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6 - Compatibility of GxP with Existing Cell Therapy Quality Standards1. Quality Standards in Cell Therapy; 2. Adaptation of Existing Standards to GxP; 3. Impact of GxP Implementation; 4. Quality by Design; 5. Recommendations for Optimizing Integration of QA Systems; 6. Conclusions; References; Glossary; List of Abbreviations; Index

Sommario/riassunto

Guide to Cell Therapy GxP: Quality Standards in the Development of Cell-Based Medicines in Non-Pharmaceutical Environments provides a practical guide to the implementation of quality assurance systems for successful performance of all cell-based clinical trials. The book includes all information that should be used in investigational medicinal product dossier (IMPD), the launching point for any clinical investigation, and beyond, bridging the gap in knowledge with the inclusion of examples of design of GLP-compliant preclinical studies, design of bioprocesses for autologous/allogeneic thera
