

# Is it time to revalidate your eQMS?

*When an eQMS launches a software update – like to add or change a feature – you might need to revalidate the system. Some updates will require revalidation of the software... and some won't. To determine whether revalidation is necessary or whether you can simply requalify the software, use this basic checklist. The more “Yes” answers, the more likely it's time for revalidation.*

**1. Is the update/change considered high risk (a substantial change), medium risk (a minimal change), or low risk (a cosmetic change)?**

☐ High Risk

☐ Medium Risk

☐ Low Risk

**2. Is the software vendor critical to your GxP operations?**

☐ Yes

☐ No

**3. Will the change impact data storage, privacy, or security?**

☐ Yes

☐ No

**4. Will the change impact your current workflows in the system?**

☐ Yes

☐ No

**5. Does the change impact any features/functionality you use in the software?**

☐ Yes

☐ No

**6. Is new user training required?**

☐ Yes

☐ No

**7. Are SOP revisions required?**

☐ Yes

☐ No

**8. Is User Acceptance Testing (UAT) required?**

☐ Yes

☐ No

