supplier and the generic drug product developer are the evolving milieu of regulatory and compendial forces that provide acceptance boundaries for the purity, safety, and efficacy for the API. Additionally, the regulatory milieu covering current good manufacturing practices, including manual and electronic documentation, must be respected and enforced at both the site of production of the API and the site of manufacture of the final dosage form targeted for marketing. On a going forward basis, the API supplier will be held accountable for the consistency of the chemical and physical properties of the material being produced on a routine basis. Good science and mutual respect for the technical issues must prevail in the relationship between the API manufacturer and generic drug product developer to assure the continued production of generic drug product, which stays within the performance boundaries of the originally filed exhibit batch(es) in the filed ANDA.

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