dcvmn
Developing Countries Vaccine Manufacturers Network

Acronyms and Abbreviations

ADR	Adverse Drug Reaction
AE	Adverse Event
AEFI	Adverse Event following Immunization
ASR	Annual Study Report
BCPNN	Baysian Confidence Propagation Neural Network
B / R	Benefit / Risk
BRMP	Benefit Risk Management Plan
CAPA	Corrective and Preventive Action
CCDS	Company Core Data Sheet
CCSI	Company Core Safety Information
CFR	Code of Federal Regulation
CIOMS	Council for International Organizations of Medical Sciences
CHMP	Committee for Medicinal Products for Human Use
CSR	Clinical Study Report
CTD	Common Technical Document
DCSI	Developmental Core Safety Information
DHPC	Direct Health Care Professional Communication
DLP	Data Lock Point
DIBD	Development International Birth Date
DRMP	Development Risk Management Plan
DSUR	Development Safety Update Report
EBS	Empiric Baysian Screening
EB05	Fifth percentile of EBGM
EBGM	Empirical Baysian Geometric Mean
EMA	European Medicines Agency
ESTRI (M2)	Electronic Standards for Transmission of Regulatory Information

EU	European Union
FDA	Food and Drug Administration (USA)
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
GVP	Good PharmacoVigilance Practice
HCP	Health Care Professional
IB	Investigator's Brochure
IBD	International Birth date
ICH	International Council on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICSRs	Individual Case Safety Reports
ISO	International Organization for Standardization
KAP	Knowledge, Attitude, Practices
LSST	Large Simple Safety Study
MA	Marketing Authorization
MAH	Marketing Authorization Holder
MedDRA	Medical Dictionary for Regulatory Activities
MHRA	Medicines and Healthcare products Regulatory Agency (UK)
MGPS	Multi-item gamma poisson shrinker
NDA	New Drug Application
PASS	Post-Authorization Safety Study
PADER	Periodic Adverse Drug Experience Report
PBRER	Periodic Benefit Risk Evaluation Report
PMS	Post Marketing Safety Study
PRR	Proportional Reporting Ratio
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance
QPPV	Qualified Person for Pharmacovigilance

RA	Regulatory Affairs Department
REMS	Risk Evaluation and Mitigation Strategy
RM	Risk Management
RMM	Risk Minimization Measures
RMP	Risk Management Plan
RMS	Risk Management System
RSI	Reference Safety Information
SAE	Serious Adverse Event
SA(D)R	Serious Adverse (Drug) Reaction
SMT	Safety Management Team
SmPC /SPC	Summary of Product Characteristics
SOP	Standard Operating Procedure
SPC	Summary of Product Characteristics
SUSAR	Suspected Serious Unexpected Adverse Reactions
TOC	Table of Content
VacSCP	Vaccine Safety Communication Plan
VAERS	Vaccine Adverse Event Reporting System (US vaccine safety database)
Vigibase	WHO global ICSR database
WHO	World Health Organization