



Life Science Outsourcing

Shelf-Life Planning Checklist

Use this tool to validate and document your aging strategy.

1. Packaging Configuration

- Have you selected a realistic worst-case configuration for your shelf-life study?
- Is your configuration consistent with those used in transit and sterilization validation?

2. Accelerated Aging Protocol

- ASTM F1980 test method selected and documented
- Temperature and relative humidity logged and justified
- TAA (aging factor) appropriately calculated and recorded
- Aging chamber calibrated and validated

3. Real-Time Aging Strategy

- Initiated for long-term data collection (if applicable)
- Stored at labeled conditions with documentation plan
- Integrated into long-term risk mitigation strategy

4. Post-Aging Testing

- Seal strength tested (ASTM F88)
- Dye/microbial barrier integrity evaluated
- Visual inspection documented

5. Justification and Documentation

- Shelf life justification narrative drafted
- Supporting material data and historical performance included
- Shelf life claim aligns with data and risk profile