Industry Challenges and Successes in Harmonizing Specifications Over Multiple Regulatory Regions

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Specifications for biotherapeutic products are a critical component of the product's overall control strategy and a regulatory requirement. The common goal is to ensure consistent product safety and efficacy while also maintaining product supply to patients. Product quality attributes (PQAs), product knowledge and an understanding of attribute criticality captured throughout product development inform specification setting. The International Council of Harmonization (ICH) Quality Guidelines provide a framework for standardization of specification setting by participating member regions. The specifications for some attributes are guided by regional compendia and regulatory guidance. Linking the potential patient impact to PQAs through an assessment of potency, PK, immunogenicity and safety is foundational to identifying the criticality of PQAs. Setting acceptance criteria globally has presented challenges due to differing regional requirements, such as testing performed, datasets, and flexibility for changes. A recognition that some of these differences may delay timely patient access and product lifecycle improvements, while not improving drug safety or performance, has energized industry and regulator collaboration on removing such barriers. This talk explores some of the industry challenges and successes in harmonizing specifications over multiple regions.