



PV Master Suite

PV system

1. Do you have business continuity process in place?	<input type="checkbox"/> YES <input type="checkbox"/> NO
2. Do you have the document describing used definitions and abbreviations available for personnel across the processes?	<input type="checkbox"/> YES <input type="checkbox"/> NO
3. Do you have process in place establishing the quality within the pharmacovigilance process?	<input type="checkbox"/> YES <input type="checkbox"/> NO
4. Is the process establishing the quality and its implementation in the company described and available to all staff?	<input type="checkbox"/> YES <input type="checkbox"/> NO
5. Do you have matrix of the responsibility in PV processes available for all involved staff in the processes?	<input type="checkbox"/> YES <input type="checkbox"/> NO
6. Do you have in place system of trainings for all staff involved in PV processes?	<input type="checkbox"/> YES <input type="checkbox"/> NO
7. Are your computerized systems used in PV process validated for the GxP use?	<input type="checkbox"/> YES <input type="checkbox"/> NO
8. Does the QPPV have in your organization (structure) appropriate empowerment/support to establish all the mandatory pharmacovigilance duties? Is there actual information about QPPV in your PSMF?	<input type="checkbox"/> YES <input type="checkbox"/> NO
9. Do you have in place the quality objectives in your PV process and the planning how to achieve them?	<input type="checkbox"/> YES <input type="checkbox"/> NO
10. Is your pharmacovigilance system master file describing all pharmacovigilance processes?	<input type="checkbox"/> YES <input type="checkbox"/> NO
11. Is your actual pharmacovigilance system master file available in XEVMPD for your products?	<input type="checkbox"/> YES <input type="checkbox"/> NO
12. Do you have in place the quality policy for all your PV subcontractors?	<input type="checkbox"/> YES <input type="checkbox"/> NO

If you have any questions or require further clarification on the topics discussed above, please don't hesitate to reach out to us through our contact channels (info@nextpvservices.com, www.nextpvservices.com, or [LinkedIn](#)).

Team of NextPV experts is ready to support you!

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