Towards Globally Accepted Specifications of Pharmaceutical Products: A Summary of the Current State

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Background

Product specifications are critical components of the overall product quality control strategy for any new biotherapeutic during clinical development and commercial licensure. Setting the appropriate specifications that are harmonized for the global market can be challenging even with the current active effort to align global quality guidelines. To further understand the current state, a survey was performed through the Global Specification Harmonization Working Group within IQ (International Consortium for Innovation and Quality in Pharmaceutical Development).

Methods

A survey was performed among 11 biopharmaceutical companies ranging from small biotech to large pharma. In the survey, general product information was first collected and subsequent questions were tailored based on previous response. The survey was designed to collect market specific health authority feedback and allowing participants to further dive into the rationale, outcome, and impact of each specification question.

Results

The survey received responses for 43 unique molecules (15 biologics). Overall, Purity-Charge Variant, Purity-Size Variant, Potency, Glycans, and Bacterial Endotoxin are among the attributes that received most regulatory questions. Most questions originated from difference of opinions on whether a test is required (29%) or from agencies' request to tighten the acceptance criteria based on batch history, stability data, and clinical exposure (40%). In most cases (except for Glycan related questions), tighter acceptance criteria were implemented globally or for specific markets as the outcome. In addition, BET, as a compendial test, also received a high amount of questions, reflecting inconsistency between ICH and local agency expectation.

Conclusions

The results indicate that the acceptance of same product specification has been inconsistent across different markets, even for tests with compendial chapters. Based on shared experience across multiple companies, this inconsistency often led to significant impact on supply chain management and product availability to patient.