Guide to Cell Therapy GxP: Quality Standards in the Development of Cell-Based Medicines in Non-pharmaceutical Environments

Joaquim Vives, Gloria Carmona

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Guide to Cell Therapy GxP is a practical guide to the implementation of quality assurance systems for the successful performance of all cell-based clinical trials. The book covers all information that needs to be included in investigational medicinal product dossier (IMPD), the launching point for any clinical investigation, and beyond. *Guide to Cell Therapy GxP* bridges a knowledge gap with the inclusion of examples of design of GLP-compliant preclinical studies; design of bioprocesses for autologous/allogeneic therapies; and instruction on how to implement GLP/GMP standards in centers accredited with other quality assurance standards. *Guide to Cell Therapy GxP* is an essential resource for scientists and researchers in hospitals, transfusion centers, tissue banks, and other research institutes who may not be familiar with the good scientific practice regulations that were originally designed for product development in corporate environments. This book is also a thorough resource for PhD students, Post-docs, Principal Investigators, Quality Assurance Units, and Government Inspectors who want to learn more about how quality standards are implemented in public institutions developing cell-based products.

- Easy access to important information on current regulations, state-of-the-art techniques, and recent advances otherwise scattered on various funding websites, within conference proceedings, or maintained in local knowledge
- Features protocols, techniques for trouble-shooting common problems, and an explanation of the advantages and limitations of a technique in generating conclusive data
- Includes practical examples of successful implementation of quality standards

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