Long-term experiences in cryopreservation of mobilized peripheral blood stem cells using a closed-bag system: a technology with potential for broader application.

In several European countries, preparation of cellular products with open manufacturing systems as used for cryopreservation of peripheral blood stem cells (PBSCs) needs to be performed in a clean-room facility. However, this form of manufacturing is highly expensive and laborious. Thus, safe techniques providing improved efficacy regarding time and material, which are in accordance with legal requirements are highly desirable. We have developed, validated, and applied a simple method for cryopreservation of PBSCs within a functionally closed-bag system using the closed cryo freeze prep set. This process fulfills good manufacturing practice requirements and allows for the cryopreservation of PBSCs without a clean-room facility. In addition to cryopreservation of PBSCs, we have recently successfully modified our system for processing, portioning, and cryopreservation of allogeneic donor lymphocytes. Since 2010, cryopreservation of PBSCs using a closed-bag system has been performed in our facility on a routine basis and 210 patients and healthy donors have been included in this analysis. No significant reduction in viability of CD34+ cells and no process-related contamination were observed. Outcome of hematopoietic stem cell transplantation regarding time of engraftment and infectious
complications is comparable to products manufactured in conventional clean-room facilities. Our data confirm that cryopreservation of PBSCs within a functionally closed-bag system is safe, effective, and economical. Furthermore, the system has the potential to be extended to other manufacturing processes of cellular products.