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The biology and measurement of stem cell potency and quality for cellular therapeutic transplantation products

Besides ensuring histocompatability between donor and patient, the measurement of cellular potency prior to stem cell transplantation is probably the most important parameter that will predict whether the stem cell product exhibits engraftment potential. Stem cell potency is a quantitative measure of biological functionality of the "active ingredients", without which engraftment will not occur. Since stem cells only proliferate, it is important that the proliferation potential (potency) and ability (quality) are measured, especially for thawed cell products, shortly before transplantation so that the release criteria necessary for use are assessed. Stem cells exist in a continuum of different degrees of primitiveness. Technology is not available to measure different degrees of primitiveness. For hematopoiesis, a minimum of two stem cell types (primitive and mature) has been found sufficient. The mesenchymal stem cell (MSC) compartment is more difficult to quantify. However, the same principles apply to both systems. Proliferation is measured for different stem cell populations using a 3-point cell dose response. The slope or steepness of the response provides a direct measurement of stem cell proliferation potential. The steeper the slope, the more primitive the cell and the greater the potency. By comparing this to a reference standard of the same material, the potency ratio is calculated. A single cell dose provides stem cell quality. Release of the product can occur when both potency and quality are greater than arbitrary limits. These assay principles can comply with regulations and can be used for virtually any proliferating stem cell product.

Biography

Ivan Rich obtained his Ph.D in 1978 at the University of Ulm, in Germany and performed his postdoctoral studies at the University of Chicago. Prior to starting HemoGenix, a contract services and assay development company in 2000 where he is CEO, he was Director of Basic Research in the Division of Bone Marrow Transplantation and Professor at the University of South Carolina. He has published 50 peer-reviewed articles and edited two books. His primary field of expertise is in developmental, experimental and applied clinical hematology.

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