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Examples and practices

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Abbreviations & Glossary

The glossary is the same as that of the WHO Guideline on implementation of QMS for NRAs, Annex 13, WHO Technical Report Series, No. 1025.

Abbreviations

ADR	Adverse drug report
CAPA	Corrective and Preventive Action
CT	Clinical Trial Oversight (GBT regulatory function)
EMA	European Medicines Agency
EU	European Union
GBT	Global Benchmarking Tool
GxP	Good Practices (Manufacturing-M, Clinical-C, Distribution-D, Laboratory-L, Regulatory-R, Review-Rev)
HMA	The Heads of Medicines Agencies
IT	Information Technology
ISO	International Standardization Organization
KPI	Key Performance Indicator
LI	Licensing Establishments (GBT regulatory function)
LR	Lot Release (GBT regulatory function)
LT	Laboratory Access and Testing (GBT regulatory function)
LIMS	Laboratory information management system
LSP	Lot summary protocol
MA	Marketing Authorization (GBT regulatory function)
MAH	Marketing Authorization Holder
MC	Market Surveillance and Control (GBT regulatory function)
MOH	Ministry of Health
NRA	National Regulatory Authority
PDCA	Plan, Do, Check and Act
PV	Pharmacovigilance (equivalent to Vigilance regulatory function)
QA	Quality Assurance
QMS	Quality Management System
RCA	Root cause analysis
RI	Regulatory Inspection (GBT regulatory function)
RS	Regulatory System (GBT regulatory function)
SF	Substandard or falsified
SOP	Standard Operating Procedure
TM	Top management
VL	Vigilance (GBT regulatory function)
WHA	World Health Assembly
WHO	World Health Organization