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# Ready for pharmacovigilance inspection-USFDA

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Every Pharmacovigilance (PVG) function at one time or another, undergo governmental or health authority inspections as well as audits by license partners, internal auditors and others. Post-marketing safety data collection and adverse event reporting is a critical element of the agency's post-marketing safety surveillance program for United States Food and Drug Administration (USFDA) regulated drug products. The USFDA has several obligations for pharmaceutical companies to ensure that patient safety is considered as priority along with good pharmacovigilance practices. There is a consistent increase in efforts from USFDA inspectors to ensure that companies comply with all regulations, which is most important in terms of human interest. In cases of non-compliance, various enforcement actions can be considered by USFDA which can result in withdrawal of marketing authorization of products or other serious outcomes. An audit is necessary before an inspection, as it provides an overview of PVG activities required for identification of gaps with respect to present regulations, which is very crucial in terms of brand value.

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