PV Preparedness Self-Assessment

Implementing or updating a PV system can be a daunting task but can be accomplished more easily and with more confidence when you know what seasoned experts do to prepare for their projects. Since success is imperative, it's essential to start with a strategy that's inclusive and a plan that's comprehensive. The following questions address the various areas and perceptions that are best addressed earlier in the evaluation and planning phases. They are offered as a tool to assist you in surfacing and preparing for challenges endemic to replacing, augmenting, or updating existing Pharmacovigilance Programs. Since each organization's program is unique, there is no score to tally.

1. To what extent do you feel that employing digitized technology (e.g., Automation, Artificial Intelligence) will improve your PV business process?
    a. ◯ Pessimistic
    b. ◯ Uncertain, and pessimistic
    c. ◯ Uncertain, and optimistic
    d. ◯ Hopeful
    e. ◯ Optimistic
    f. ◯ Confident

2. To what extent has your organization prioritized digitalization in the PV/Safety programs?
    a. ◯ Not planning an initiative
    b. ◯ Considering the need to upgrade digitalization
    c. ◯ Planning an initiative
    d. ◯ A program is underway
    e. ◯ Completed a program to upgrade the digital aspects of our program

3. To what extent do staff demonstrate receptivity to modernizing PV programs?
    a. ◯ Unreceptive to modernizing
    b. ◯ Somewhat unreceptive due to other operational or other priorities
    c. ◯ Neutral due to either skepticism about the need, risk, or benefits
    d. ◯ Somewhat receptive
    e. ◯ Highly receptive

4. To what extent has the organization assessed the potential benefits of expanding the use of AI/ML-powered applications in the PV program?
    a. ◯ Not interested
    b. ◯ Interested in assessing
    c. ◯ Actively assessing
    d. ◯ Planning implementation
    e. ◯ Planning an expansion

5. To what extent do IT leaders feel that the current PV system employs modern technology?
    a. ◯ Unsure of their feelings
    b. ◯ Not confident
    c. ◯ Somewhat confident
    d. ◯ Confident

6. To what extent are executive leaders demonstrably receptive to updating or improving the PV system?
    a. ◯ Resistant
    b. ◯ Skeptical
    c. ◯ Neutral
    d. ◯ Optimistic
    e. ◯ Enthusiastic

7. Is your company considering moving to a cloud-based solution for your PV process?
    a. ◯ Yes
    b. ◯ No
    c. ◯ We are already using a cloud-based solution

8. To what extent do you have concerns about moving to a cloud-based solution?
    a. ◯ Pessimistic
    b. ◯ Uncertain, and pessimistic
    c. ◯ Uncertain, and optimistic
    d. ◯ Hopeful
    e. ◯ Optimistic
    f. ◯ Confident
    g. ◯ We are already using a cloud-based solution

9. To what extent are you currently applying AI technology to support or manage literature intake associated with AE reports?
    a. ◯ We are not currently applying AI technology.
    b. ◯ We are currently using AI technology, but not in this area
    c. ◯ We are applying AI technology to a limited extent
    d. ◯ We are applying AI technology to manage this process

10. Are you generating regulatory Periodic reports from your PV system?
    a. ◯ Yes
    b. ◯ No
    c. ◯ Unsure
    d. ◯ Not applicable to our operations

11. If you are *not* generating regulatory Periodic reports from your PV system, is it because you find your system insufficient for this task?
    a. ◯ Yes, our system is insufficient for this task
    b. ◯ No, our PV system has the capability, but we choose not to use it
    c. ◯ No, our PV system has the capability, but we've augmented it with another system

12. To what extent do enterprise leaders feel the current PV system poses *unacceptable* risks?
    a. ◯ Unsure of their feelings
    b. ◯ They feel there is minimal risk
    c. ◯ They feel there is a moderate risk
    d. ◯ They feel there is a high degree of risk with the current system

13. To what extent do staff believe that delaying the modernization of PV/Safety programs poses *unacceptable* risks?
    a. ◯ Unsure of their feelings
    b. ◯ They feel there is minimal risk
    c. ◯ They feel there is a moderate risk
    d. ◯ They feel there is a high degree of risk with the current system

14. To what extent is the organization's leadership knowledgeable about PV systems' digitalization capabilities and features?
    a. ◯ Not at all
    b. ◯ Minimally
    c. ◯ Unsure
    d. ◯ Somewhat knowledgeable
    e. ◯ Well informed

15. To what extent has the organization planned, or undertaken, a program to assess system gaps and requirements for the digitalization of your PV/Safety processes?
    a. ◯ Not planned
    b. ◯ Planning an assessment
    c. ◯ Conducting an assessment
    d. ◯ Reviewing the results of a completed assessment

16. To what extent has the organization evaluated specific PV programs for implementation?
    a. ◯ Planning to start
    b. ◯ Identified candidate apps
    c. ◯ Evaluating candidate apps
    d. ◯ Completed evaluations
    e. ◯ Currently planning upgrades to, or implementation of, a new PV/Safety program
    f. ◯ Currently implementing upgrades to the PV/Safety program
    g. ◯ Completed upgrades to the PV/Safety program

17. To what extent has the organization dedicated resources, either among internal staff, or through the services of a third party, to assess, select, plan, and manage the implementation of a new PV system?
    a. ◯ No special allocations planned now
    b. ◯ Intend to dedicate resources in the future
    c. ◯ Planning the scope of resources
    d. ◯ Committed resources for internal staff only
    e. ◯ Committed resources for internal and external staff

18. To what extent does your organization have experience, or been involved, in selecting and implementing a new digitally enabled PV/Safety System?
    a. ◯ No experience at all
    b. ◯ Minimal experience
    c. ◯ Some experience
    d. ◯ Significant experience

19. To what extent has the organization established budgets for enhancing the PV/Safety program that includes allocating staff time for managing the implementation of a new system?
    a. ◯ There is no plan to enhance the PV/Safety program at this time
    b. ◯ There is a plan, but the team has yet to create a budget
    c. ◯ Budget being compiled
    d. ◯ Budget is in review prior to approval
    e. ◯ Budget has been approved
    f. ◯ Funds are being /have been allocated

20. **To what extent has the organization allocated time and budget for staff training on a new system?**
    a. ◯ There is no current plan to conduct staff training on the PV/Safety program
    b. ◯ Team has yet to create a plan
    c. ◯ A plan is being compiled
    d. ◯ The plan is being reviewed
    e. ◯ The plan is approved

21. **To what extent do you believe, or feel, that your current PV system provider demonstrates currency with present and planned federal regulations?**
    a. ◯ We do not have a PV system provider
    b. ◯ We feel that our PV system provider could be better informed
    c. ◯ We feel that our PV system provider is probably well informed
    d. ◯ We feel confident that our PV system provider is current with present regulations, but may not be monitoring those being planned or considered
    e. ◯ We feel confident that our PV system provider is current with present regulations, and is probably monitoring those being planned or considered
    f. ◯ We feel confident that our PV system provider is current on both present *and* planned regulations through their monitoring and reporting to us