A comparative analysis of qualification process for pharmaceutical process equipment

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SUSTAINABLE BIOTECHNOLOGICAL PROCESSES (tech.)

Introduction

- Pharmaceutical industry has a great responsibility in patient safety.
- Qualification, as part of Good Manufacturing Practice (GMP), aims to ensure good quality of pharmaceuticals.

- My objective was to perform qualification for two pharmaceutical process equipment types, air samplers and tube sealers, and compare their qualification workflows to find the most efficient pipeline.

Materials and methods

Documentation:
- User requirement specification (URS), validation plan (VP), installation and operational qualification (IQOQ) protocol, validation summary report (VSR)

Testing:
- Air samplers: IQOQ in-house
- Tube sealers: supplier's IQOQ, supplementary IQOQ in-house

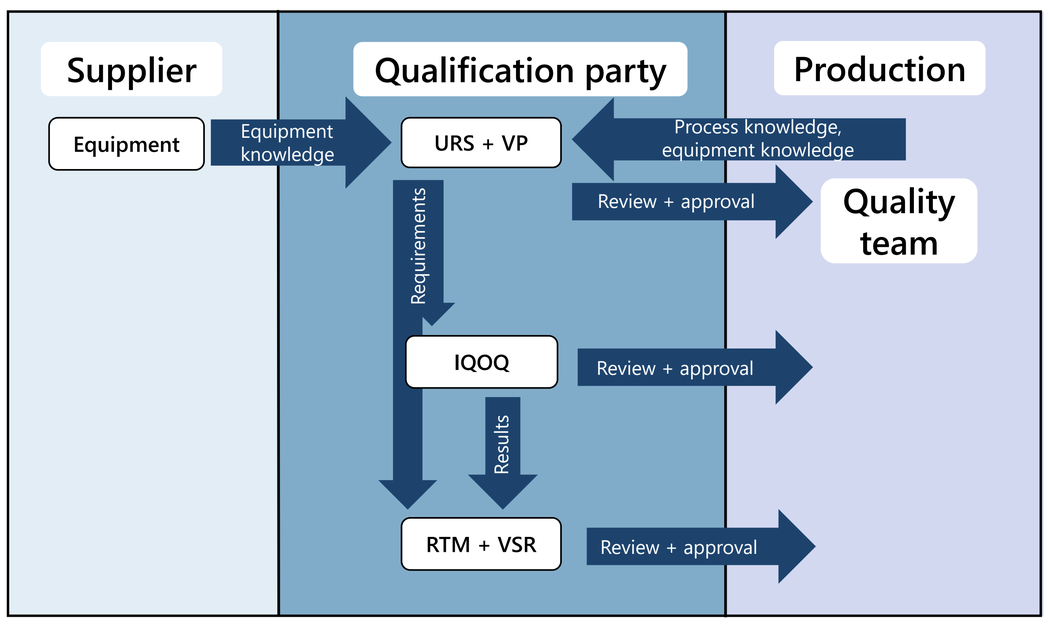

Figure 1 Air samplers' qualification workflow flow chart.

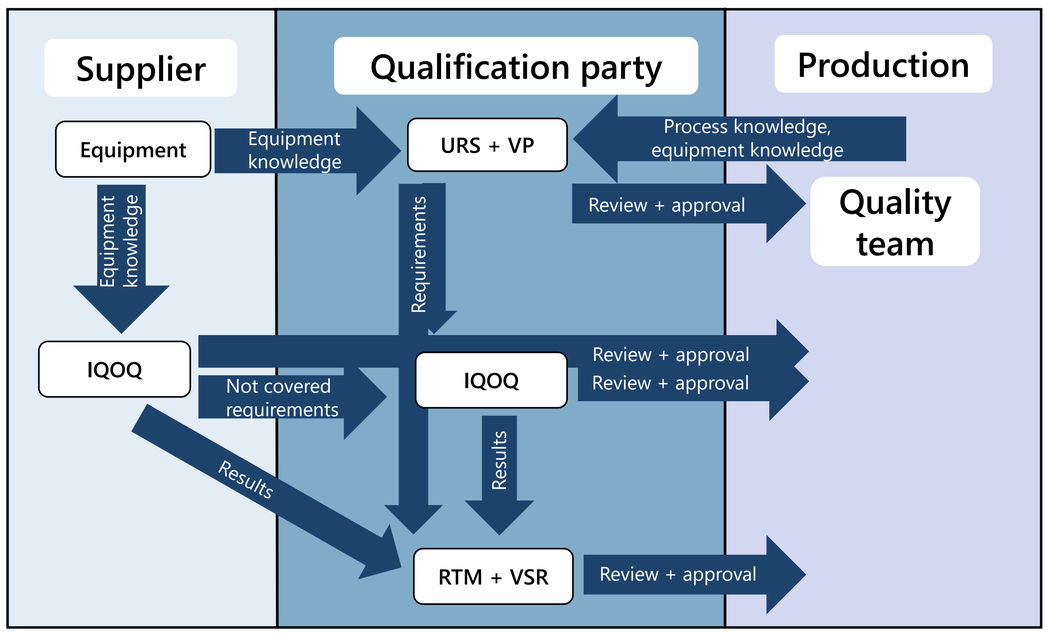

Figure 2 Tube sealers' qualification workflow flow chart.

Results

Air samplers:
- Simpler process (see Figures 1 and 2)
- Time efficient - less steps in the process and fewer tests (see Table 1)
- Cheaper - everything performed in-house

Tube sealers:
- More complex process (see Figures 1 and 2) and therefore time consuming
- More tests and more thorough (see Table 1)
- More expensive due to external parties

Table 1 Installation qualification tests (IQ) and operational qualification tests (OQ) for air samplers and tube sealers. My tests are listed on darker background, supplier's tests are on light background, and supplier's tests outside the scope of the user requirement specification are on light background with light font.

Air sampler	Tube sealer
Documentation verification (IQ)	Documentation check (IQ)
Equipment's main components and installation (IQ)	*Communication check (IQ)*
Material, surface, and finish verificaiton (IQ)	Sealing parameter check (IQ)
Calibration verification (IQ)	*Basic function test (IQ)*
Sampling tool compatibility verification (OQ)	*System password check (OQ)*
Control system verification (OQ)	*Zero position validation (OQ)*
Software verification (OQ)	*Service position (OQ)*
Equipment alarm and error message test (OQ)	*Temperature validation (OQ)*
Capacity verification (OQ)	Initialization blockage and cover test (OQ)
	Start after power failure (OQ)
	Sealing sequence check and quality check of sealing (OQ)
	Installation verification (IQ)
	Material, surface, and finish verification (IQ)
	Cleaning agent verification (OQ)
	Sealing counter test (OQ)

Conclusions

- Expertise in the equipment is vital → more thorough qualification, less likely to take missteps.
- Important to find the line between essential tests and over-quality.
- If expertise is found in-house, conducting all qualification internally proves to be a cost-effective and time efficient approach. If no such resources are available, buying qualification from a supplier emerges as viable alternative.