



## Translation of biomaterials from bench to clinic

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### ABSTRACT

Scientific research originates from curiosity and interests. Translational research of biomaterials should always focus on addressing specific needs of the targeted clinical applications. The guest editors of this special issue hope that the included articles have provided cutting-edge biomaterials research as well as insights of the translation of biomaterials from bench to clinic.

The definition of biomaterial has been updated from “*a nonviable material used in a medical device, intended to interact with biological systems*” [1] to “*a material designed to take a form which can direct, through interactions with living systems, the course of any therapeutic or diagnostic procedure*” [2]. Such an update represents the expansion and development of biomaterials science and engineering. The definition also characterizes the nature of biomaterials as multi-disciplinary, cross-functional and translational.

The ultimate goal of biomaterials’ translation is to develop safe and effective medical products that could benefit human healthcare [3]. It is important to clarify that biomaterials are not equal to final medical products. The translation of biomaterials is to define and develop medical products based on biomaterials technologies.

The translation process of biomaterials from basic/applied research to successful clinical applications and commercial products needs to go through multiple phases. The translational research needs to first identify and address unmet clinical needs. Positive lab results should be further confirmed through validated and large-scale industrial setting. Medical products based on such research need to be designated to medical devices, combination devices, or drugs/biological products with a clear understanding of clinical mode of actions. A robust quality management system is required to regulate the research, development, and manufacturing processes of the products towards commercialization. Physicochemical and non-clinical bench performance tests, biocompatibility and biosafety evaluations and pre-clinical animal studies need to be conducted with the compliance and potential development of standards, tools, and methods as-needed. Clinical trials guided by regulations and good clinical practices need to be executed with the appropriate indications, inclusion criteria, control group and endpoints. Post-market surveillance would also require strong scientific understanding after regulatory approval and commercialization. Taken together, the safety and efficacy of medical products translated from biomaterials technologies should be validated with solid scientific

evidence for targeted clinical applications.

The objectives of this special issue are to report the followings: (1) State-of-the-art research on biomaterials, with an emphasis on novel materials, processing, and evaluation methods to facilitate clinical translation; (2) Processes, issues and lessons-learned for the translation of biomaterials; (3) Regulatory science and evidence-based research for the translation of biomaterials.

A total of 24 articles [4–27] are included in this special issue. These articles can be categorized in terms of authors, biomaterials and targeted clinical areas, and article types. Authors from China, Finland, Korea, Germany, and United States include leading scientists in the field, clinicians, young scientists as well as regulatory scientists. Metallic, ceramic, polymeric and composite biomaterials are reported with targeted orthopedic, cardiovascular, dental, microsurgery, general surgery, nanomedicine, and sports medicine applications. As an emerging field, regulatory science has been gradually developed to play an important role during the translation of innovative biomaterial-based medical products. Several articles in this special issue are on regulatory science and discuss the new standards, tools, and approaches to evaluate the safety, efficacy, quality, and performance of medical products [10,13,17,19]. This special issue also covers a wide range of article types including research article [1–9,11,12,15,16,18–20,23–26], reviews [14,17,21,22,27], perspectives [10,13] and opinion paper [18].

Scientific research originates from curiosity and interests. Translational research of biomaterials should always focus on addressing specific needs of the targeted clinical applications. The guest editors of this special issue hope that the included articles have provided cutting-edge biomaterials research as well as insights of the translation of biomaterials from bench to clinic.

### Declaration of competing interest

The authors have no conflict of interest.

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