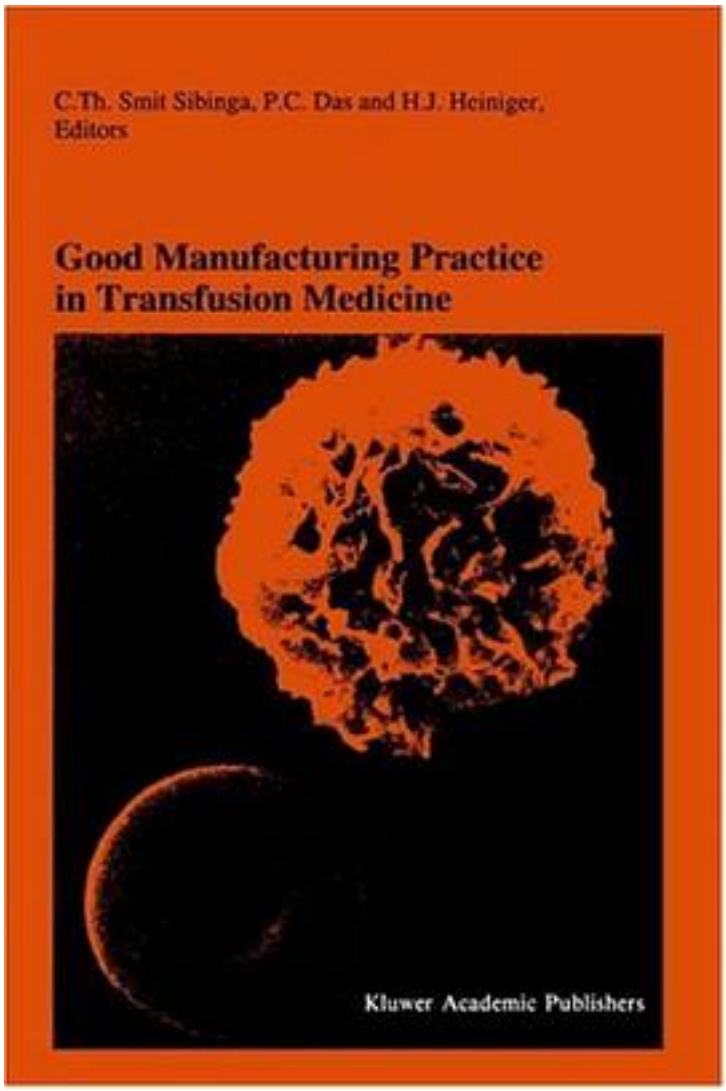
Good Manufacturing Practice in Transfusion Medicine (Developments in Hematology and Immunology)



Good Manufacturing Practice in Transfusion Medicine (Developments in Hematology and Immunology)_下载链接1_

著者:Sibinga, C. Th Smit; Sibinga; Smit Sibinga, C. Th

出版者:Springer

出版时间:1994-08-31

装帧:Hardcover

isbn:9780792330097

Transfusion medicine provides an excellent bridge connecting the healthy community donors with the patient's needs at the bedside; the dominant philosophy has been on patient care and science, but it is now realised that blood banks manufacture increasing amounts of blood components to administer to patients -- a role analogous to manufacturing functions. The concept of Good Manufacturing Practice (GMP) is therefore relatively new. While quality has always been important, the impact of GMP, Total Quality Management (TQM) and Quality Assurance (QA) will be profound. As the regulatory agencies, like the FDA in the U.S.A. and the EEC Commission in Europe, increase their enforcement activities, doctors, technical experts and managers will have to face many issues of quality assurance including documentation, validation, audit system, regulatory laws, licensing, teaching and training of staff and their job descriptions, standards, processing facilities, procedure validations, automation, record keeping, internal and external quality control of products and their release. The expansion of this philosophy to include Good Clinical Practice (GCP) is an even greater challenge demanding consensus therapy protocols and quality management of transfusion through auditing by the hospital transfusion committees. Such comprehensive plans will profoundly affect the financial and organisational structure of blood transfusion in the future.

作者介绍:

目录:

标签

评论

Good Manufacturing Practice in Transfusion Medicine (Developments in Hematology and Immunology)_下载链接1_

书评

Good Manufacturing Practice in Transfusion Medicine (Developments in Hematology and Immunology)_下载链接1_