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IQ and PQ for Commercial GCP Systems

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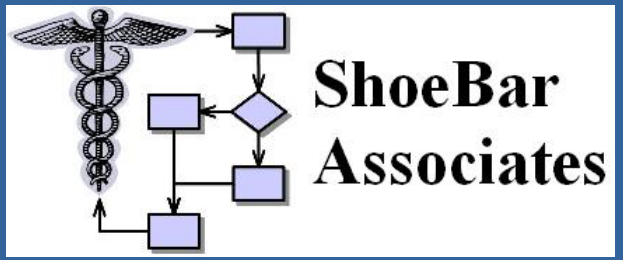

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IQ and PQ: An Overview

- Not just for setting up a system, but for later fixes.
- IQ – first a planning exercise
- IQ – also a recording exercise
- PQ – measure what is applicable; define what you mean
- Do the homework – you'll inevitably need to fix or update!

IQ / OQ/ PQ Model

From *General Principles of Software Validation*:
"For many years, both FDA and regulated industry have attempted to understand and define software validation within the context of process validation terminology. For example, industry documents and other FDA validation guidance sometimes describe user site software validation in terms of installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ)."

"... While IQ/OQ/PQ terminology has served its purpose well and is one of many legitimate ways to organize software validation tasks at the user site, this terminology may not be well understood among many software professionals, and it is not used elsewhere in this document."

IQ / OQ/ PQ Model

From ISPE *GAMP 5*:

"The use of qualification terminology in relation to computerized systems and the relationship between OQ and PQ in particular, varies from company to company."

"... Some computerized systems are intimately involved in many regulated business activities outside the manufacturing area ... Such IT systems have no direct correlation with the manufacturing process and associated process validation. Acceptance of the system is dependent on the satisfactory completion of a functional test, such as the traditional OQ or equivalent tests, prior to a controlled cut over into the live environment. (Some further testing, e.g. stress or performance testing, may be necessary which some organizations call PQ but it is not an activity parallel to the PQ testing of controlled process equipment.)"

IQ / OQ/ PQ Model

- Terms are borrowed from manufacturing (process qualification)
- May not always translate to CSV
- ***However***, this kind of thinking can help in setup and support of GCP systems
- Consider the benefits:
  - Ensure a system is set up properly
  - Provide information for later support / modification
  - Create a baseline for system behavior (if appropriate)

IQ – The Planning

Is everything available that will be needed to install XYZ?

(Consider these just a list of examples.)

- What hardware requirements?
  (speed, memory, disk space, graphics / video)
- What operating system?
- What other software required?
  (browser, database, report engine, .NET framework, drivers, …)
- What network setups are needed (e.g. mapped drives)?
- Are any specific input or output devices required?
- If client / server, what requirements for server vs. for client?

IQ – Making a Record

If you know what you did, you can fix / update it later!

(Again, these are only examples.)

- Locations: application, data files
  (Network path, server name, computer name, drive, directory)
- Configuration settings
- Security: directory privileges
- Users (including any “phantom” or “system” users)
- Linkages (drive mappings, database links, or shortcuts)
- Did the application open successfully?
  (or did you have to modify something and try again?)

PQ – Do you need it?

- What are your performance criteria?
  - number of simultaneous users or connected devices
  - response speed
  - processing time for large dataset
- Measure once the installation and function have been confirmed
- Consider these results a baseline.

PQ: Consider a Traditional Example

SW controlled system, chemical passivation of skeletal-repair implants

- **IQ**: power, DI water, comp. air, UV, ultrasound, network interface hooked up; record model / serial / version no's. Switch on.
- **OQ**: flow rate, temp, air press, feed rates correct; *check all SW functions (dwell times, alarms)*
- **PQ**: run N batches, inspect pieces & chemically analyze for residuals

In this case, IQ – OQ – PQ have clear meaning

What do OQ/PQ Mean to YOU?

- For GCP software – think about these definitions, and your team's understanding of them
- If "OQ" to you is verifying SW functions as specified (login privileges, rules, data checks, error msgs), great – define it that way
- If "PQ" to you is end-user testing in final installed environment (study-specific configurations, alongside other apps, conducted by target users, generic instructions), great – *DEFINE IT THAT WAY*
- Don't confuse your team, or overstimulate your inspector / auditor!

Do your homework!

- Installation – plan it out
- Installation – keep a record
- Performance – get a meaningful baseline
- Well planned and executed, these steps provide value for long-term support.