Quality Over the Life of a Generic Drug

What a Manufacturer does:

Develops a product

Identifies and reproduces the critical attributes of an innovator drug

Develops a process

Develops appropriate manufacturing process and controls

Establishes their tests and criteria for releasing drug product to market

Submits FDA application

Manufactures product that passes all tests

Demonstrates drug is *equivalent* to innovator

Shows product is stable over shelf-life

Markets drug

Scales up and validates manufacturing process

Assures *each batch* passes release tests

Maintains supply

Performs ongoing stability testing

Maintains data integrity

Manages changes and notifies FDA when needed

What the FDA does:

No *single* tool is sufficient, so tools are complementary and based on *risk*:

Releases guidance on generic product development

Establishes quality standards

Engages with manufacturers developing complex products or processes

Assesses applications for product and process quality and equivalence to innovator

Conducts inspection if warranted based on risk assessment

Conducts inspections and remote regulatory assessments

Conducts data-driven market surveillance (public reports, etc.)

Conducts risk-based product sampling & testing

Assesses high-risk manufacturing changes before implementation

Guidance and standards can include tests and criteria for equivalence & market release

Pre-ANDA and Emerging Technology Programs can help guide manufacturers facing complex issues

Equivalence includes having the same active, form, route, strength, etc. and performing in the same manner as the innovator drug

Preapproval inspection is needed if warranted based on the risks of the product or process and the site's history

Surveillance inspections are prioritized using risk factors including inspection/compliance history of the facility and its country/region, and the inherent risk of its products

With >140,000 products in CDER, it is not feasible to test all drugs for all attributes

Analysis of post-market quality data helps sample drugs and test attributes with potential quality risks, such as a suspected impurity or contaminant

This drives FDA actions that minimize harm to consumers