FORUM

Abkürzungsverzeichnis Arzneimittelzulassung/CMC

A

AE	Adverse Event
AF	Application Form (s. auch eAF)
AGES	Agentur für Gesundheit und Ernährungssicherheit
AkdÄ	Arzneimittelkommission der Ärzte
ALBVVG	Arzneimittel-Lieferengpassbekämpfungs- und Versorgungsverbesserungsgesetz
AM	Arzneimittel
AMG	Arzneimittelgesetz
AMWHV	Arzneimittel- und Wirkstoffherstellungsverordnung
AMNOG	Arzneimittelmarktsneuordnungsgesetz (frühe Nutzenbewertung hierin beschrieben)
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
ATC-Code	Anatomisch Therapeutisch Chemischer Code der WHO
ATMP	Advanced Therapeutic Medicinal Products
AWB	Anwendungsbeobachtung

B

BA-/ BE-Studien	Bioäquivalenzstudien
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte
BMG	Bundesministerium für Gesundheit (www.bmg.bund.de)
BMWP	Biosimilar Medicinal Products Working Party
BOB	Bundesoberbehörde
BOS	Break-Out Session
BPG	Best Practice Guide
BVL	Bundesinstitut für Verbraucherschutz und Lebensmittelsicherheit
BWP	Biotechnology Working Party

C

CA	Competent Authority
CAB	Change Advisory Board
CAP	Centralised Authorised/Approved Product
CAPA	Corrective And Preventive Actions
CAR-T	Chimeric Antigen Receptor-T-Lymphozyten (gentechnologisch veränderte T-Zellen)
CAT	Committee for Advanced Therapies
CCDS	Company Core Data Sheet
CCSI	Company Core Safety Information
CDS	Core Data Sheet
CD	Community Directive oder Commission Decision
CEP	Certificates of Suitability
CESP	Common European Submission Platform
CESSP	Common European Single Submission Portal
CHMP	Committee for Medicinal Products for Human Use (früher CPMP)
CIOMS	Council for international organisations of medical sciences
CMC	Chemistry, Manufacturing, Control
CMD(h)	Coordination Group for Mutual Recognition and Decentralised Procedures - human
CMD(v)	Coordination Group for Mutual Recognition and Decentralised Procedures - veterinary
CMS	Concerned Member States
CO	Clinical overview
COMP	Committee for Orphan Medicinal Products
CP	Centralised Procedure
CPP	Certificate of Pharmaceutical Product
CR	Controlled release
CRA	Clinical Research Associate (“Monitor”)
CRD	Common Renewal Date
CRF	Case Report Form
CRO	Clinical Research Organisation
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
DIMDI	Deutsches Institut für Medizinische Dokumentation und Information
DMC	Data Monitoring Committee (= Data and Safety Monitoring Board (DSMB))
DME	Designated Medical Event
DMF	Drug Master File
DP	Drug Product
DRA	Drug Regulatory Affairs
DS	Design Space oder Drug Substance
DSUR	Development Safety Update Report
DUS	Drug Utilisation Study

E

eAF	Electronic Application Form
EC	Ethikkommission /Ethics committee
eCTD	Electronic Common Technical Document
EDMF	European Drug Master File

EDQM	European Directorate Quality of Medicines
EEA	Europäischer Wirtschaftsraum (EU + IS, NO, LI)
EK	Ethikkommission
EMA	European Medicines Agency (www.ema.europa.eu)
EPAR	European Public Assessment Report
ePI	elektronische Produktinformation
ERA	Environmental Risk Assessment
EU	European Union
EudraCT	European Clinical Trials Database
EUDRANET	European Union Drug Regulatory Authorities Network
EURD-List	List of European Reference Dates and Frequency of PSUR Submission
EuGH	Europäischer Gerichtshof (curia.eu.int)
EUTCT	The European Union Telematics Controlled Terms
EVMPD	EudraVigilance Medicinal Product Dictionary (siehe auch XEVMPD)
EWG	Expert Working Group
EWP	Efficacy Working Party
EWR	Europäischer Wirtschaftsraum

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

GA	Gegenanzeige
G-BA	Gemeinsamer Bundesausschuss
GCC	Countries Golf Cooperation Countries
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GK	Gemeinschaftskodex, Richtlinie 2001/83/EG
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GSAV	Gesetz für mehr Sicherheit in der Arzneimittelversorgung
GVP	Good Pharmacovigilance Practice

H

HA	Health Authority
HCP	Healthcare Professional
HMA	Head of Medicines Agencies (www.hma.eu)
HMP	Herbal Medicinal Products
HTA	Health technology assessment
HWG	Heilmittelwerbegesetz

I

IB	Investigators Brochure
IBD	International Birth Date
IC	Informed consent
ICH	International Conference on Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use)
ICMRA	International Coalition of Medicines Regulatory Agencies
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
IPRF	International Pharmaceutical Regulators Forum
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen
IRB	Institutional review board
ISE	Integrated summary of efficacy
ISRB	Integrated summary of risk benefit
ISS	Integrated summary of safety

K

KPI	Key Performance Indicator
KOL	Key opinion leader
Kom	Europäische Kommission (pharmacos.eudra.org)

L

LCM	Lifecycle Management
LoQI	List of Outstanding Issues
LoQ	List of Questions

M

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)
MPG	Medizinproduktegesetz
MRA	Mutual recognition agreement
MRFG	Mutual Recognition Facilitation Group (gab es bis 2005)
MRI	Mutual Recognition Information (i.e. MRI Product Index)
MRP	Mutual Recognition Procedure
MS	Member States

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
NtA	Notice to Applicants
NW	Nebenwirkung

O

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

P

PAES	Post Authorisation Efficacy Study
PAM	Post Authorisation Measures

PASS	Post Authority Safety Study
PBRER	Periodic Benefit-Risk Evaluation Report
PDCO	Paediatric Committee der EU-Kommission
PEI	Paul-Ehrlich-Institut, Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel (www.pei.de)
PIL	Patient Information Leaflet
PIP	Pediatric Investigation Plan/pädiatrisches Prüfkonzept
PL	Package leaflet
PLM-Portal	Product Lifecycle Management Portal
PMF	Plasma Master File
PMS	Product Management Services
PNR	Pharmazeutische Unternehmernummer
POM	Prescription-only Medicines
PrAr	Preliminary Assessment Report
PRAC	Pharmacovigilance Risk Assessment Advisory Committee
PSMF	Pharmacovigilance System Master File
PSRPH	Potential Serious Risk to Public Health
PSUR(s)	Periodic Safety Update Report(s)
PSUSA	PSUR Single Assessment Procedure
PU	Pharmazeutischer Unternehmer
PUMA	Paediatric Use Marketing Authorisation
PV/PhV	Pharmakovigilanz
PVAR	Preliminary Variation Assessment Report
PVS	Pharmacovigilance System

Q

Q&A	Questions and Answers
QM(S)	Qualitätsmanagement(system)
QOS	Quality Overall Summary
QP	Qualified Person
QPPV	Qualified Person for Pharmacovigilance
QRD	Quality Review of Documents
QS	Qualitätssicherung
QWP	Quality Working Party

R

RKI	Robert-Koch-Institut (www.rki.de)
RL	Richtlinie
RMM	Risk minimisation measures
RMP	Reference Medicinal Product
RMP	Risk Management Plan
RMS	Reference Member State
RMS	Referentials Management Services
RP	Regierungspräsidium
RSI	Request for Supplementary Information
RUT	Readability User Test
Rx	Verschreibungspflichtig

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 Certificat
SPOR	Substance, Product, Organisation, Referentials
SSI	Structured Substance Information fil
SUSAR	Suspected Unexpected Serious Adverse Reaction
SWP	Safety Working Party

T

THMP	Traditional Herbal Medicinal Product
TME	Targeted Medical Event
TOC	Table of Content
TOS	Therapieoptimierungsstudie
TSE	Transmissible Spongiforme Enzephalopathie
TT	Timetab

U

UAW	Unerwünschte Arzneimittelwirkung

V

VAMF	Vaccine Antigen Master File

W

WH	Warnhinweise
WHO	World Health Organisation
WS	Worksharing (z. B. bei Variations)
WW	Wechselwirkungen

X

XEVMPD	Extended Eudravigilance Medicinal Product Dictionary
XEVPRM	EudraVigilance Product Report Message
XML	Extensible Markup Language

Z

ZLG	Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten

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