Glossary of Global Industry Acronyms and Abbreviations

ADR	Adverse drug reaction
AE	Adverse event
CIOMS	Council for International Organizations of Medical Sciences
CRA	Clinical research associate
CRC	Clinical research coordinator
CRF	Case Report Form
CRO	Contract research organization
CV	Curriculum vitae
Device	Treats, cures, mitigates or manages a disease or condition through other than chemical means
Drug	Treats, cures, mitigates or manages a disease or condition and is not a device
DSMB	Drug Safety Monitoring Board
EC/IEC	Ethics Committee/Independent Ethics Committee
IB/IDB	Investigator's Brochure/Investigator's Drug Brochure
IC/PIC/ICF	Informed consent/Patient Informed Consent/Informed Consent Form
ICD-9-CM	International Classification of Disease Codes, 9th Revision –Clinical Modification
ICH	International Conference on Harmonization
IMPD	Investigational Medicinal Product Dossier
IP/IMP	Investigational Product/Investigational Medicinal Product
IRB	Institutional Review Board
ISO	International Organization for Standardization
IVRS	Interactive voice response system
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GSP	Good Statistical Practice
MedDRA	Medical Dictionary for Drug Regulatory Activities
MoH	Ministry of Health
NCE	New chemical entity
NCR	No carbon required
NME	New molecular entity
PI	Principal Investigator
PMS	Post-Marketing Surveillance
QA	Quality assurance
QC	Quality control
RandD	Research and Development
RDE	Remote data entry
RFP	Request For Proposal

Glossary of Global Industry Acronyms and Abbreviations (continued)

SAE	Serious adverse event
SAR/SADR	Serious Adverse Reaction/Serious Adverse Drug Reaction (moved to industry specific)
SC/SSC	Study coordinator/Site Study Coordinator
SD	Source Documents
SDV	Source data verification
SMO	Site Management Organization
SOP	Standard Operating Procedure
UADE	Unanticipated Adverse Device Effect

Glossary of Americas Acronyms and Abbreviations

United States

ANDA	Abbreviated New Drug Application (used for generics)
ASCII	American Standard Code for Information Interchange (computer files)
CANDA	Computer Assisted New Drug Application
CAPLA	Computer Assisted Product License Application
CBER	Center for Biologics Evaluation and Research (FDA)
CCRC	Certified clinical research coordinator.
CDER	Center for Drug Evaluation and Research (FDA)
CDRH	Center for Devices and Radiological Health (FDA)
CFR	Code of Federal Regulations 24 (usually cited by part and chapter, as 21 CFR 312)
CLIA	Clinical Laboratory Improvements Amendments
COSTART	Coding Symbols for Thesaurus of Adverse Reaction Terms (FDA)
DEA	Drug Enforcement Administration (FDA)
DHHS	Department of Health and Human Services
DIA	Drug Information Association
FDA	Food and Drug Administration
FR	Federal Register
HIPAA	Health Insurance Portability and Accountability Act
HHS	U.S. Department of Health and Human Services
IDE	Investigational Device Exemption (FDA)
IND	Investigational New Drug application (FDA)
IRB	Institutional review board (*sometimes independent review board)*
NAI	No Action Indicated (most favorable FDA post-inspection classification)
NDA	New Drug Application (FDA)
NIH	National Institutes of Health
NINDS	National Institute of Neurological Disorders and Stroke (NIH)
OAI	Official Action Indicated (serious FDA post-inspection classification)
PHI	Protected Health Information
PhRMA	Pharmaceutical Research and Manufacturers of America
PLA	Product License Application (FDA)
PMS	Post-marketing Surveillance
VAI	Voluntary Action Indicated (FDA post-audit inspection classification)
WL	Warning letter (most serious of post-FDA audit letters, demands immediate action within 15 days)

Glossary of Europe Industry Acronyms and Abbreviations

ABPI	Association of British Pharmaceutical Industries
CA	Competent Authority (Regulatory Authority)
CSE	Clinical Supply Europe
CTA	Clinical Trial Authorization (i.e. valid request to the Competent Authority to perform the trial)
CTSW	Clinical Trial Supply Warehouse
CTX	Clinical Trial Exemption (MCA, UK)
CRC	Central Randomization Center
DA	Document Administrator
DCRF	Data Clarification and Resolution Form
EU	European Union
EUDir	European Union Directive
EMEA	European Medicines Evaluation Agency
EUDRACT	European Union database managed by EMEA
ICR	Institute of Clinical Research (UK)
ISO	International Organization for Standardization
MHRA	Medicines and Healthcare Products Regulatory Agency (UK)
MS	Member state: Country that is a member in the European Union
PMO	Project Medical Officer
PSF	Product Specification File
QP	Qualified Person
QDPC	Quintiles Data Processing Centre
SUSAR	Suspected Unexpected Serious Adverse Reaction