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VIII. 2026–2027 Compliance Checklist & Template

B. Remote PMDA Inspection Readiness Template

Given the April 2026 policy change regarding remote inspections, technological and linguistic readiness is paramount.

Readiness Component	PMDA Compliance Requirement	Verification Status
System Integrity	Adherence to PMDA guidelines for cloud and video systems.	Validation of Gateway System document access/screen-sharing rights for the interpretation team; secured digital communication channels verified.
RSI Team Contingency	Guaranteeing seamless flow throughout the 8-hour inspection.	Designated backup interpreter protocol confirmed; confirmation of rotational schedule for the 2–3 person team to mitigate fatigue and accuracy decay.
Document Translation Capacity	Readiness for non-Japanese/non-English documents.	Interpreter availability for instant sight translation of proprietary documents requested by the inspector.
GXP Familiarity Check	Ensuring all inspectors' terminology is immediately understood.	Pre-audit brief covering the facility's specific SOPs, recent GXP reports, and definitions of identified deficiencies.
Linguistic Liability Waiver	Documentation of professional responsibility.	Template language confirming the interpreter's professional liability insurance and acknowledging their critical role in maintaining GXP compliance.