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Integrated Solutions Overview

Proposal for Evaluation and Testing of Product Platforms

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EARLY COMPATIBILITY SCREENING

In early development it must be demonstrated to regulatory authorities that a proposed packaging system is suitable for its intended use. Initial experiments must be carried out to demonstrate that a packaging system:

- Adequately protects the dosage form
- Is compatible with the dosage form
- Is composed of materials that are considered safe for use with the dosage form and the route of administration
- Functions properly as an assembled container closure system if/when using a performance feature

To address these concerns, West Analytical Services will conduct small scale filling and stopper placement services for a single vial, syringe, or cartridge system for engineering studies. The system will be filled in an ISO 5 clean room and sterile gowning and gloves will be utilized during the filling of the product to minimize any contamination.

Early Screening/gross compatibility studies between the drug product and the system at accelerated conditions are performed over an 8-week period and analyzed every 2 weeks at Time 0, 2, 4, 6 weeks and 8 weeks.

PHASE I STUDY

Upon selection of the primary package and/or device, baseline data is generated that will be further refined and support the selection for the remainder of the product's life. Establishing proper baseline data is critical to future success.

Phase I studies include the drug product and system at both room temperature and accelerated conditions where testing is performed over a 6-month period and analyzed at Time 0, 1, and 6 months for Room Temperature and 0, 1, and 3 months at Accelerated conditions. The focus of testing will be on functional compatibility.

PHASE II STUDY

Continuing with the generation of baseline verification data in support of the appropriate packaging and/or chosen delivery system, Phase II studies evaluate performance, functionality, and begin to further understand and identify any associated chemical compatibility concerns.

PHASE III STUDY

With baseline data and defined Critical Quality Attributes, the packaging and delivery system is evaluated against the defined attributes as the drug product / device manufacturing is scaled up to a submission batch. West offers continued support of data requirements for your regulatory submission offering Assurance that your application meets today's regulatory standards.

Phase III studies to include the drug product and system at both room temperature and accelerated conditions where testing is performed over the shelf life of the product. Testing at Phase III focuses on verification testing for the combination product.

LIFECYCLE MANAGEMENT

Data, information, and knowledge gained in product development and scale-up are intended to support the continual improvement of the product and process. Critical Quality Attributes of drug/CCS and delivery system output requirements provide clarity & define the standards to be met in technical transfers and change control processes. ICH Q12 conveys a regulatory expectation for continuous management of a product over its Lifecycle.

West Analytical Services can further support product commercialization through any of the following:

- Complaint support & regulatory services for West devices
- Training
- Device Manufacturing and Assembly
- Drug & Device Packaging solutions
- Device Serialization
- Drug handling including cold storage
- Quality control release testing
- Bridging Studies
- Support of tech transfers or change management

Further details will be outlined in Integrated Solutions proposal.