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### Stability considerations from early stage development through Phase-IV of Pharmaceutical drug products

Stability studies are key components of pharmaceutical drug products during early stage development through phase-IV that supports in establishing the drug product re-test date and shelf life by evaluating the data generated under controlled environmental storage conditions. Real time data is an ongoing stability in the drug development process while the clinical trial is ongoing and during late stage of development process. Drug manufacturer must assure that product remains stable during the course of clinical trials in early development process and it remains stable during the shelf life in late development stages and during post marketing until it reaches to the expiration date. To meet this obligation, manufacturer makes commitments to the regulatory authorities during ANDA/NDA submission. This paper describes the stability considerations of pharmaceutical drug products for early stage development (pre-clinical and Phase-1 and Phase-2), ICH stability studies to support NDA application in Phase-3 and monitoring ongoing stability and stability due to post approval changes in Phase-IV, of pharmaceutical drug product cycle.

### Biography

Dharmi Trivedi has Master's degree in Science majoring in Chemistry from Saurashtra University, India. She is a professional pharmaceutical Quality and Compliance specialist and has over 20 years of experience in Pharmaceutical Industries including, Quality and Compliance, Quality Control and Research and development. During her career she has gained expertise in cGMP areas that include investigations, CAPAs, change control, process validation, Quality Management System (QMS), third party Organization (TPO) management, stability program, and external/internal audits.

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