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Biomaterials: A FDA Perspective

Both novel and traditional materials can provide unique opportunities, as well as unique challenges, when used in medical devices. In the presentation, we will explore this dichotomy through examples of materials used in cardiovascular devices. Specifically, we will focus on bioabsorbable, nano-scale, and specially tailored materials. In this context, we will also attempt to clarify the often-used misnomer of an "FDA approved material", as FDA approves medical devices based on a specific indication and not on the materials comprising the device, which is a critical distinction. When using a traditional material with a history of successful use there may be a perception or expectation that an easier approval pathway exists, which may not be the case.

For example, although some bioabsorbable materials have a long history of use, utilizing these materials in new applications (indications) creates new challenges. Similarly, the chemical entity of specific nano-materials may be established, but the uniqueness of the size-scale also raises new concerns. Finally, the use of tailored materials for specific application (e.g. calibrate rate of drug release coatings in drug eluting stents) is also on the rise. In some cases, the individual material components have been used previously, so the systemic toxicity has been established. However, the local biocompatibility for this new indication poses unknown risk. Through discussion of these topics, our objective is to clarify some of the considerations that should be accounted for in the design of novel materials, or application of traditional ones, in medical devices.