Global Pharmacovigilance Readiness Checklist

An extensive pharmacovigilance (PV) overview to ensure compliance with patient safety and regulatory requirements

Comprehensive Checklist of Safety Responsibilities

Building the right strategy to continually evaluate safety across the product lifecycle is complex. UBC's team of pharmacovigilance experts understand the rapidly evolving safety & regulatory landscape and have developed a PV readiness checklist to help take a comprehensive and earlier approach to safety within the drug development and commercialization process. We offer flexible solutions in any or all of these categories to make it easier to maintain patient safety and ensure high regulatory compliance. Are you ready?

SAFETY SYSTEMS

Are you investing in a comprehensive safety platform and need guidance on the market-leading features and functionality, as well as deployment?

- ☐ Global Safety Database
- ☐ Safety Reporting Functions
- ☐ Custom SQL Reporting Capabilities
- ☐ Support for Immediate Report Generation and User Support
- ☐ Inspection-ready Quality Management System Supporting PV System

DATA MIGRATION

Do you have the expertise to efficiently integrate data from multiple sources or to migrate an existing system into a new environment?

- ☐ Manual Migration
- ☐ Highly Automated Case Migration
- ☐ Quality Management and Oversight
- ☐ Legacy Data Cleaning

SIGNAL MANAGEMENT

How are you ensuring timely identification, investigation, and validation of potential safety signals?

- ☐ Qualitative and Quantitative Signal Detection and Assessment
- ☐ EudraVigilance Data Analysis System (EVDAS) Monitoring
- ☐ FDA Adverse Event Reporting System (FAERS) Public Access Monitoring

GLOBAL CASE PROCESSING

Do you have a dedicated team of trained healthcare professionals who understand the regulatory reporting requirements and nuances of the product safety profile?

- ☐ Clinical Trial Case Processing
- ☐ Post-Marketing Case Processing
- ☐ Workflow Management (Intake, Triage, Data Entry, Narrative Writing, QC, Medical Review)
- ☐ Reconciliation (SAE, Medical Information, Product Complaints, Call Center, and Partners)
- ☐ FAERS & EV Individual Case Safety Report (ISCR) Monitoring

REGULATORY REPORTING

Do you have the confidence that all regulatory submissions are country compliant for your program and will stand up to a formal regulatory audit?

- ☐ Secured Gateway Setup with Regulatory Authorities and Partners
- ☐ Electronic Regulatory Reporting (FDA & EMA)
- ☐ National Competent Authorities Regulatory Reporting (e.g., MHRA, BFARM, ANSM, PMDA)
- ☐ Partner Cross-Reporting
- ☐ Aggregate Reporting to Regulatory Authorities

PERIODIC REPORTING / SAFETY WRITING

Do you have key templates, best practices, operational standards, and structured communication approaches to address your safety writing responsibilities?

- ☐ PADER
- ☐ PSUR/PBRER
- ☐ DSUR
- ☐ Draft Responses to Regulatory Authorities
- ☐ Benefit Risk Assessment
- ☐ Two- and Six-Month Line Listings as Required by National Regulatory Authorities

SAFETY REGULATORY INTELLIGENCE

How is your organization addressing the ever-changing global clinical trial and post-marketing regulatory requirements in the markets in which you compete to ensure reporting compliance?

- ☐ Centralized Documentation of New or Changing Regulations
- ☐ Impact Analysis and Implementation in PV System
- ☐ Weekly Monitoring and Monthly Client Newsletter

PRODUCTS TO ENHANCE OPERATIONAL DELIVERY

Do you have the tools in place to streamline and simplify data mining and analytics?

- ☐ Oracle Argus Cloud Database
- ☐ Visually Impactful Tableau® Analytics Dashboards
- ☐ DistillerSR to Manage and Track Global Literature Reviews
- ☐ Case Processing Automation (Machine Learning, AI, OCR)
- ☐ UBC Signal Detection for Quantitative Safety Signal Investigation
- ☐ UBC Signal Management Software (Signal Tracking)

PROJECT-SPECIFIC PLANS

Are you confident in your ability to address your PV planning, communication with regulators, and training plan quality?

- ☐ Project Management and Communication Plan
- ☐ Operational Plans (e.g., Adverse Event Reporting Plan, Data Entry Conventions, Signal Detection Plan, Literature Review, Periodic Reporting Plan, Expedited Reporting Plan)
- ☐ Quality Agreement
- ☐ Training Plan

LITERATURE REVIEW

Is your organization and team knowledgeable about global and local literature reviews required to meet regulatory requirements?

- ☐ Define and Validate Literature Search Strategy
- ☐ Global Literature Searching
- ☐ Retrospective Literature Review
- ☐ Aggregate Reports Literature Review
- ☐ Local Literature Review

MEDICAL INFORMATION CALL CENTER

How do you communicate essential product information in the areas of drug/device information and product safety to prescribers and consumers?

- ☐ Product Quality Complaints
- ☐ Medical Inquiries
- ☐ Adverse Event Intake
- ☐ Development of FAQ Documents
- ☐ Development of Standard Response Letters (SRL)

OPERATIONAL EXPERTISE

Are you prepared to scale your critical safety responsibilities and readiness as you move toward market approval?

- ☐ Sponsor/Marketing Authorization Holder (MAH) PV System Gap Analysis
- ☐ PV Training Development and Delivery
- ☐ Mock/Global Regulatory Inspection and Audit Support
- ☐ SOP Review and Writing
- ☐ Marketing Application Dossier Support
- ☐ Safety Data Exchange Agreement Writing and Review
- ☐ Product Labeling (e.g., Investigator Brochure, Package Insert) Writing and Review
- ☐ Training Materials and Attendance at Investigator Meetings

EU PHARMACOVIGILANCE

Have you considered the set-up and maintenance of your safety system to ensure compliance with regulatory agencies in the EU?

- ☐ EU QPPV / Deputy QPPV
- ☐ Local PV Services
- ☐ EV and Extended EV Medicinal Product Dictionary (xEVMPD) Registration and Maintenance
- ☐ Pharmacovigilance System Master File (PSMF) Preparation and Maintenance
- ☐ EU Risk Management Plan (RMP) Preparation and Update

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