FORUM

Abbreviation list
Drug Regulatory Affairs/CMC

A

AAS	Atomic absorption spectroscopy
AE	Adverse Event
AF	Application Form
API	Active Pharmaceutical Ingredient
AR	Assessment Report
AR/ADR	Adverse Reaction/Adverse Drug Reaction
ARD	Applicant's Response Document
ASMF	Active Substance Master File
ASR	Annual Safety Report
ATMP	Advanced Therapeutic Medicinal Products
AUC	Area under curve

B

BCS	Biopharmaceutics Classification System
BE	Bioequivalence
BMWP	Biosimilar Medicinal Products Working Party
BOS	Break-Out Session
BPG	Best Practice Guide
BWP	Biotechnology Working Party

C

CA	Competent Authority
CAB	Change Advisory Board
CAP	Centralised Authorised/Approved Product
CAPA	Corrective and Preventive Actions
CAT	Committee for Advanced Therapies
CCDS	Company Core Data Sheet
CCSI	Company Core Safety Information
CDS	Core Data Sheet
CD	Community Directive or Commission Decision
CEP	Certificate of Suitability to the monographs of the European Pharmacopoeia

CESP	Common European Submission Platform
CESSP	Common European Single Submission Portal
CHMP	Committee for Medicinal Products for Human Use (former CPMP)
CI	Confidence Interval
CIOMS	Council for International Organisations of Medical Sciences
CMA	Critical Material Attribute
C_{max}	Maximum plasma concentration
CMC	Chemistry Manufacturing and Controls
CMD(h)	Coordination Group for Mutual Recognition and Decentralised Procedures - human
CMD(v)	Coordination Group for Mutual Recognition and Decentralised Procedures - veterinary
CMO	Contract Manufacturing Organisation
CMS	Concerned Member States
CO	Clinical Overview
COMP	Committee for Orphan Medicinal Products
CoS	Certificate of Suitability
CP	Centralised Procedure
CPP	Critical Process Parameters
CPV	Continuous Process Verification
CQA	Critical Quality Attribute
CR	Controlled Release
CRA	Clinical Research Associate
CRD	Common Renewal Date
CRF	Case Report Form
CRO	Clinical Research Organisation
CRS	Chemical reference substances
CS	Clinical Summary
CSI	Core Safety Information
CSR	Clinical Study Report
CT	Clinical Trial
CTA	Clinical Trial Application
CTD	Common Technical Document
CTS	Communication Tracking System
CVMP	Committee for Medicinal Products for Veterinary Use

D

D	Day
DAR	Draft Assessment Report (DCP)
DCP	Decentralised Procedure
DDL	Dear Doctor Letter
DDPS	Detailed Description of the Pharmacovigilance System
DHPC	Direct Healthcare Professional Communication
DMC	Data Monitoring Committee
	(= Data and Safety Monitoring Board (DSMB))
DME	Designated Medical Event
DMF	Drug Master File
DoE	Design of Experiments
DP	Drug Product
DRA	Drug Regulatory Affairs
DS	Drug Substance
DSUR	Development Safety Update Report
DUS	Drug Utilisation Study

E

eAF	electronic Application Form
EC	Established Condition
EC	Ethics committee
eCTD	electronic Common Technical Document
EDMF	European Drug Master File
EDQM	European Directorate Quality of Medicines
EEA	European Economic Area (EU + IS, NO, LI)
EMA	European Medicines Agency (www.ema.europa.eu)
EPAR	European Public Assessment Report
ERA	Environmental Risk Assessment
EU	European Union
EudraCT	European Clinical Trials Database
EUDRANET	European Union Drug Regulatory Authorities Network (EMA)
EURD-List	List of European Reference Dates
	and Frequency of PSUR Submission
ECJ	European Court of Justice (curia.eu.int)

ERA	Environmental Risk Assessment
EUTCT	The European Union Telematics Controlled Terms
EVMPD	EudraVigilance Medicinal Product Dictionary (→ XEVMPD)
EWG	Expert Working Group
EWP	Efficacy Working Party

F

FAR	Final Assessment Report
FDA	Food and Drug Administration
FFP	Finished Pharmaceutical Product
FMEA	Failure Mode and Effects Analysis
FRAR	Final Renewal Assessment Report
FUM	Follow Up Measures
FVAR	Final Variation Assessment Report

G

GCC Countries	Golf Cooperation Countries
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GVP	Good Pharmacovigilance Practice

H

HA	Health Authority
HCl	Hydrochloric acid
HCP	Healthcare Professional
HMA	Head of Medicines Agencies (www.hma.eu)
HMP	Herbal Medicinal Products
HTA	Health Technology Assessment
HVAC	Heating, Ventilation, and Air Conditioning

I

IB	Investigators Brochure
IBD	International Birth Date
IC	Informed consent
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMRA	International Coalition of Medicines Regulatory Agencies
ICP	Inductively coupled plasma
ICSR	Individual Case Safety Report
IDMP	Identification of Medicinal Products
IGDRP	International Generic Drug Regulators Programme
IIT	Investigator Initiated Trial
IME	Important Medical Event
IMPD	Investigational Medicinal Product Dossier
INN	International Non-proprietary Name
IP	Intellectual property
IPC	In Process Control
IPRF	International Pharmaceutical Regulators Forum
IR	Infrared
IRB	Institutional Review Board
ISE	Integrated Summary of Efficacy
ISO	International Organization for Standardization
ISPE	International Society for Pharmaceutical Engineering
ISRB	Integrated Summary of Risk Benefit
ISS	Integrated Summary of Safety
IVIVC	In-Vitro In-Vivo Correlation

K

KPI	Key Performance Indicator
KOL	Key Opinion Leader

L

LCM	Lifecycle Management
LOD	Limit of Detection
LoOI	List of Outstanding Issues
LoQ	Limit of Quantitation
MAA	Marketing Authorisation Application
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
MDM	Master Data Management
MedDRA	Medical Dictionary for Drug Regulatory Affairs
MERS	Multi-agency Electronic Regulatory System
MICE	Medicine in Children (EU Initiative)
MRA	Mutual Recognition Agreement
MRFG	Mutual Recognition Facilitation Group (until 2005)
MRI	Mutual Recognition Information (i.e. MRI Product Index)
MRP	Mutual Recognition Procedure
MS	Mass Spectometry

N

NAP	National Authorised Product
NBE	New Biological Entity
NCA	National Competent Authority
NCE	New Chemical Entity
NeeS	Non eCTD Electronic Submission
NIS	Non-Interventional Study
NMR	Nuclear Magnetic Resonance
NOR	Normal Operation Range
NtA	Notice to Applicants

O

OOS	Out of Specification
OTC	Over-the-Counter
OMS	Organisations Management Services

P

PACMP	Post-Approval Change Management Protocol
PAES	Post Authorisation Efficacy Study
PAI	Pre approval inspection
PAM	Post Authorisation Measures
PAR	Proven Acceptable Range
PASS	Post Authority Safety Study
PAT	Process Analytical Technology
PBRER	Periodic Benefit-Risk Evaluation Report
PDCO	Paediatric Committee of the European Comission
PDE	Permitted Daily Exposure
Ph. Eur.	European Pharmacopoeia
PIL	Patient Information Leaflet
PIP	Pediatric Investigation Plan
PL	Package Leaflet
PLCM	Product Life Cycle Management
PMF	Plasma Master File
PMS	Product Management Services
POM	Prescription-only Medicines
PrAr	Preliminary Assessment Report
PRAC	Pharmacovigilance Risk Assessment Advisory Committee
PSD	Particle Size Distribution
PSMF	Pharmacovigilance System Master File
PSRPH	Potential Serious Risk to Public Health
PSUR(s)	Periodic Safety Update Report(s)
PSUSA	PSUR Single Assessment Procedure
PUMA	Paediatric Use Marketing Authorisation
PV/PhV	Pharmacovigilance
PVAR	Preliminary Variation Assessment Report
PVS	Pharmacovigilance System

Q

Q&A	Questions and Answers
QBR	Question based Review
QBD	Quality by Design
QOS	Quality Overall Summary
QP	Qualified Person
QPPV	Qualified Person for Pharmacovigilance
QRD	Quality Review of Documents
QTPP	Quality Target Product Profile
QWP	Quality Working Party

R

RA	Regulatory Affairs
RMM	Risk Minimisation Measures
RMP	Reference Medicinal Product
RMP	Risk Management Plan
RMS	Reference Member State
RMS	Referentials Management Services
RSI	Request for Supplementary Information
RUT	Readability User Test

S

SA	Scientific Advice
SAE	Serious Adverse Event
SAWP	Scientific Advice Working Party
SME	Small and Medium enterprises
SmPC	Summary of Product Characteristics
SMS	Substance Management Services
SOP	Standard Operation Procedure
SPC	Supplementary Protection Certificate
SPOR	Substance, Product, Organisation, Referentials

SSI	Structured Substance Information file
SUSAR	Suspected Unexpected Serious Adverse Reaction
SWP	Safety Working Party

T

THMP	Traditional Herbal Medicinal Product
T_{max}	Time to reach maximum plasma concentration
TME	Targeted Medical Event
TOC	Table of Contents
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TT	Timetable

U

USP	United States Pharmacopoeia

V

VAMF	Vaccine Antigen Master File

W

WHO	World Health Organisation
WS	Worksharing (e.g. with variations)

X

XEVMPD	Extended Eudravigilance Medicinal Product Dictionary
XEVPRM	EudraVigilance Product Report Message
XML	Extensible Markup Language
XRF	X-ray fluorescence

Other offers

Practical regulatory affairs and vigilance knowledge

Our regulatory courses and conferences provide practical information on the fundamentals and trends in marketing authorisation, regulatory maintenance and post-marketing surveillance. More information.

e-Learning – Click and learn

The FORUM Institut offers a flexible form of training with quality e-learning courses.
You decide for yourself when and where to learn. Test free now.

In-house seminars – Tailored solutions

All our seminars are also perfect for in-house training.
Request a personalised quotation now.

FORUM · Institut für Management GmbH · Vangerowstraße 18 · 69115 Heidelberg · Germany
Phone: +49 6221 500-500 · Fax: +49 6221 500-555 · www.forum-institut.com