A Validation/Qualification Solution for *R*

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To date, *R* is not widely used in regulated environments, e.g., clinical trials for pharmaceuticals and medical devices. A common misperception exists that *R* cannot support the various regulatory requirements for validation/qualification. We present a straightforward framework for successfully complying with regulatory software validation requirements including FDA 21 CFR Part 11 and other GxP documents. Recognizing that validation/qualification applies to the software and to its installation and operation, we present a solution that facilitates qualification of an *R* installation to meet IQ/OQ/PQ standards. We cite previous *useR!* proceedings on the topic, and discuss the combination of factors enabling growth in the use of *R* in regulated environments, including guidance from the R Foundation and the availability of tools supporting validation/qualification.

References

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