CHAPTER 7

REGULATION OF NANOMATERIALS IN BIOMEDICAL APPLICATIONS

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7.1 INTRODUCTION

The world today has begun to harness the value of nanomaterials in biomedical and healthcare applications for better medical diagnosis, clinical treatment, clinical equipment, and effective medicine to provide early identification of diseases and more efficient illness treatment. Notably, in an ever-evolving setting of biomedical research and innovation, incorporating nanomaterials has emerged as a revolutionary force with enormous promise for the progress of diagnostics, therapies, and medical devices. Nanomaterials' unique physicochemical features have paved the path for ground-breaking uses, providing new opportunities to address difficult healthcare concerns. As the fields of nanoscience and biomedicine merge, there is an urgent need for comprehensive regulatory frameworks to assure responsible research, safe deployment, and ethical use of nanomaterials in medical applications. Considering this, the outstanding properties of nanomaterials have made them practical in various biomedical applications, as shown in Figure 7.1.

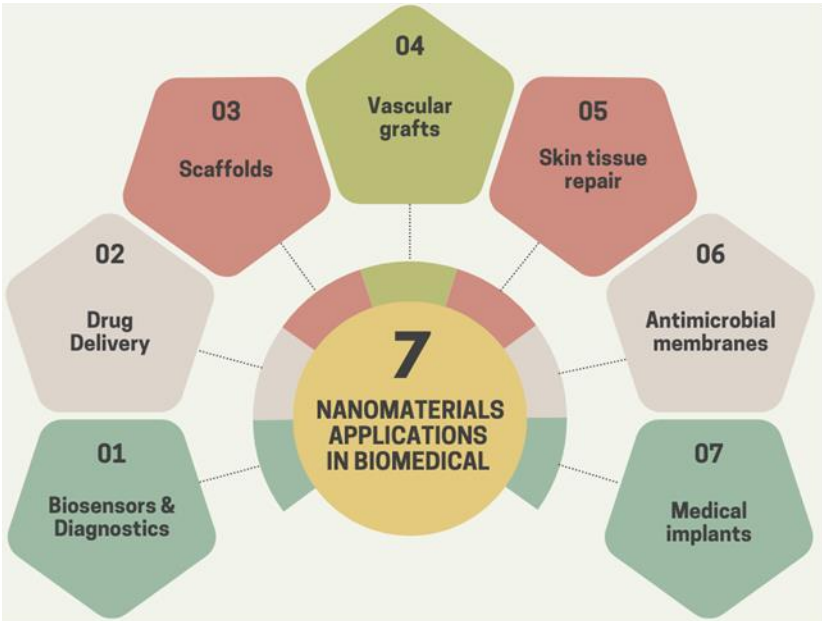

Figure 7.1 Nanomaterials in various biomedical applications (Source: Rojas et al., 2015)

As shown in Figure 7.1, nanomaterials have emerged in various biomedical fields, such as biosensors, drug delivery, medical diagnosis, scaffolds, vascular grafts, skin tissue, antimicrobial membranes, and medical implants. In the case of biosensors and diagnostics is the first critical step that must be completed correctly before any treatment can be administered for more effective health recovery and increased patient survival rates. Physical examination is the most commonly used form of medical diagnosis. However, the diagnosis may become more difficult when the symptoms and indicators become less specific. For example, standard diagnostic techniques have trouble reliably assessing the presence of tumours in their early stages and discriminating between benign and malignant stages. Incorporating nanomaterials has demonstrated its ability to increase diagnosis efficiency at the initial stages of tumour or cancer development (Russell et al., 2020).

Over the past decades, a variety of nanomaterials, including nanoparticles, nanorods, nanospheres, nanoshells, and nanostars, have found widespread applications in biomedical fields. One application of nanomaterials in scaffold microarchitecture and biomimicry is through 3D printing technology. 3D printing can be used to deposit cells and biomaterials in a 3D matrix to promote tissue regeneration. It provides excellent accuracy and control over a scaffold's internal architecture and outward shape, and it may create complex structures that closely resemble the architecture of biological tissue. Implants, such as artificial pacemakers and cochlear implants, are used to manage the function of abnormalities in humans. These materials must have a high strength-to-weight ratio, large surface area, and biocompatibility. Incorporating nanomaterials into polymers, ceramics, or metals presents problems, including achieving a consistent volume proportion of the filler within the matrix (Velu et al., 2019). Other than that, carbon-based materials (graphene, CNT, activated carbon), metals, and metal oxides are all examples of nanomaterials utilised in wastewater treatment. These nanomaterials are commonly used for a variety of features, including photocatalytic and antimicrobial activity, as well as high adsorptive capacity (Yusuf et al., 2021).

Despite the numerous applications of nanomaterials, scientific research (Chavez-Hernandez et al., 2024; Foulkes et al., 2020) and regulatory practices highlight the significance of effectively regulating the utilisation of nanomaterials. This strategy is indispensable to tapping into the benefits obtained by nanotechnology while simultaneously mitigating the potential hazards posed to human health and the environment.

Currently, various products utilising nanomaterials are subject to both general and specific legislation systems. For example, the Toxic Substances Control Act (TSCA), an agency in the United States (US), empowers the Environmental Protection Agency (EPA) to evaluate and address the risks associated with both newly developed and already existing chemical substances, including nanomaterials. The utilisation of nanomaterials in food, cosmetics, and medical products is required to