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1 Introduction

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The term "regenerative medicine" has become globally recognized and accepted, and the science driving discovery and development of regenerative medicines is rapidly evolving. The types of biopharmaceutical products classified as regenerative medicines differs by country but typically are made up of cellular or genetic therapies or tissue engineered therapies. New technologies are constantly being developed, and there is a need for more flexibility in the regulatory governance of these innovative products.

Regulation of Regenerative Medicines: a Global Perspective is a comprehensive examination of the regulatory framework of regenerative medicines for those regulatory professionals working in the biopharmaceutical industry, the government, or academia. As the regenerative medicine landscape continues to expand and evolve, there is a growing need for regulatory innovation of these complex therapies. This book strives to provide wide-ranging information on the regulations governing regenerative medicines from development to commercialization.

This book is divided into three distinct sections. Section I contains general information about regenerative medicines from definitions to the unique properties of regenerative medicines. Section II discusses special considerations, manufacturing concepts, and distribution challenges. Lastly, Section III covers the regulatory framework in multiple global regions including Australia, Canada, China, Europe, Japan, Singapore, and the US and looks forward to the future of regenerative medicine.

Chapter 2 provides an overview of the history of regenerative medicines. The chapter provides insight into the evolution of regenerative medicine from cloning and stem cells to recombinant DNA technology to the "tissue rules" and gene therapy. The chapter discusses the evolving US regulatory landscape and the involvement of the National Institutes of Health and the US Food and Drug Administration in the early regulation of regenerative medicines. There are many similarities and differences between small molecules and large molecules (i.e., biological products) but the differences become more glaring when talking about regenerative medicines which are comprised of cell therapy (i.e., CAR-T), gene therapy, and tissue engineering. **Chapter 3** provides an overview of the unique properties that make up certain types of regenerative medicines including a brief summary on manufacturing, off-target effects of gene therapies, and immunogenicity. Manufacturing of regenerative medicines has unique challenges which are covered extensively in **Chapter 8**. Additionally, in **Chapter 4**, good manufacturing practice and current good tissue practices are examined when human cell and tissues are a constituent part of a combination product. Chemistry, manufacturing, and controls