FORUM

Abbreviation list Medical Devices

A

AAMI	Association for the Advancement of Medical Instrumentation
ADE	Adverse Drug Event/Adverse Device Effect
ADR	Adverse Drug Reaction(s) (side effect)
AE	Adverse Event
AER	Adverse Event Reporting
AF	Application Form
AIMD	Active Implantable Medical Devices
AIMDD	Active Implantable Medical Devices Directive
ANSI	American National Standards Institute
API	Active Pharmaceutical Ingredient
AR	Assessment Report
AR/ADR	Adverse Reaction/Adverse Drug Reaction
ARD	Applicant's Response Document
ASADE	Anticipated Serious Adverse Drug Event
ASHIPs	Associations of Statutory Health Insurance Physicians in Germany (Kassenärztliche Vereinigungen)
ASMF	Active Substance Master File
ASR	Annual Safety Report
ATC-Code	Anatomical Therapeutic Chemical Classification System
ATD	Anti Tampering Device
ATMP	Advanced Therapy Medicinal Products
ATP	Adenosintriphosphate
Aut idem	lat. „or the same"

B

BAFA	Bundesamt für Wirtschaft und Ausfuhrkontrolle = Federal Office for Economic Affairs and Export Control
BER	Biological Evaluation Report
BfArM	German Federal Institute for Drugs and Medical Devices (www.bfarm.de/EN/home)

BfR	German Federal Institute for Risk Assessment (www.bfr.bund.de)
BMBF	German Federal Ministry of Education and Research
BMG	German Federal Ministry of Health (www.bmg.bund.de)
BMWP	Biosimilar Medicinal Products Working Party
BPG	Best Practice Guide
BSI	German Federal Office for Security in Information Technology
BSI	British Standards Institution
BVL	German Federal Office of Consumer Protection and
BVMed	German Federal Association of Medical Technology
BWP	Biotechnology Working Party

C

CA	Competent Authority
CAB	Change Advisory Board
CAMD	Competent Authorities for Medical Devices
CAP	Centralized Authorized/Approved Product
CAPA	Corrective and Preventive Action
CAT	Committee for Advanced Therapies
CCDS	Company Core Data Sheet
CCSI	Company Core Safety Information
CDP	Clinical Development Plan
CDRH	FDA's Center for Devices and Radiological Health (CDRH regulates the manufacture of radiation emitting electronic products)
CDS	Core Data Sheet
CE	Communauté Européenne, CE-Mark
CE	Clinical Evaluation
CEAR	Clinical Evaluation Assessment Report
CECP	Clinical Evaluation Consultation Procedure
CEN	Comité Européen de Normalisation
CENELEC	European Committee for Electrotechnical Standardization
CEP	Clinical Evaluation Plan
CER	Clinical Evaluation Report
CES	Certificates of Suitability

CESP	Common European Submission Platform
CFR	Code of Federal Regulations
CHMP	Committee for Medicinal Products for Human Use
C.I.A.	Confidentiality, Integrity, Availability (–Triade)
CIE	Clinical Investigations and Evaluation
CIOMS	Council for international organizations of medical sciences
CIP	Clinical Investigation Plan
CIV ID	Clinical Investigation Identification Number (generated by Eudamed)
CLP	CLP-Verordnung - Classification, Labelling, Packaging
CMC	Chemistry, Manufacturing, Control
CMD(h)	Coordination Group for Mutual Recognition and Decentralized Procedures
CMO	Contract Manufacturing Organization
CMR	Carcinogenic, Mutagenic or toxic to Reproduction
CMS	Concerned Member States
CND	Classificazione Nazionale Dispositivi Medici (also see Eudamed, EMDN and GMDN)
COCIR	European Coordination Committee of the Radiological Electromedical and Healthcare IT Industry
CoE	Council of Europe
COMP	Committee for Orphan Medicinal Products
CP	Centralized Procedure
CPP	Certificate of Pharmaceutical Product
CRA	Clinical Research Associate (“Monitor”)
CRD	Common Renewal Date
CRF	Case Report Form
CRM	Customer Relation Management (System)
CRO	Clinical Research Organization
CS	Common Specifications
CSDB	Corporate Serial number Data Base
CSR	Clinical Study Report
CT	Computed-Tomography
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	Decentralized Procedure
DD	Device Deficiencies
DDCP	Drug Device Combination Products
DDL	Dear Doctor Letter
DDPC	Drug Device Product Combination
DDPS	Detailed Description of the Pharmacovigilance System
DES	Data Encryption Standard
DG	Directorate-General
DHT	Digital Health Technologies
DiGA	German: Digital Health Application
DIN	German Institute for Standardization
DIS	Draft International Standard
DHPC	Direct Healthcare Professional Communication
DHF	Design History File
DMC	Data Monitoring Committee (see DSMB)
DMF	Drug Master File
DMR	Device Master Record
DMP	Disease Management Program
D&O	Directors-and-Officers
DoC	Declaration of Conformity
DPIA	Data Protection Impact Assessment (see PIA)
DRA	Drug Regulatory Affairs
DRG	Diagnosis Related Groups
D-RIA	Design Risk Assessment (see RIA)
DSMB	Data and Safety Monitoring Board
DSUR	Development Safety Update Report
DQ	Design Qualification (see IQ, OQ, PQ)

E

EAEPC	European Association of Euro-Pharmaceutical Companies
eAF	Electronic Application Form
EAN	European Article Number, now GTIN
E.A.R.	European Authorized Representative
EBM	Uniform valuation scale (remuneration system for SHI-accredited physicians and SHI-accredited psychotherapists in Germany) (see ASHIPs and NASHIP)
ECC	Error Correction Code
ECHA	European Chemicals Agency
eCTD	Electronic Common Technical Document
EDI	Electronic Data Interchange
EDIB	European Data Innovation Board
EDMA	European Diagnostic Manufacturers Association
EDMF	European Drug Master File
EDBA	European Data Protection Board (see EDSA)
EDSA	European Data Protection Board
EDQM	European Directorate Quality of Medicines
EEA	European Economic Association (EU, IS, NO, LI)
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EMA	European Medicines Agency
EMBO	European Molecular Biology Organization
EMDN	European Medical Device Nomenclature (see GMDN)
EMEA/EMA	European Medicines Agency (www.ema.europa.eu)
EMVO	European Medicines Verification Organization
EMVS	European Medicines Verification System
EN	European Norm
EO	Economic Operator
EOS/EoS	End of Service
EPAR	European Public Assessment Report
ERB	Ethical Review Board (see IEC, IRB, REB)
ERP	Enterprise Resource Planning
ESG	Environmental, Social and Governance

ESM	European Stakeholder Model (now EMVO)
ETSI	European Telecommunications Standards Institute
EUDAMED	European Database on Medical Devices
EUDRANET	European Union Drug Regulatory Authorities Network (EMA)
EUDRAGMDP	Electronic tool containing complete information on all pharmaceutical manufacturers
EUTCT	European Union Telematics Controlled Terms
EVMPD	Eudra Vigilance Medicinal Product Dictionary
Expamed	Expert panels on medical devices and in vitro diagnostic medical devices
ExP	Expert Panel(s)

F

FAS	Full Analysis Set
FAT	Factory Acceptance Test (see SAT)
FAQ	Frequently Asked Questions
FDA	US Food and Drug Administration
FFP	Finished Pharmaceutical Product
FMD	Falsified Medicines Directive (Directive 2011/62/EU)
FMEA	Failure Mode and Effects Analysis
FMECA	Failure Mode and Effects and Criticality Analysis
FRAR	Final Renewal Assessment Report
FSCA	Field Safety Corrective Action
FSMP	Food for special medical purposes
FSN	Field Safety Notice
FTA	Fault Tree Analysis
FUM	Follow Up Measures
FVAR	Final Variation Assessment Report

G

GAMP	Good Automated Manufacturing Practice
GCP	Good Clinical Practice
GDP	Good Distribution Practice/Good Documentation Practice
GDPR	General Data Protection Regulation
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
GHTF	Global Harmonization Task Force (now IMDRF)
GLP	Good Laboratory Practice
GMDN	Global Medical Device Nomenclature for the purpose of regulatory data exchange (see EMDN)
GMP	Good Manufacturing Practice
GS1	International organization developing and maintaining standards including barcodes (GS: Global Standards) (https://www.gs1.org/)
GSP	Good Storing Practice
GSPR	General Safety and Performance Requirements
GTIN	Global Trade Identifier Number in GS1-System
GUI	Graphical User Interface
GVP	Good Pharmacovigilance Practice
GxP	Good “Spacer for Guideline“ Practice

H

HAS	Haute Autorité de Santé (french HTA agency)
HACCP	Hazard Analysis and Critical Control Points
HASOP	Health Assessments Standard Operation Procedure
HAZOP	Hazard and Operability
HCP	Health Care Professionals
HIMSS	Healthcare Information and Management Systems Society
HMA	Head of Medicines Agencies (www.hma.eu)
HMP	Herbal Medicinal Products
HTA	Health Technology Assessment

I

IAEA	International Atomic Energy Agency
IB	Investigator‘s Brochure
IBD	International Birth Date
IEC	International Electrotechnical Commission
ICD	International Classification of Diseases
ICF	Informed Consent Form
ICH	International Conference on Harmonization (of Technical Requirements for Registration of Pharmaceuticals for Human Use)
ICH-GCG	ICH-Global Cooperation Group
ICMJE	International Committee of Medical Journal Editors
ICMRA	International Coalition of Medicines Regulatory Agencies
ICRP	International Commission on Radiological Protection
ICSR	Individual Case Safety Report
ID	Identification/Identity/Identifier
IDMP	Identification of Medicinal Products
IEC	International Engineering Consortium
IEC	Independent Ethics Committee (see ERB, IRB, REB)
IFU	Instructions for Use
IGDRP	International Generic Drug Regulators Pilot
IIS	Investigator Initiated Study/Studies (see IIT/IST)
IIT	Investigator Initiated Trial
IST	Investigator Sponsored Trial
ITT	Intent-to-Treat
IMDRF	International Medical Device Regulators Forum (former GHTF)
IMPACT	International Medicinal Products Anti-Counterfeiting Taskforce of WHO
IMPD	Investigational Medicinal Product Dossier
IMRaD	Introduction, Methods (materials & methods) Results and Discussion (see EMED)
INN	International Non-proprietary Name
IPEC	International Pharmaceutical Excipient Council
IPRF	International Pharmaceutical Regulators Forum
IQ	Installation Qualification (see DQ, OQ, PQ)

IRB	Institutional Review Board (see ERB, IEC, REB)
ISF	Investigator Site File
ISM	Industrial, Scientific, Medical (Applications)
ISO	International Organization for Standardization
IT	Information Technology
IVD	In vitro diagnostic(s)
IVDD	In Vitro Diagnostic Directive
IVDR	In Vitro Diagnostic Regulation

J-L

JIF	Journal Impact Factor
JRC	Joint Research Center
LC	Life Cycle
LCM	Life Cycle Management (see PLCM)
LIS	Laboratory Information System
LoE	Level of Evidence
LOINC	Logical Observation Identifiers Names and Codes
LoQ	List of Questions
LoOI	List of Outstanding Issues
LRA	Litigation Risk Assessment

M

MA	Marketing Authorization
MAA	Marketing Authorization Application
MAH	Marketing Authorization Holder
MAID	Manufacturer, Authorized Representative, Importer, Distributor
MAUDE	Manufacturer and User Facility Device Experience (Database)
MD	Medical Device(s)
MDA/MDN/ MDS/MDT	Medical device codes for the typology and mapping of devices and resource allocation in conformity assessment
MDCG	Medical Device Coordination Group

MDD	Medical Device Directive
MDEG	Medical Devices Expert Group
MDR	Medical Device Regulation
MDSW	Medical Device Software
MEDDEV	Guides for the application of the EC directives for medical devices, MEDical DEVices
MedDRA	Medical Dictionary for Drug Regulatory Affairs
MedTech Europe	Alliance of European Medical Technology Industry Association
MES	Manufacturing Execution System
MFR	Manufacturer
MHRA	Medicines and Healthcare products Regulatory Agency (UK)
MICE	Medicine in Children (EU Initiative)
MIR	Manufacturer Incident Report (MIR)
MOOSE	Meta-analysis of Observational Studies in Epidemiology
MRA	Mutual Recognition Agreement
MRFG	Mutual Recognition Facilitation Group (until 2005)
MRP	Mutual Recognition Procedure
MRSA	Methicillin-resistant Staphylococcus aureus
MS	Member States

N

N	Packing size N1, N2, N3
NAP	National Authorized Product
NB	Notified Body
NBE	New Biological Entity
NB-MED	Notified Bodies for medical devices
NBOG	Notified Body Operations Group
NCA	National Competent Authority
NCAR	National Competent Authority Report
NCCT	Non-commercial clinical trial
NCE	New Chemical Entity
NeeS	Non eCTD Electronic Submission
NEMA	National Electrical Manufacturers Association

NGS	Next Generation Sequencing
NHRN	National Healthcare Reimbursement Number
NICE	National Institute for Health and Clinical Excellence in UK
NIS	Non-Interventional Study
NIST	National Institute for Standards and Technology
NMPA	National Medical Products Administration (former CFDA China Food and Drug Administration) (http://english.nmpa.gov.cn/)
NMVO	National Medicines Verification Organization
NMVS	National Medicines Verification System
NtA	Notice to Applicants
NTIN	National Trade Identifier Number

O

OBP	Onboarding Partner
OEE	Overall Equipment Effectiveness
OEM	Original Equipment Manufacturer
OOS	Out of Specification
OQ	Operational Qualification (see DQ, IQ, PQ)
OTC	Over the Counter (drug or medical device)
OTSC	Over-The-Scope-Clip (endoscopic clip)

P

PAES	Post Authorization Efficacy Study
PAM	Post Authorization Measures
PANGEA	International effort to disrupt online sale of counterfeit and illicit health products of INTERPOL
PASS	Post Authority Safety Study
PBRER	Periodic Benefit-risk Evaluation Report
PC	Product Code
PDCO	Pediatric Committee (of EMA)

PE	Performance Evaluation
PEP	Performance Evaluation Plan
PER	Performance Evaluation Report
PFAS	Per- and Polyfluoroalkyl Substances
PHA	Process Hazard Analysis or Preliminary Hazard Analysis
PhVWP	Pharmacovigilance Working Party
PIA	Privacy Impact Assessment (see DPIA)
PICO	Population, Intervention, Control, Outcome
PIL	Patient Information Leaflet
PIP	Pediatric Investigation Plan
PL	Package Leaflet
PLCM	Product Life Cyle Management (see LCM)
PLM	Privat Label Manufacturer
PMDA	Pharmaceuticals and Medical Devices Agency (japanese supreme authority)
PMCF	Post-market Clinical Follow-up
PMCFP	Post-market Clinical Follow-up Plan
PMCFR	PMCF-Report
PMF	Plasma Master File
PMID	PubMed-ID (see PubMed-Number)
PMPF	Post-Market Performance Follow-up
PMS	Post-market surveillance
PMSP	Post-Market Surveillance Plan
PMSR	Post-Market Surveillance Report
PMSV	Post-Market Surveillance and Vigilance
POC	Point of Care
POM	Prescription-only Medicines
PP	Per Protocol (set)
PPN	Pharmaceutical Product Number
PQ	Performance Qualification (see DQ, IQ, OQ)
PRAC	Pharmacovigilance Risk Assessment Advisory Committee
PrAr	Preliminary Assessment Report
PRISMA	Prevention and Recovery Information System for Monitoring and Analysis
PRRC	Person Responsible for Regulatory Compliance
PSR	Periodic Summary Report(s)

PSRPH	Potential Serious Risk to Public Health
PSUR/PSURs	Periodic Safety Update Report
PSUR	Post-Market Surveillance Update Report
PSUSA	PSUR Single Assessment Procedure
PUMA	Pediatric Use Marketing Authorization
PV/PhV	Pharmacovigilance
PVAR	Preliminary Variation Assessment Report
PVS	Pharmacovigilance System
PVSMF	Pharmacovigilance Master File

Q

Q&A	Question & Answer
QA	Quality Assurance
QM	Quality Management
QMS	Quality Management System
QOS	Quality Overall Summary
QP	Qualified Person
QPPV	Qualified Person for Pharmacovigilance
QRD	Quality Review of Documents
QWP	Quality Working Party

R

RCT	Randomized Controlled Trials
REB	Research Ethics Board (see ERB, IEC, IRB)
REC	Research Ethics Committee
REP	Representative
RFID	Radio Frequency Identification
RIA	Risk Assessment (see D-RIA)
RKI	Robert Koch Institute (ww.rki.de) German federal government agency and research institute responsible for disease control and prevention

RMP	Reference Medicinal Product
RMP	Risk Management Plan
RMS	Reference Member State
RoHS	Registration, Evaluation, Authorization and Restriction of Chemicals
RSI	Request for Supplementary Information
RUT	Readability User Test
Rx	Prescription Drug

S

SA	Scientific Advice
SADE	Serious Adverse Drug/Device Event
SAE	Serious Adverse Event
SAL	Sterility Assurance Level
SAR	Suspected Adverse Reaction
SAWP	Scientific Advice Working Party
SDV	Source Data Verification
SAL	Sterility Assurance Level
SAT	Site Acceptance Test (see FAT)
SCAR	Supplier Corrective Action Request
SME	Small and Medium enterprises
SmPC	Summary of Product Characteristics
SoA	State of the Art (see SOTA)
SaMD	Software as a Medical Device
SOP	Standard Operation Procedure
SOTA	State-of-the-Art (see SoA)
SPC	Supplementary Protection Certificate
SRN	Single Registration Numbers
SSAR/SSAE	Suspected Serious Adverse Reaction/Event
SSCP	Summary of Safety and Clinical Performance
SSI	Structured Substance Information file
SSRS	System Software Requirements Specification
SSP	Summary of Safety and Performance (in vitro diagnostics)
STED	Summary Technical Documentation

STRIDE	(security) Spoofing, Tampering, Repudiation, Information disclosure (privacy breach or data leak), Denial of service, Elevation of privilege
SUSAR	Serious Unexpected Suspected Adverse Reaction
SVHC	Substances of Very High Concern
SW	Software
SWP	Safety Working Party

T

TACE	Transarterial chemoembolization
TAVI	Transcatheter Aortic Valve Intervention
TD	Technical Documentation
TDAR	Technical Documentation Assessment Report
TEP	Tamper Evident Packaging
TF	Task Force
THMP	Traditional Herbal Medicinal Product
TIR	Technical Information Report
TMF	Trial Master File
TOC	Table of Content
TR	Technical Report(s)
TS	Technical Specification
TSE	Transmissible spongiform encephalopathy
TVF	Tamper Verification Feature

U

UAE	Unexpected Adverse Event
UCUM	Unified Code for Units of Measure
UDI	Unique Device Identification/Identifier
UDI-DI	Unique Device Identification - Device Identifier
UE	Unexpected Event
UI	Unique Identifier

UL	Underwriters Laboratories
UMDNS	Universal Medical Device Nomenclature System (now GMDN)
URL	Uniform Resource Locator
URS	User Requirement Specification
USADE	Unanticipated Serious Adverse Drug/Device Event
USAR	Unexpected Serious Adverse Reaction

V-W

VAMF	Vaccine Antigen Master File
WCO	Worlds Customs Organization
WEEE	Waste of Electrical and Electronic Equipment
WG	Working Group
WHO	World Health Organization, and one of the ICH Observers
WS	Work-sharing

X-Z

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

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