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Cell content and viability assessments for human cell therapy products: Towards effective development of suitable assays and controls

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Abstract

Comprehensive and robust manufacturing controls are crucial in the development of commercially successful advanced cellular therapy products (CTP). The Alliance for Regenerative Medicine (ARM) and the International Society for Cell Therapy (ISCT) are undertaking a joint project to examine analytical methods for product quality and consistency in CTP development. This group has identified cell content (quantity) and cell viability as two fundamental and universal measurements that will be used by developers to define total and viable / non-viable cell content for any CTP. The project will create a roadmap to guide developers through the cell therapy product development process and to establish confidence through assay qualification and validation. This collaboration is an initial effort to address FDA requests to help establish appropriate controls during product development.

This presentation will describe the need and current status of analytical methods that can help ensure consistency and comparability for cell content and viability specifications. Consideration of the selection and qualification of these assays are important considerations early in the development process and can be used in conjunction with purity and potency assays since a single method may not adequately cover the spectrum of characterization that is needed to ensure a quality product. An overview of US, EU and ICH guidance with respect to content and viability assessments of CTP will also be discussed. Incorporation of these assays are an important part of an adequate and robust control strategy, which better ensures that a safe and potent product will be consistently manufactured.

Biography

Brent L. Atkinson, Ph.D. has held Vice President and Director level positions at small, mid, and large medical companies where he has developed and commercialized cellular therapeutics and biomaterials for orthobiologic applications. Responsibilities have included leadership of preclinical and clinical studies, planning and submission of regulatory filings, direction of manufacturing, and management of the intellectual property portfolio. He has authored over 30 publications, is an inventor on eight issued patents and holds a Doctorate in Molecular Biology from Columbia University. Atkinson Biologics specializes in translating cellular therapeutic products from conception through development and ultimately to commercialization.