Abstract: Autologous and allogeneic stem cell transplantation (SCT) represents a therapeutic option widely used for hematopoietic malignancies. One important milestone in the development of this treatment strategy was the development of effective cryopreservation technologies resulting in a high quality with respect to cell viability as well as lack of contamination of the graft. Stem cell preparations have been initially performed within standard laboratories as it is routinely still the case in many countries. With the emergence of cleanrooms, manufacturing of stem cell preparations within these facilities has become a new standard mandatory in Europe. However, due to high costs and laborious procedures, novel developments recently emerged using closed bag systems as reliable alternatives to conventional cleanrooms. Several hurdles needed to be overcome including the addition of the cryoprotectant dimethylsulfoxide (DMSO) as a relevant manipulation. As a result of the development, closed bag systems proved to be comparable in terms of product quality and patient outcome to cleanroom products. They also comply with the strict regulations of good manufacturing practice. With closed systems being available, costs and efforts of a cleanroom facility may be substantially reduced in the future. The process can be easily extended for other cell preparations requiring minor modifications as donor lymphocyte preparations. Moreover,
novel developments may provide solutions for the production of advanced-therapy medicinal products in closed systems.