WINDSHIRE CONSULTING

**Gap Analysis Checklist: transition to PDA TR 60 (2026) Process Validation Standards**

This checklist is designed to help validation leads and quality assurance managers quickly assess a facility's readiness for the operationalized requirements of the new 2026 revision. It is organized by lifecycle stage and focuses on the most significant technical shifts.

**Part 1: Foundational & Organizational Alignment**

- [ ] Does the site **Process Validation Master Plan (PVMP)** explicitly reference the three-stage lifecycle model of PDA TR 60 (2026)?
- [ ] Is there a defined **Knowledge Management (KM)** strategy (aligned with ICH Q10/Q12) for capturing and updating process understanding across the product's lifecycle?
- [ ] Has a **Digital Maturity Assessment** been conducted to ensure data infrastructure (e.g., LIMS, MES, historian) is capable of supporting automated Stage 3 monitoring?
- [ ] Do internal training materials reflect the updated **continuum-of-criticality** definitions for CPPs, KPPs, and non-key parameters?

**Part 2: Stage 1 (Process Design)**

- [ ] Are **Quality by Design (QbD)** principles formally documented, with a clear link established between Critical Process Parameters (CPPs) and Critical Quality Attributes (CQAs)?
- [ ] Is **Raw Material Variability** (including supplier quality attributes) treated as a design input and modeled during process development?
- [ ] Has a preliminary **Stage 3 CPV monitoring strategy** (including performance indicators) been drafted *during* the design phase, rather than post-qualification?

**Part 3: Stage 2 (Process Qualification)**

- [ ] Does the process performance qualification (PPQ) protocol utilize modernized statistical methods for **sample size determination** and **equivalence testing**?
- [ ] Is there a procedure in place for the **verification of multivariate models** and the validation of automated feedback loops (if dynamic control is used)?
- [ ] Has the **Process Design Space** been verified through PPQ data or acceptable simulated data (Digital Twins)?

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**Part 4: Stage 3 (Continued Process Verification)**

- [ ] Does the CPV plan utilize **Multivariate Statistical Process Control (MSPC)** tools (e.g., Hotelling's $T^2$), SPE)?
- [ ] Are **Statistical Alert and Action Limits** formally defined and distinguished from internal action levels and regulatory specifications?
- [ ] Is there a documented procedure linking Stage 3 trends back to Stage 1, defining the exact **Triggers for Re-Validation** or process redevelopment?
- [ ] Does the **Periodic Product Review (PPR)** process incorporate all Stage 3 monitoring data for that period?

**Part 5: Legacy Products ( Grandfathered Portfolios)**

- [ ] Has a formal **Legacy Product Retrospective Review** been scheduled for all established commercial processes?
- [ ] Are legacy parameters **risk-ranked** to identify high-risk variables that require modernization of their control strategy?
- [ ] Is there a defined **On-Ramp Protocol** to incrementally move legacy products into a structured Stage 3 CPV monitoring program?

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**Scoring & Next Steps:**

If you have marked "No" to more than three items or are unsure about your site's readiness for the Multivariate Statistical Process Control (MSPC) requirement, it may be time for a more comprehensive, expert-led gap analysis. Contact our team at info@windshire.com or +1 844-686-5750 to schedule a confidential technical review of your validation master plan.