Pharmaceutical Quality System (PQS) Alignment with BT Product Development Considerations

PQS requirements must be adhered to for breakthrough product development while providing appropriate flexibility to accommodate accelerated activities for breakthrough product development timelines. Thus, the accelerated development PQS strategy for each product will be unique, as it depends on the timing of the BT designation.

Helping you get your product to market faster

DSI can support all critical product and process characterization activities that should be addressed earlier and can help facilitate manufacturing readiness for breakthrough products. To learn more manufacturing considerations for expedited drug development programs, the following approaches could be considered for discussion and agreement with FDA.

Some activities that might be considered to speed development activities include the following:

- Flexibility, based on molecule, available product, and plat- form knowledge will be required
- Only those activities with no impact on patient safety or product supply should be deferred
- A quality risk assessment must be applied to all activities that will be deferred, and the rationale, and controls needed to ensure deferred activities are completed documented
- Some activities that are normally completed prior to license application may need to be deferred and submitted:
  - Post-submission, complete at inspection
  - Post-inspection, prior to approval
  - Post-market commitments
- The manufacturing readiness plan can be used for developing internal filing and inspection readiness checklists to ensure all deferred activities are completed or addressed
  - Any PQS deferrals must be documented in a manufacturing readiness plan and monitored to ensure completion

WHAT CAN DSI DO FOR YOU?

Regulatory Affairs **CMC** **QA**

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