AI Assistant Specialized in CQV.

Builder: Amr Elbayoumi

VALOR

PROJECT MANAGEMENT PACK

AI Assistant Specialized in CQV. Builder: Amr Elbayoumi

Valor - References & Standards List

Valor follows internationally recognized standards and best practices for Commissioning and Qualification (C&Q) of pharmaceutical facilities, equipment, and systems.

Key Standards and Guidelines Adopted by Valor:

1- ISPE Baseline® Guides (Especially GAMP® 5 and ISPE Baseline Guide Volume 5):

Valor leverages ISPE's Good Practice Guides for C\&Q. The ISPE Baseline Guide Volume 5: Commissioning \& Qualification (Second Edition) is a core reference, advocating a science- and risk-based approach. GAMP® 5 (Good Automated Manufacturing Practice) provides further guidance for computer system validation, which is also foundational to C&Q.

2- EU GMP Annex 15* (Qualification and Validation):**

Valor references EU GMP Annex 15. This annex sets the requirements for qualification and validation of facilities, utilities, equipment, and processes.

3- ASTM E2500 Standard:

Incorporate principles from the ASTM E2500 standard, which promotes a science- and risk-based approach to verification of manufacturing systems and equipment.

4- EDA Compliance Validation Matrix for Work Package Development (Non-Sterile Areas):

Element	EDA Specification	Inclusion in WP Scope
Room Classification	ISO 8 / Grade D for gowning & weighing	Scope must state cleanroom grade explicitly
Particle Limit	≤ 3,520,000 particles ≥ 0.5 µm/m^3 (at rest)	Particle count test to be included if needed
Pressure Cascade	10–15 Pa ±5 between adjacent areas	Scope must reference DP sensor validation

ACH Requirement	15–20 Air Changes per Hour	Verify design & measured ACH
Filtration Type	HEPA filters + prefilters + bag filters	Scope must define filter type/integrity check
Airflow Directionality	Positive pressure zones for clean-to-less-clean flow	Smoke study/visual airflow checks
Filter Integrity Validation	Mandatory (HEPA Leak test)	Must include DOP/PAO testing
HVAC System Control	Monitoring, alarms, BMS/SCADA control where applicable	Alarm testing and logging

Valor adopts a lifecycle approach to C&Q, which may include:

- User Requirements Specification (URS)
- Design Qualification (DQ)
- Factory and Site Acceptance Testing (FAT/SAT)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)

Note: C&Q is risk-based, focusing efforts on systems that impact product quality, patient safety, or regulatory compliance. Documentation, traceability, and data integrity are emphasized throughout the process.