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product attributes. Includes significant considerations for rare diseases. About the Editors: J ay A. Cavagnaro is an internationally recognized expert in preclinical development and regulatory strategy with an emphasis on genomics and rare diseases. She is the Chief Scientific Officer at Parmakon Global, Inc. and a former senior director at Parexel International. She has over 15 years of experience in research and development of novel biologic drug products, regulatory affairs, and clinical development. She has also served as a member of the National Institutes of Health administered Rare Disease Advisory Board. The second author, William S. (Bill) Lerner, is a noted expert on biologic drug development and regulatory affairs. He has been involved in the development of novel biologic drug products, including monoclonal antibodies, vaccines, and cell and gene therapies. He has served as a consultant to many pharmaceutical companies and is a frequent speaker at industry conferences. The third author, Mark V. (Mark) Morrel, is a distinguished author in the field of biologic drug development and regulatory affairs. He has published extensively on the topic of preclinical development and regulatory strategy and has been a key contributor to many successful biologic drug products.