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The importance of measuring quality and potency of a stem cell therapeutic product

The potency of a stem cell therapy product is defined as the quantitative and validated measurement of biological activity of the "active" stem cell components that result in the intended effect. Regardless of whether a cell therapeutic product is minimally manipulated, expanded or otherwise treated prior to administration into a patient, the potency of the product should always be determined. If a product is cryopreserved after manipulation and remains in storage for long periods of time, the potency should be measured on a sample after cryopreservation and again prior to use in the patient to ensure no deterioration. Stem cell "quality" indicates that biological activity is not lost before and after a specific manipulation or procedure. Stem cell potency on the other hand, not only measures "quality", but is also a predictive assessment of the properties of the "active" stem cell components to provide an indication that the product will perform as intended when used in the patient. This is the response as a direct result of using the "active" components in the product and is not necessarily the same as clinical outcome. Understanding the properties of the product are key to ensuring that the product is safe, effective and exhibits sufficient potency so as not to result in graft failure.

Biography

Ivan N Rich obtained his PhD 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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