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SCIENCE & RISK-BASED VALIDATION

WHY DO YOU NEED THIS APPROACH TO COMMISSIONING AND VALIDATION?

- It can provide better testing. It can catch problems that traditional testing misses.
- It can be faster and less expensive – by reducing *unnecessary* paperwork.
- The old approach may not be accepted in the future.

WHAT IS THIS APPROACH?

- It is a change in testing paradigm that evolved from FDA challenges to provide a better approach to testing.
- “**RISK-based**” approaches look at the risk to patient outcome – the risk of something happening, the risk of it impacting the patient, the risk of it being undetected.
- “**RISK-based**” approaches can either minimize a risk or mitigate it.
- “**SCIENCE-based**” testing implies an understanding of the internal characteristics of a system. The ‘black box’ must be ‘opened’ (either by the vendor’s tests or by user tests).
- “**SCIENCE-based**” testing requires meaningful tests developed by, and with results evaluated by, subject matter experts. Otherwise the testing has little scientific validity.
- This approach helps avoid *unnecessary* deviations.
 - Many of these are just “paper chases”.
 - If a deviation *does not actually lead to a change in the system* (or in documentation or training) then it hasn’t done anything to reduce patient risk.
 - Such a test is a waste because the patient outcome is not improved.
- Traditional validation has worked fairly well in the past because dedicated, experienced, knowledgeable people have implicitly built good tests into their protocols.
 - Often this has been in spite of, rather than as a result of, the validation methodology.
 - As systems become more complex, industry can’t rely on this implicit coverage to catch everything.

WHY GSC CAN HELP YOU:

- **GSC** comes from the traditional engineering community where concepts similar to risk-based validation have been used in design, analysis, and testing for decades. It is not new to us.
- **GSC** brings broad subject matter expertise to the problem.
- **GSC** has decades of experience with biotechnology clients.

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