

## **Assignment Questions**

1. Discuss the differences between long-term, accelerated, and intermediate stability studies in terms of conditions, duration, and regulatory role. How does each contribute to establishing a scientifically justified shelf life?
2. Imagine you are designing a stability protocol for a new drug product intended for global submission. Explain how ICH Q1 guidelines and climatic zone-based protocols would influence your study design, sample size, and documentation requirements.