ALMAC

Glossary

AMP	Auxiliary Medicinal Products
Annex XI	AnnexVILabelling of Investigational Medical Products & Auxiliary Medicinal Products
CAPA	Corrective Action Preventive Action
CTA	Clinical Trial Authorisation
CTR	Clinical Trial Regulation
CTIS	Clinical Trial Information System
EU	Europe
GDPR	General Data Protection Regulation
GMP	Good Manufacturing Practice
IP	Investigational Product
IMP	Investigational Medicinal Product
IMPD	Investigational Medicinal Product Dossier
MHRA	Medicines & Healthcare products Regulatory Agency
NIMPs	Non-Investigational Medicinal Products
NI	Northern Ireland
OOS	Out of Specification
PQS	Pharmaceutical Quality System
PSF	Product Specification File
PUPSIT	Pre-Use, Post- Sterilisation Integrity Testing
QC	Quality Control
QP	Qualified Person
sIMPD	Simplified Investigational Medicinal Product Dossier
SOPs	Standard Operating Procedures
UK	United Kingdom