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Approach to comparability studies for cell-gene therapy autologous product from quality perspective and regulatory expectations

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Abstract

Comparability studies, governed by a higher-level comparability plan for an autologous product/process, are routinely executed through development and commercialization stages of a biological product. The factors driving such studies originate from introduction of changes in materials, methods, equipment, process and facilities.

The comparability plan should be established in accordance with the principles of ICH Q5E and other regulatory guidance to ensure that the introduced changes would not adversely impact the safety and efficacy of the final product. Risk assessment of impacts of proposed changes on product quality is a part of the comparability plan. This presentation will emphasize and discuss the

- Regulatory expectations for performing comparability studies

- Developing a strategy for implementation of comparability plan

- Challenges of carrying out comparability studies in autologous products

During early development stage, when a process/product is not validated yet, changes are targeted at either optimization of the product/process or required expansion of capabilities. One of the major discussions revolves around setting up acceptance criteria for a quality product that is deemed comparable. The comparability strategy primarily would focus on meeting established release criteria or a set of characterization tests would also be used to compare drug products. This decision is dependent on the exact change being evaluated. Meeting the predetermined acceptance criteria assures success for the process optimization and its transfer.

For an autologous product with a large and inherent variability in starting material being introduced from the donor, a comparability study might require running split run/s with the same starting material. There are no changes in scale for autologous products and all development, verification and qualification activities are performed at the scale of a single patient, which complicates the scenario of carrying out comparability studies in traditional ways.

Biography:

Zeb Khan has over 20 years of experience working on quality systems and supporting operational quality for solid dosage and biologic product types. Her expertise is focused on creating efficient and compliant systems to support quality product. Zeb_Khan@vrtx.com

Speaker Publications:

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