

LIFECYCLE APPROACH TO VALIDATION SUPPORTS ACCELERATED APPROVALS

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Key Words: Continued Process Verification (CPV); Breakthrough; Orphan.

The product lifecycle management paradigm provides a structured pathway for both process and analytical validation. This framework relies on statistical approaches integrated with science and engineering.

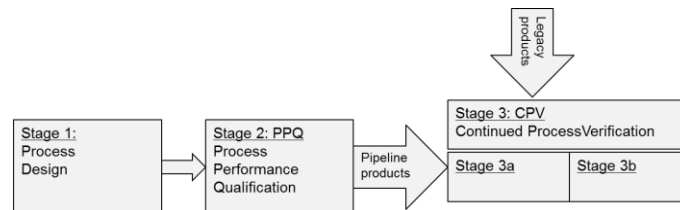


Figure 1 – Stages of Process Validation

Fast-moving products with orphan drug status or breakthrough designation must still meet the standard regulatory requirements and process for obtaining marketing approval; this requires an efficient, methodical, and well-organized approach.

This presentation will include examples of the product lifecycle management approach to process and analytical validation applied to orphan and breakthrough designation products moving rapidly through review. Statistical concepts and techniques essential to application of this strategy will be highlighted.