PHARMACOVIGILANCE PLAN IN PLACE

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

Develop a plan for pharmacovigilance activities.

Systems and processes that ensure that information about all suspected adverse reactions that are reported, collected and collated in an accessible manner.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
▪ Pharmacovigilance plan in place	a) Process to collate and review complaints to determine if they represent reportable adverse drug events b) Process to report adverse events to the appropriate regulatory authority bodies (e.g., for FDA - CDER, CBER, CDRH) c) Develop a strategy to maintain compliance with annual reporting requirements (e.g., Product Safety Update Reports filing for the drug component)	