Egyptian Drug Authority
Central Administration of Inspection on Pharmaceutical Institutions

General Administration for Factories Inspection

Notice to Applicant.

REGULATORY GUIDELINES REFERENCES FOR BIOLOGICAL PRODUCTS

WHO · ICH · PIC/S

Biological Products · Vaccines · Blood Products · Distributors

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Document Organization

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SECTION 1 — WHO Guidelines: Biological Products, Vaccines & Blood Products

Biological-specific WHO Technical Report Series (TRS) guidelines applicable to biological manufacturers, vaccine producers, blood establishments, plasma fractionation plants and biosimilar developers

#	TRS No.	Annex	Guideline Title	Applicability	Link
1	999	2	WHO good manufacturing practices for biological products	All biological manufacturers; vaccines; cell-derived products; biotechnology	WHO ↗
2	996	3	WHO good manufacturing practices for biological products (updated)	All biological manufacturers; vaccines; blood-derived products (updated edition)	WHO ↗
3	961	4	WHO good manufacturing practices for blood establishments	Blood collection centers; blood banks; plasma fractionation facilities	WHO ↗
4	941	4	WHO Recommendations for production, control and regulation of human plasma for fractionation	Plasma fractionation plants; human plasma-derived product manufacturers	WHO ↗
5	924	4	WHO Guidelines on viral inactivation and removal procedures intended to assure the viral safety of human blood plasma products	Plasma fractionation manufacturers; viral clearance validation	WHO ↗
6	840	2	WHO Requirements for the collection, processing and quality control of blood, blood components and plasma derivatives	Blood collection establishments; blood banks; plasma processing facilities	WHO ↗
7	977	2	WHO Guidelines on evaluation of similar biotherapeutic products (biosimilars — SBPs)	Biosimilar manufacturers; biological product comparability studies	WHO ↗
8	1044	2	Quality assurance of pharmaceuticals: a compendium of guidelines and related materials (sterile, validation, technology transfer)	All biological manufacturers; inspectors; QA teams	WHO ↗
9	961	2	WHO good practices for pharmaceutical microbiology laboratories	QC microbiology laboratories; sterility testing; bioburden; environmental monitoring	WHO ↗
10	1052	4	WHO good practices for pharmaceutical quality control laboratories	All QC laboratories; biological and vaccine product testing; blood product testing	WHO ↗

SECTION 2 — WHO Guidelines: General GMP & Good Storage and Distribution Practices (GSDP)

Foundational WHO GMP guidelines (TRS main principles, APIs, validation, water, HVAC, data integrity, technology transfer) and GSDP/cold chain guidelines applicable to all biological, vaccine and blood product manufacturers and distributors

#	TRS No.	Annex	Guideline Title	Applicability	Link
1	986	2	WHO good manufacturing practices for pharmaceutical products: main principles	All pharmaceutical manufacturers; foundational GMP — applicable across all biological, vaccine and blood product facilities	WHO ↗
2	957	2	WHO good manufacturing practices for active pharmaceutical ingredients	Biological drug substance (API) manufacturers; vaccine active substance production	WHO ↗
3	957	3	WHO good manufacturing practices for pharmaceutical products containing hazardous substances	Manufacturers handling hazardous biological substances; cytotoxic product manufacturers	WHO ↗
4	885	5	Good manufacturing practices: supplementary guidelines for the manufacture of pharmaceutical excipients	Excipient manufacturers supplying biological product manufacturers	WHO ↗
5	1033	3	Good manufacturing practices: water for pharmaceutical use	All manufacturers — PW and WFI systems; critical for biological products	WHO ↗
6	1025	3	Production of water for injection by means other than distillation	Manufacturers using membrane-based WFI production	WHO ↗
7	970	2	WHO GMP — water for pharmaceutical use (earlier edition)	Manufacturers referencing earlier WHO water system guidance	WHO ↗
8	981	2	WHO guidelines on quality risk management	All manufacturers and inspectors — QRM principles applicable across GMP, GSDP and inspection activities	WHO ↗
9	1019	3	Good manufacturing practices: guidelines on validation	All manufacturers — process, cleaning, analytical and computer validation	WHO ↗

#	TRS No.	Annex	Guideline Title	Applicability	Link
10	**992**	3	WHO Guidelines on GMP: validation — Appendix 7: non-sterile process validation	Non-sterile biological product manufacturers; process validation	WHO ↗
11	**937**	4	Supplementary guidelines on GMP: validation	Validation supplement applicable to biological manufacturing validation programmes	WHO ↗
12	**1033**	2	Points to consider when including health-based exposure limits (HBELs) in cleaning validation	Manufacturers with shared or multi-product facilities; cleaning validation for biological products	WHO ↗
13	**1033**	4	Guideline on data integrity	All GxP manufacturers and QC laboratories; ALCOA+ data integrity principles	WHO ↗
14	**996**	5	Guidance on good data and record management practices	All GxP manufacturers; QC laboratories; manufacturing records; electronic data	WHO ↗
15	**1044**	4	WHO guidelines on technology transfer in pharmaceutical manufacturing	Vaccine technology transfer; mRNA platform transfer; biosimilar technology transfer	WHO ↗
16	**961**	7	WHO guidelines on transfer of technology in pharmaceutical manufacturing	Technology transfer for biological drug substances and drug products	WHO ↗
17	**1010**	8	Guidelines on heating, ventilation, and air-conditioning systems for non-sterile pharmaceutical products [Part 1]	All manufacturers with controlled production environments	WHO ↗
18	**1019**	2	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation	HVAC interpretation guidance for non-sterile biological manufacturing	WHO ↗
19	**961**	5	WHO HVAC guidelines for non-sterile pharmaceutical dosage forms	HVAC systems in biological and vaccine non-sterile manufacturing areas	WHO ↗
20	**992**	4	General guidance on hold-time studies	Drug substance and drug product hold times in biological manufacturing	WHO ↗
21	**961**	14	WHO guidelines for drafting a site master file	All manufacturers required to submit an SMF for GMP inspection or registration	WHO ↗

#	TRS No.	Annex	Guideline Title	Applicability	Link
22	**1025**	2	IAEA and WHO guideline on GMP for radiopharmaceutical products	Radiopharmaceutical manufacturers; nuclear medicine products	WHO ↗
23	**996**	4	Guidance on good manufacturing practices: inspection report	All GMP inspectors; inspection report writing and deficiency classification	WHO ↗
24	**1025**	5	Quality management system requirements for national inspectorates	National regulatory authority inspection departments; QMS for inspectorates	WHO ↗
25	**902**	7	Guidelines on pre-approval inspections	Biological, vaccine and blood product manufacturers — pre-authorisation GMP inspections	WHO ↗
26	**823**	2	Provisional guidelines on the inspection of pharmaceutical manufacturers	All GMP inspectors — foundational inspection guidance	WHO ↗
27	**1010**	9	Guidance on good practices for desk assessment of compliance with GMP, GLP and GCP for medical products regulatory decisions	Regulatory reviewers and inspectors conducting remote/desk assessments	WHO ↗
28	**1025**	7	Good storage and distribution practices for medical products	Wholesale distributors; blood product logistics; vaccine cold chain operators	WHO ↗
29	**961**	9	Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products	Vaccine and blood product manufacturers and distributors; cold chain operators	WHO ↗
30	**992**	5	Technical supplements to Model Guidance for storage and transport (Supplements 1–16)	Cold chain qualification; temperature mapping; transport qualification; refrigeration equipment	WHO ↗
31	**1025**	8	Points to consider for setting the remaining shelf-life of medical products upon delivery	Blood product distributors; vaccine distributors; shelf-life management at point of delivery	WHO ↗

SECTION 3 — ICH Guidelines: Quality, Safety & Efficacy Series

29 ICH guidelines across Quality (Q-series), Safety (E/S-series) and Multidisciplinary (M-series) applicable to biological, vaccine and blood product manufacturers and QC laboratories

#	ICH Guideline	Title / Description	Category	Applicable To	Link
1	**ICH Q5A(R2)**	Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin	Quality — Biotech	Biological and biotech product manufacturers; virus testing; viral clearance studies	ICH ↗
2	**ICH Q5B**	Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products	Quality — Biotech	Recombinant protein manufacturers; vaccines using recombinant technology	ICH ↗
3	**ICH Q5C**	Stability Testing of Biotechnological/Biological Products	Quality — Biotech	All biological product manufacturers; vaccine stability; blood product stability	ICH ↗
4	**ICH Q5D**	Derivation and Characterisation of Cell Substrates Used for Production of Biotechnological/Biological Products	Quality — Biotech	Cell bank manufacturers; biological product producers using cell lines; vaccine manufacturers	ICH ↗
5	**ICH Q5E**	Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process	Quality — Biotech	Biological manufacturers making process changes; biosimilar comparability studies	ICH ↗
6	**ICH Q6B**	Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products	Quality — Biotech	All biological, vaccine and blood product manufacturers — product specifications and release testing	ICH ↗
7	**ICH Q7**	Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients	Quality — GMP	API manufacturers; biological drug substance manufacturers	ICH ↗
8	**ICH Q8(R2)**	Pharmaceutical Development	Quality — GMP	Product development for biological formulations; design space; control strategy	ICH ↗
9	**ICH Q9(R1)**	Quality Risk Management	Quality — GMP	All GxP manufacturers and inspectors — risk-based	ICH ↗

				approach to GMP, GSDP and inspection	
10	**ICH Q10**	Pharmaceutical Quality System	Quality - GMP	All pharmaceutical and biological manufacturers — PQS framework	ICH ↗
11	**ICH Q11**	Development and Manufacture of Drug Substances (Chemical and Biotechnological/Biological Entities)	Quality - GMP	Biological drug substance (DS) manufacturers; vaccine active substance production	ICH ↗
12	**ICH Q12**	Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management	Quality-GMP	Biological product lifecycle management; post-approval changes; PAC framework	ICH ↗
13	**ICH Q13**	Continuous Manufacturing of Drug Substances and Drug Products	Quality -GMP	Manufacturers implementing continuous bioprocessing; continuous fill-finish	ICH ↗
14	**ICH Q2(R2)**	Validation of Analytical Procedures	Quality- Analytical	QC laboratories — validation of analytical methods used in biological product testing	ICH ↗
15	**ICH Q14**	Analytical Procedure Development	Quality - Analytical	QC laboratories developing analytical methods for biological and vaccine products	ICH ↗
16	**ICH Q6A**	Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and Drug Products (Chemical Entities)	Quality - Analytical	QC laboratories; biological product impurity and chemical testing	ICH ↗
17	**ICH Q3A(R2)**	Impurities in New Drug Substances	Quality -Impurities	Biological drug substance manufacturers — impurity profiling and acceptance criteria	ICH ↗
18	**ICH Q3B(R2)**	Impurities in New Drug Products	Quality- Impurities	Biological drug product manufacturers — degradation products; acceptance thresholds	ICH ↗

SECTION 4 — PIC/S Guidelines: GMP Guide, Annexes, GDP & Inspection Documents

21 PIC/S documents — PE 009 GMP Guide (all relevant annexes), PE 011 GDP, PI series (inspection, validation, data integrity, aseptic) and PD series (inspection report, joint inspections)

#	PIC/S Document	Title	Scope	Applicable To	Link
1	**PE 009-16**	GMP Guide for Medicinal Products (Main Guide) — Part I: Basic Requirements for Medicinal Products; Part II: Basic Requirements for Active Substances (APIs); Part III: GMP-related documents	Full GMP — all chapters and annexes	All pharmaceutical manufacturers including biological	PIC/S ↗
2	**PE 009-16 Annex 1**	Manufacture of Sterile Medicinal Products (2022 revised)	Sterile manufacturing; aseptic processing; media fills; environmental monitoring	Sterile biological, vaccine, blood product manufacturers	PIC/S ↗
3	**PE 009-16 Annex 2**	Manufacture of Biological Medicinal Substances and Products for Human Use	Biological products; vaccines; blood-derived products; cell therapy; gene therapy	All biological product manufacturers; vaccine producers	PIC/S ↗
5	**PE 009-16 Annex 5**	Good Distribution Practice	Distribution of medicinal products; storage requirements; wholesale	Distributors; wholesalers; blood product logistics	PIC/S ↗
6	**PE 009-16 Annex 6**	Manufacture of Medicinal Gases	Medicinal gases GMP	Gas manufacturers; manufacturers using medicinal gases in biological production	PIC/S ↗
7	**PE 009-16 Annex 11**	Computerized Systems	Validation of computerized systems; data integrity; electronic records; audit trails	All manufacturers with GxP computerized systems	PIC/S ↗

8	**PE 009-16 Annex 13**	Manufacture of Investigational Medicinal Products	Clinical trial IMP manufacturing; blinding; randomization; labelling	Biological/vaccine clinical trial manufacturers; IMPs	PIC/S ↗
9	**PE 009-16 Annex 14**	Manufacture of Medicinal Products Derived from Human Blood or Plasma	Blood establishment GMP; plasma fractionation; viral inactivation	Blood establishments; plasma fractionation plants; blood product manufacturers	PIC/S ↗
10	**PE 009-16 Annex 15**	Qualification and Validation	Process validation; equipment qualification; cleaning validation; analytical method validation	All manufacturers	PIC/S ↗
11	**PE 009-16 Annex 16**	Certification by a Qualified Person	Batch release; QP responsibilities; import testing; continuous process verification	All medicinal product manufacturers with QP batch release	PIC/S ↗
12	**PE 009-16 Annex 20**	Quality Risk Management	Risk management principles; FMEA, HACCP, fault tree analysis in pharmaceutical manufacturing	All manufacturers	PIC/S ↗
13	**PE 011-1**	Guide to Good Distribution Practice for Medicinal Products	GDP for wholesalers and distributors; storage; temperature control; transport; traceability	All distributors; blood product distributors; vaccine cold chain operators	PIC/S ↗
14	**PI 002-3**	Aide-Memoire for the Inspection of Pharmaceutical Manufacturers	Inspection checklist guidance; GMP compliance assessment methodology	Inspectors conducting GMP inspections of all facility types	PIC/S ↗
15	**PI 006-3**	Recommendations on Validation Master Plan, Installation and Operational Qualification, Non-Sterile Process Validation, Cleaning Validation	Validation framework; technology transfer validation	All manufacturers — validation and technology transfer activities	PIC/S ↗

16	**PI 007-6**	Recommendations on the Validation of Aseptic Processes	Aseptic process simulation; media fill design; contamination risk	Sterile biological, vaccine, blood product manufacturers	PIC/S ↗
17	**PI 011-3**	Good Practices for Computerized Systems in Regulated GxP Environments	GAMP principles; CSV; electronic records; electronic signatures	All GxP computerized system operators	PIC/S ↗
18	**PI 012-3**	Aide-Memoire: Inspection of Pharmaceutical Quality Control Laboratories	Laboratory inspection guidance; OOS; reference standards; analytical methods	QC laboratory inspections — biological, vaccine and blood product testing	PIC/S ↗
19	**PI 041-1**	Guidance on Data Integrity	ALCOA+ principles; data governance; paper and electronic records; audit trails	All GxP facilities — manufacturing, laboratories, distribution	PIC/S ↗
20	**PD 005**	PIC/S Inspection Report Guidance	Inspection report format; deficiency classification (critical/major/other)	Inspectors — all inspection types	PIC/S ↗
21	**PD 009**	PIC/S Joint Inspection Programme	Joint and collaborative inspection procedures; mutual recognition	Regulatory authorities; applicable when conducting joint inspections	PIC/S ↗

SECTION 5 — Comparability Reference Table: WHO · ICH · PIC/S by Inspection Topic

Cross-reference matrix mapping 24 inspection topic areas to applicable WHO, ICH and PIC/S guidelines — for rapid identification of applicable standards during inspection preparation

Inspection Topic	Related WHO (TRS Annex)	Related PIC/S	Related ICH	Applicable To
Main GMP Principles	TRS 986 Annex 2 (2014)	PE 009-16 Part I Chapters 1–9	ICH Q10, ICH Q9	All biological, vaccine, blood product manufacturers & distributors
Biological Products GMP	TRS 999 Annex 2 TRS 996 Annex 3	PE 009-16 Annex 2	ICH Q5A–Q5E ICH Q11	All biological manufacturers; vaccine producers; cell therapy
Sterile Manufacturing / APS	TRS 961 Annex 6 TRS 1044 Annex 2	PE 009-16 Annex 1 PI 007-6 (APS)	ICH Q5A ICH Q10	Sterile biological, vaccine and blood product fill-finish manufacturers
Blood Establishments & Plasma Fractionation	TRS 961 Annex 4 TRS 941 Annex 4 TRS 924 Annex 4 TRS 840 Annex 2	PE 009-16 Annex 14 PE 011-1	ICH Q5A (Viral Safety) ICH Q6B	Blood collection centres; plasma fractionation; blood product manufacturers
Biosimilar Development & Comparability	TRS 977 Annex 2 TRS 999 Annex 2 / TRS 996 Annex 3	PE 009-16 Annex 2 PI 006	ICH Q5E ICH Q11 ICH Q12	Biosimilar manufacturers; biological product comparability studies
HVAC Systems	TRS 1010 Annex 8 TRS 1019 Annex 2 TRS 961 Annex 5	PE 009-16 Part I Chapter 3 PE 009-16 Annex 1	ICH Q9	All manufacturers with controlled environments
Water Systems — PW & WFI	TRS 1033 Annex 3 TRS 1025 Annex 3 TRS 970 Annex 2	PE 009-16 Part I Chapter 3 PE 009-16 Annex 1	ICH Q9	All manufacturers; critical for biological products
Quality Risk Management	TRS 981 Annex 2	PE 009-16 Annex 20 PI 006	ICH Q9 (foundational) ICH Q10	Applicable across all manufacturing and inspection activities

Inspection Topic	Related WHO (TRS Annex)	Related PIC/S	Related ICH	Applicable To
Quality Management System	TRS 986 Annex 2 TRS 1025 Annex 5	PE 009-16 Part I Chapters 1–2	ICH Q10 ICH Q9 ICH Q8	All manufacturers; national inspectorates
Validation Program	TRS 1019 Annex 3 TRS 992 Annex 3 TRS 937 Annex 4	PE 009-16 Annex 15 PI 006-3	ICH Q2(R2) ICH Q8(R2) ICH Q9 ICH Q10	All manufacturers — process, cleaning, analytical, computer validation
Data Integrity	TRS 1033 Annex 4 TRS 996 Annex 5	PI 041-1 PE 009-16 Chapter 4	ICH Q10	All GxP-regulated manufacturers and laboratories
Computerized Systems	TRS 1033 Annex 4 TRS 996 Annex 5	PI 011-3 PE 009-16 Annex 11	ICH Q10 ICH Q9	All manufacturers with GxP computerised systems (LIMS, MES, ERP, BMS, EMS)
GMP Inspection General	TRS 996 Annex 4 TRS 1010 Annex 9 TRS 1025 Annex 5 TRS 902 Annex 7 TRS 823 Annex 2	PE 009-16 Part I PI 002-3 PD 005	ICH Q10 ICH Q9	All GMP inspections — pre-approval, routine, for-cause, follow-up
Environmental Monitoring	TRS 961 Annex 6 TRS 1044 Annex 2	PE 009-16 Annex 1 PI 007-6	ICH Q9	All sterile manufacturers; biological and vaccine production areas
Equipment Qualification (IQ/OQ/PQ)	TRS 1019 Annex 3 TRS 992 Annex 3	PE 009-16 Annex 15 PI 006-3	ICH Q9 ICH Q8	All manufacturers; bioreactors, fermenters, lyophilisers, filling lines
Quality Control Laboratory	TRS 1052 Annex 4 TRS 961 Annex 2	PE 009-16 Part I Chapter 6 PE 009-16 Annex 1 PI 012	ICH Q2(R2) ICH Q6A ICH Q6B	All QC laboratories; biological, vaccine and blood product testing
Analytical Method Validation	TRS 1052 Annex 4 TRS 1019 Annex 3	PE 009-16 Chapter 6 PE 009-16 Annex 15	ICH Q2(R2) ICH Q14 ICH Q6B	QC laboratories; biological product characterization and release testing
Specifications — Biological Products	TRS 999 Annex 2 TRS 996 Annex 3	PE 009-16 Annex 2	ICH Q6B ICH Q5A–Q5E ICH Q11	Biological, vaccine and blood product manufacturers; product specification setting
OOS Investigation	TRS 1052 Annex 4 TRS 986 Annex 2	PE 009-16 Part I Chapter 6 PE 009-16 Annex 15	ICH Q2(R2) ICH Q6B	All QC laboratories; biological product batch release testing

Inspection Topic	Related WHO (TRS Annex)	Related PIC/S	Related ICH	Applicable To
Blood Product Distribution & Cold Chain	TRS 1025 Annex 7 TRS 961 Annex 9 TRS 992 Annex 5 TRS 1025 Annex 8	PE 011-1 PE 009-16 Annex 14 PE 009-16 Annex 5	ICH Q1A ICH Q5C	Blood product distributors; vaccine cold chain operators; wholesalers handling biologics
Technology Transfer	TRS 1044 Annex 4 TRS 961 Annex 7	PI 006	ICH Q10 (Section 3.2.2) ICH Q11	Vaccine technology transfer; mRNA platform transfer; biosimilar technology transfer