Compliance Readiness Checklist

Use this checklist to document implementation readiness for the revised chapters.

Readiness Activity	Done	N/A
Complete and approve a formal impact assessment for USP <2021> and <2022>.	☐	☐
Confirm that applicable dietary ingredients, raw materials, and finished dietary supplements are included in the microbiological control strategy.	☐	☐
Review microbiological specifications and product-specific testing requirements for alignment with the revised chapters.	☐	☐
Update test methods, worksheets, laboratory templates, and controlled procedures to reflect the revised media, organisms, inoculum levels, acceptance criteria, and incubation periods.	☐	☐
Evaluate existing method suitability data and document whether it remains applicable under the revised conditions.	☐	☐
Execute additional suitability studies or requalification activities where the impact assessment identifies a gap.	☐	☐
Assess any alternative methods and confirm that validation and suitability documentation remain adequate for the intended use.	☐	☐
Review affected validation, verification, transfer, and method lifecycle records.	☐	☐
Train affected laboratory, quality, and manufacturing personnel on approved procedural changes before implementation.	☐	☐
Verify that required media, cultures, materials, and laboratory capacity are available to support the revised procedures.	☐	☐
Implement changes through the applicable change-control process and define an effective date.	☐	☐
Perform a post-implementation check to confirm that revised methods and records are being used consistently.	☐	☐