Pharmacovigilance Requirements in the EU - Overview with focus on specific EU needs

Legal Basis		
	Directive 2010/84/EU	amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating tomedicinal products for human use
	Regulation EC No 1235/2010	amending 726/2004 & 1394/2007
	Implementing Regulation (EU) No 520/2012	on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament
	Directive 2001/83/EC as amended	Community code relating to medicinal products for human use
	Regulation EC no 726/2004 as amended	Community procedures for the authorisation and supervision of medicinal productsfor human and veterinary use and establishing a European Medicines Agency
	Directive 2001/20/EC	implementation of good clinical practice in the conduct of clinical trials. **To be replaced by new Clinical Trial Regulation (Regulation (EU) No 536/2014)**
	EudraLex - Volume 10	Clinical Trials Guidelines. Chapter II - Safety Reporting: Detailed guidance on the collection , verification and presentation of adverse event/reaction reports arising from clinical trials (CT-3) June 2011
	New Clinical Trials Regulation No 536/2014	

GVP Module or Reg	Requirement / Task	Pre-Market	Marketing Application	Post-Market	Description
Module I & II	Qualified Person for Pharmacovigilance (QPPV)		X	X	Person based on the EEA. Medically trained or with access to medically trained person. QPPV backup. 24h/7d available contact point for EMA and authorities in the EU. Appropriate delegation of tasks documented. Sufficient authority to influence the performance of the PV system. Previously trained by the MAH in the PV system and medicinal products covered.
Module II	Pharmacovigilance System Master File (PSFM)		X	X	MAH are required to maintain a PSMF permanently available for submission or inspection. Located in the EEA (site where PV activities are performed or where QPPV is based). Required at the time of a new marketing authorisation application. Content compliant with GVP Module III - includes audit findings
Module VI & CT-3	Reporting of ADRs to EudraVigilance	X		X	Serious and non-serious ADRs for MAH in Post-Marketing phase. SUSARs Sponsors of clinical trials in the EEA.
Regulation 726/2004 & CT-3	Maintenance of XEVMPD (Extended EudraVigilance Medicinal Product Dictionary)	X		X	For all Investigational and Authorised products.
Module IX	Signal Detection in EudraVigilance performed by MAH			X	All MAH required to monitor signals from EVDAS. 1-year Pilot phase since 22 Feb 2018 only MAH of products on the Pilot List. At 6 months frequency as minimum. More frequent for additional monitoring products.
Module VI	Literature monitoring			X	EMA responsible for monitoring of substances included in List; MAH- screen substances not on the List & Local publications
Module VII	Non-interventional safety studies (PASS, PAES)			X	PASS may be required at the time of marketing authorisation (MA) application and be a condition of the MA imposed by HA. EMA & PRAC Oversight (multinational >1 country; Member State (National = 1 country). Oversight of protocol agreements & results assessment.
Module II	Article 57 Database (Regulation (EC) No 726/2004			X	Listing of all medicinal products authorised in the EU. Product-related data, contact information for the QPPV and the location of PSMF.
Module V	Risk Management Plans		X	X	Required for all products authorised in the EU and at the time of initial marketing authorisation applications.
Module XVI	Effectiveness of Risk Minimization Measures (RMM)			X	
Module VII	Periodic Safety Update Reports (PSUR, in PBRER Format)			X	
EudraLex Volume 10 - Chapter II ICHE2F	Development Safety Update Reports (DSUR)	X			
Dir 2001/83/EC & Reg 726/2004	Monitoring of PRAC & CHMP Assessments, and EMA web portal			X	
Module I & II	Performance Indicators			X	To continuously monitored the good performance of PV activities. Critical processes defined in Module I, II. Specifics for each process in each relevant module of GVPs.
Module III & EudraLex Volume 10	Inspections	X		X	
Module IV & EudraLex Volume 10	Audits	X		X	Active audit program. Audit plans to include global processes that impact products in the EEA. List of Audit findings to be included in PSMF. Risk-based audits at regulat intervals, conducted by individuals with no direct involvement in the matters being audited. CAPA actions including Follow-up audits of deficiencies arranged were necessary.