[**Working Toward Standards for Cell Therapy Products**](http://blog.akronbiotech.com/2015/04/05/working-toward-standards-for-cell-therapy-products/)

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Release criteria for cell therapy products typically tend to vary among manufacturers. When the products are cell-based, moreover, establishing a set of analytical data to characterize said product is frequently an arbitrary decision driven by convenience, assay availability, experience and convention. These rules, however, do not imply a legally-bound responsibility on the part of the supplier, they merely offer that particular cell therapy product’s quality information.

It has been widely documented that one of the major obstacles to any commercial impact of cell therapy products has been the lack of a single reliable set of standards against which such products are characterized.

Measurement of biological activity of a growth factor, for instance, often relying on cellular behavior in a dose-response assay, assumes an inherent variability which is dependent on the specific treatment conditions and the analytical environment during the biological assay. Variability, as we previously discussed, may be introduced due to factors independent of cellular behavior, and this would include raw material source or protocol modifications. Traceability becomes important in ensuring that such variables are not contributors to the final product quality, but, again, no standards currently exist to force suppliers to abide by them.

It is at this point important to mention that the cell therapy industry has attempted to bring clarity to these issues by forming various standardization agencies. These are, broadly:

* Manufacturing standards (ISO)
* International accreditation agencies (FACT, AABB)
* Pharmacopeias (USP, EP, JP)

All of the above organizations work within their own remits to address certain aspects of the cell therapy development process, to ultimately generate more compliant products and processes. These agencies do not only represent cell therapy products – they broadly address various consumer and medical products and materials. However, while there are many agencies, there is still a strong need for further harmonization efforts to bring about consensus among the different agencies and avoid uncertainties when developing a specific cell therapy product.

One such harmonization alliance is AHCTA (Alliance for Harmonization of Cell Therapy Accreditation), whose objective is to “*[create] a single set of quality, safety and professional requirements for cellular therapy including haematopoietic stem cell (HSC) transplantation.*”

Achieving standards, however, ultimately requires complying with guidelines for the measurement of the quality of cell therapy products – from biological assays to parameters that are part of the product’s release testing specifications.

The National Institute of Standards and Technology (NIST) is hosting a two-day workshop on strategies to improve measurement accuracy for cell therapy products. This includes measurements such as cell viability, functionality, cell counts and includes both talks as well as hands-on tasks.