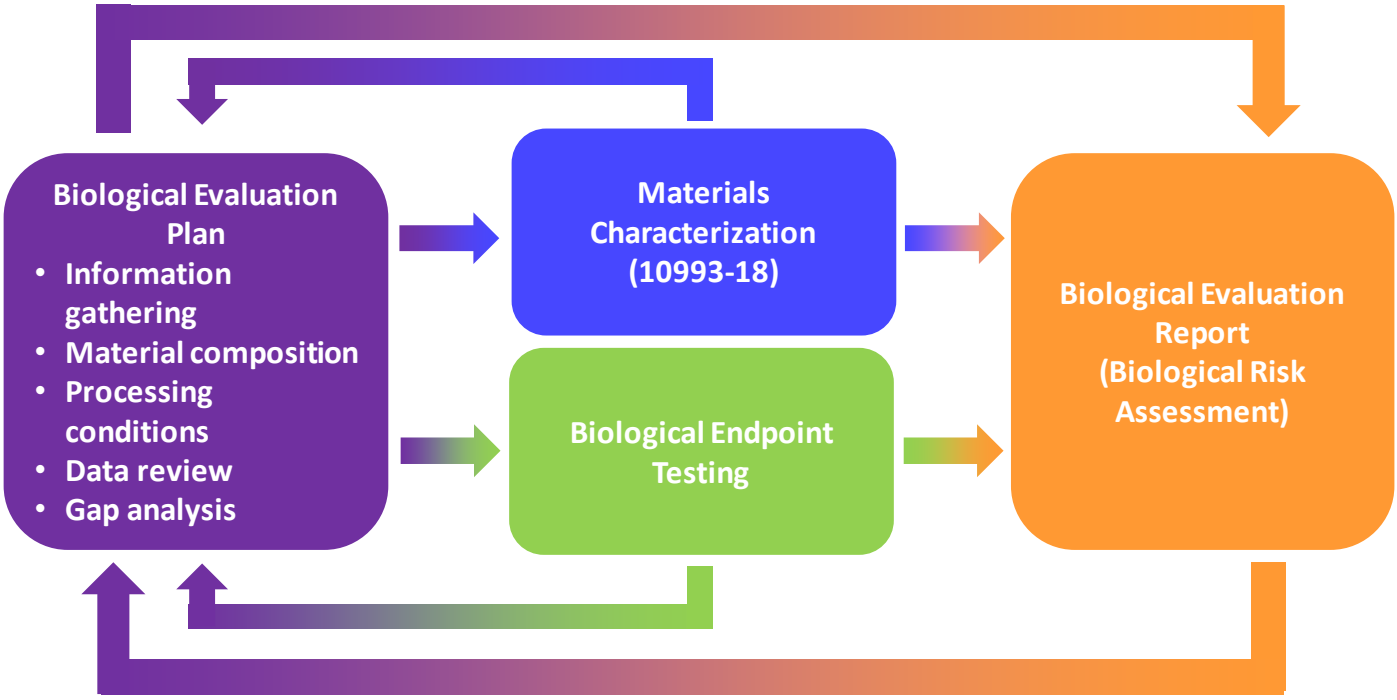
Cambridge Polymer Group

Biological Evaluation of Medical Devices

By Dr. Rebecca Bader

Summary

ISO 10993-1:2018 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" 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 "Application of risk management to medical devices." Cambridge Polymer Group has the necessary experience and expertise to provide manufacturers with the best strategy towards ensuring that the biological evaluation of medical devices meets both sets of requirements.



How Do I Address Biological Risk in My Medical Device?

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), also commonly referred to as a biological risk assessment (BRA). The BEP is tailored to each medical device and considers the nature and duration of

patient contact, as well as existing knowledge of the material composition, the physical characteristics of the device, the potential for transfer of agents of concern from the packaging, the manufacturing/processing flow chart, the testing history of the device, pre-clinical and clinical data, and post-market surveillance data from similar medical devices.

Through a gap assessment conducted in the context of the BEP, the most suitable strategy towards biological endpoint testing and/or chemical/materials characterization is identified to further evaluate risks to the patient during the intended use of the device. Although chemical characterization with reference to 10993-18 may be necessary, this requirement is dependent on the information gathered within the BEP and a risk-based evaluation of hazards posed by the material composition may be possible without a step that many manufacturers view as being expensive and long-drawn-out.

Once biological endpoint testing and materials characterization is completed, the BEP serves as the framework for a subsequent BER. The BER adds to the existing information from the BEP by documenting implementation of the testing plan drawn out within the BEP, describing the impact of the biological endpoint testing and chemical characterization (if conducted), providing additional information on prior use and known toxicological risk of the materials used within the medical device, and offering justifications for any waived tests.

From the latter information, a benefit/risk assessment can be made to draw a conclusion with regards to the biological safety of the medical device. If an unexpected result is obtained from biological endpoint testing or materials characterization, the BEP can be revised once the root cause of the unexpected result has been identified and modification(s) to the device design or processing have been made.

Manufacturing Made Some Changes. Do I Need to Redo My Biocompatibility Testing?

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. As indicated in Figure 1, and with reference to ISO 10993-1:2018, changes that were historically viewed as inconsequential require a risk-based evaluation to ensure that the change will not

Figure 1: Changes in manufacturing necessitate a risk-based re-evaluation of the biological safety of the medical device.

have an impact on patient safety during the intended use of the device.

Seemingly small changes to a raw material or cleaning process that likely posed no additional risk have resulted in regulatory hang-ups that have caused substantial delays in shipment of product. The initially crafted BEP can serve as a guide for directing subsequent testing strategies to rapidly assess risk following changes.

Should I Prepare the BEP In-House or Use a Consultant?

With reference to Clause B.3.1.4 of ISO 10993-1:2018, the biological evaluation process within a risk management system should be conducted "by assessors with the necessary knowledge and expertise to determine the appropriate strategy for the evaluation and ability to make a rigorous assessment of the available data and to make sound judgments on the requirements for any additional testing." CPG can provide this expertise and is aware of the constantly changing environment with regards to risk management and biological safety evaluation of medical devices.

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. We can work with your manufacturing, regulatory, and design team to work out the most time and cost-efficient solution, while ensuring patient safety.

About Dr. Rebecca Bader

Dr. Rebecca (Becky) Bader is the Associate Director of Chromatography and biocompatibility specialist at Cambridge Polymer Group. Prior to returning in 2023 after initially working for Cambridge Polymer Group from 2017-2020, Becky was Biocompatibility Engineering Manager at ZOLL Medical Corporation where she ensured biocompatibility and material compliance with harmonized standards and global regulatory requirements. Becky has over 20 years of experience in polymeric materials, drug delivery, medical device, and analytical chemistry. She is currently advancing analytical techniques for materials characterization at Cambridge Polymer Group.

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