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Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)

Desk Assessment of Vaccine(s) Manufacturer

Part 1	**General information**
Company information	
Name of Manufacturer	SK bioscience Co., Ltd.
Corporate address of manufacturer	38 Yeongudanji-ro, Yeonsu-gu, Incheon, 21984, Republic of Korea
Inspected site	
Name & address of manufacturing site	SK bioscience Co., Ltd. Production Site (L HOUSE) 150, Saneopdanji-gil, Pungsan-eup, Andong-si, Gyeongsangbuk-do, Republic of Korea. GPS coordinates: 36°36'04.2"N 128°32'40.3"E
Synthetic Unit/Block/Workshop	Suite 8 and Filling line 4 (Freeze Dried) – Varicella manufacturing area Suite 1 – Purified Diphtheria Toxoid Bulk manufacturing area Suite 4 – Vi Polysaccharide Bulk and Vi Polysaccharide Conjugated to Diphtheria Toxoid Bulk, as well as Filling lines 2 (for NUVAXOVID) and 3 (for SKYTyphoid Multi inj.) Suites 5 and 9 and filling line 3 (Liquid Vial) – Flu vaccines (SKYCellflu inj., SKYCellflu Multi inj., SKYCellflu Quadrivalent inj., SKYCellflu Quadrivalent Multi inj.)
Manufacturing license number	Manufacturing License No. 97 dated 16 July 2018
Desk assessment details	
Start and end date of review	18 - 29 March 2026 and 1 June 2026
Inspection record number	INSP-FVP-2024-0024
Vaccines covered by this desk assessment	• SKYCellflu Quadrivalent (SKYCellflu Quadrivalent inj., SKYCellflu Quadrivalent Multi inj.) • SKYCellflu Trivalent (SKYCellflu inj., SKYCellflu Multi inj.) • SKYVaricella inj. • SKYTyphoid Multi inj.
List of documents submitted	a) A list of all regulatory inspections performed in the last three years and their outcomes, including inspections with non-compliant outcomes. b) Current full inspection report(s), including deficiency letters, for inspections performed by a competent stringent regulatory authority in the past three years with a certified translated copy where this is not in English.

	c) A copy of the manufacturing authorization and GMP certificate granted by the local national authority together with a certified translation, where this is not in English. d) A site master file whose approval date was not more than one year ago, and any forecast modifications, together with legible color printouts of water treatment and air-handling systems, including pipeline and instrumentation drawings. e) The list of all the products and dosage forms manufactured on-site. The list should include proprietary names and International Non-proprietary Names (INN), including all types of chemicals and products (e.g., pesticides, herbal medicines, chemicals, or veterinary products, etc.). f) The most recent product quality review(s) (PQR)(s) of the concerned product(s); PQR(s) or equivalent documentation covering all required subsections and trend results, including statistical evaluation. g) The completed batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant product(s); If any of the products are sterile, the completed batch records for the most recent media fill validation that is relevant to the product(s) of interest and report on its outcome. h) The list of any recalls in the past three years related to any product manufactured on site with quality defects. i) Any warning letter, or equivalent regulatory action, issued by any authority to which the site provides or has applied to provide the product. j) A confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the product(s) has been performed and all matters dealt with. k) Master batch manufacturing and packaging record(s) of the WHO product(s) of interest. l) Any recent or foreseen out-of-stock situations with a signed statement to this effect.	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last)**	
Ministry of Food and Drug Safety Republic of Korea (MFDS - Korea) - Daegu Regional Office of Food and Drug Safety	Dates of inspection:	21 – 25 July 2025
	Type of inspection:	Routine Inspection
	Block/Unit/Workshop:	Drug substance manufacturing area (Common Area), final bulk area, finished product manufacturing area and Laboratories including Physicochemical and instrumental analysis laboratories (1F), microbiology, sterility, and virology laboratories (2F), animal testing laboratory (focused on changes). Summary of Performed Regulatory Inspection signed by the Head of Quality

		Excellence SK bioscience Co., Ltd. stated that for this inspection the production areas involved were Suite 5 and 9, Filling line 2, and Packaging which were used for the manufacturing of SKYCellflu Quadrivalent Final Bulk and SKYCellflu Quadrivalent Prefilled Syringe. The two products were selected as representative products for the inspection in the inspection report
	Type of Vaccines covered:	SKYCellflu Quadrivalent Final Bulk (Surface Antigen, Inactivated, prepared in cell culture) and SKYCellflu Quadrivalent Prefilled Syringe (Surface Antigen, Inactivated, prepared in cell culture) were selected as representative product.
	Physical areas inspected:	1. Drug Substance Manufacturing Area including Common Corridor, Preparation Room 1, Media Preparation Room. 2. Finished Product Area including Material Airlock, Material Airlock, Buffer Preparation Room, Material Loading Room, Filling Room, Packaging Room, Manual Visual Inspection Room and Cold Room 3. Laboratory including 1st Floor Quality Control Area and 2nd Floor Quality Control Area
Ministry of Food and Drug Safety Republic of Korea (MFDS - Korea) - Daegu Regional Office of Food and Drug Safety	Dates of inspection:	11 – 14 October 2022
	Type of inspection:	Routine Inspection
	Block/Unit/Workshop:	Suite 8
	Type of Vaccines covered:	SKYZoster inj. (Zoster Virus Vaccine (live) [Oka/SK])
	Physical areas inspected:	- Production area (1st Floor): Bulk Production Area (Suite 8), Final Bulk and Vial production area - Storage area (1st Floor): Raw materials storage room, Drug product storage room - Cell bank storage (1st Floor): Seed Storage Room 1,2 - Laboratory: physiochemistry and instrumental analysis laboratory (1st Floor), Microbial, sterility and virus

		laboratory (2nd Floor), Animal Laboratory (other building) - Utility System: Pharmaceutical Water, compressed gases, HVAC.
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	The on-site inspection was conducted from 24 June to 1 July 2022. It was the third on-site inspection conducted by WHO PQ Inspection team but was an initial WHO inspection for SKYTyphoid Multi inj. and NUVAXOVID. The site was concluded as compliant with WHO GMP guidelines.	
Brief description of manufacturing activities	All manufacturing activities at the L-HOUSE Andong site, including storage and QC, were performed in one building in which several areas with independent access. DS production is performed in 9 independent suites, while DP is produced in 4 filling lines (Vial Freeze-drying, Liquid Vial, Prefilled Syringe and Oral Injector).	
General information about the company and manufacturing site	SK bioscience is part of SK Life Science Business, which included vaccines, plasma products and pharmaceuticals. In 2018, SK bioscience was created as a standalone company for vaccine business. The Vaccines Manufacturing Site located in Andongsi, Gyeongsangbuk-do, Korea, is called “L HOUSE”. After being registered as a manufacturing facility in May 2013, L HOUSE initiated the production of clinical trial samples in October 2013 and received Ministry of Food and Drug Safety (MFDS) approval, which allows production of parenteral dosage forms including vaccines and other biological products in August 2014. SK bioscience has registered SKYCellflu® prefilled syringe (PFS), the first cell culture influenza vaccine in Korea (MFDS), followed by the licensure of SKYCellflu® Quadrivalent prefilled syringe (PFS) and 13-valent Pneumococcal Conjugate Vaccine (SKYPneumo Prefilled syringe). Zoster vaccine (SKYZoster inj.) was GMP approved by MFDS in September 2017. Varicella vaccine (SKYVaricella inj.) was GMP approved by MFDS in June 2018 and commercialised since September 2018. At the time of this inspection the company had 927 employees and five commercial products, among which 3 out of 5 are WHO prequalified: • SKYCellflu Quadrivalent (WHO Prequalified) • SKYCellflu Trivalent (WHO Prequalified) • SKYVaricella inj. (WHO Prequalified) • SKYZoster inj. • NUVAXOVID	

	The company also act as a CMO for manufacturing of DS of Novavax Covid-19 vaccine. In 2021 the company also manufactured Vaxzevria (AstraZeneca) Covid-19 vaccine however, it was no longer produced by SK bioscience.
Focus of the last WHO inspection	SKYTyphoid Multi inj. (Typhoid, conjugate) NUVAXOVID(Covid-19 vaccine, recombinant, adjuvanted)
Areas inspected	Suite 1 (for manufacturing of Purified Diphtheria Toxoid Bulk), Suite 4 (For manufacturing of Vi Polysaccharide Bulk and Vi Polysaccharide Conjugated to Diphtheria Toxoid Bulk), as well as Filling lines 2 (for NUVAXOVID) and 3 (for SKYTyphoid Multi inj.).
Out of scope and restrictions (last WHO inspection)	Due to time constrains areas inspected by EMA and MHRA for NUVAXOVID and SKYCovione were not covered in this inspection. Other prequalified vaccines were also not covered in detail. During the inspection there was no production of SKYTyphoid Multi inj. and NUVAXOVID. The company simulated the production of Conjugated Vi Polysaccharide at Suite 4 and formulation and filling of NUVAXOVID. Suite 1 (used for DT production) was in use for RNCV-A component of SKYCovione.
WHO vaccines covered by the last WHO inspection	SKYTyphoid Multi inj. (Typhoid, conjugate) NUVAXOVID (Covid-19 vaccine, recombinant, adjuvanted)
Additional products covered by this desk assessment:	None.
Abbreviations	**Meaning**
API	Active Pharmaceutical Ingredients
APS	Aseptic Process Simulation
BMR	Batch manufacturing record
BPR	Batch production record
CAPA	Corrective and preventive action
CC	Change control
DS	Drug Substance
GMP	Good manufacturing practices
NC	Nonconformity
NRA	National regulatory agency
PQR	Product quality review
PQS	Pharmaceutical quality system
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system

QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
SOP	Standard operating procedure
SMF	Site Master File
Ph. Eur.	European Pharmacopoeia
UF/ DF	Ultra Filtration/ Dia Filtration

Part 4	**Summary of the assessment of supporting documentation**

a) Manufacturing authorization and GMP certificate granted by the local authority:

The company submitted

1. Certificate of Pharmaceutical Manufacturing License No 2025-E1-0064 dated 28 August 2025 which was issued for export to Switzerland. In the Certificate it was stated that SK bioscience Co., Ltd. had License No. 97 issued on 16 July 2018.
2. GMP Certificate No. 2025-E1-0082 issued on 11 September 2025 based on the results of inspection on 25 July 2025. The Certificate was valid up to 13 October 2028. The manufacturing operation under the scope of the certificate was for manufacturing of biopharmaceutical products (culture, purification, virus inactivation, bulk manufacturing of vaccines) and quality control testing (physico-chemical test, microbiological test (non-sterility), sterility test, and animal test)
3. GMP Certificate No. 2025-E1-0078 issued on 11 September 2025 based on the results of inspection on 25 July 2025. The Certificate was valid up to 13 October 2028. The manufacturing operation under the scope of the certificate was for manufacturing of biopharmaceutical products (injection (vaccine)) and quality control testing (physico-chemical test, microbiological test (non-sterility), sterility test, and animal test)

b) Site Master File (SMF)

Site Master File No. PRT/REP-000012 revision 15.0 dated 24 July 2025 was submitted. Overall, the information on the SMF was in accordance with the WHO TRS No. 961, Annex 14.

Based on the previous inspection report, it was indicated that several contamination control strategies were implemented on site. Each suite and production areas are separated by personnel flow and material flow, and only authorized operators are allowed to enter. Production areas cleanliness is classified and managed according to EU Annex1 guideline. For flexible production of diverse vaccine types, L HOUSE has equipped single-use and multi-modular vaccine manufacturing systems on a commercial scale.

The company also submitted document to clarify the manufacturing process of the WHO Prequalified products, which summarized as follows:

Product Name	Manufacturing Facility	Major Manufacturing Equipment
SKYTyphoid Multi inj.	Suite 1 and 4	Fermenter Chromatography UF/ DF System
	Filling line 3	Filling Machine

		Capping Machine
	Packaging line 2	Labeller Cartoning Machine
SKYVaricella inj.	Suite 8	Cell factory Bioreactor UF/DF System
	Filling line 4	
	Packaging line 2	Labeler Cartoning Machine
SKYCellflu Quadrivalent Prefilled Syringe	Suite 5 and 9	Fermenter Chromatography UF/ DF System
	Filling line 2	Syringe Filling Machine
	Packaging line-1	Labeller Blister Packaging Machine Cartoning Machine

c) List of all the Vaccines or other products (intermediates, dosage forms) manufactured on-site:

Name	Dosage Forms	API
SKYCellflu Final bulk (surface antigen, inactivated, prepared in cell culture)	Final Bulk	[A/Victoria/4897/2022(IVR-38) (H1N1)] [A/Croatia/10136RV/2023(NYMC X-425A) (H3N2)] [B/Michigan/01/2021]
SKYCellflu Quadrivalent Final bulk (surface antigen, inactivated, prepared in cell culture)	Final Bulk	[A/Victoria/4897/2022(IVR-238) (H1N1)] [A/Thailand/8/2022, IVR-237(H3N2)] [B/Michigan/01/2021] [B/Phuket/3073/2013
SKYCellflu® inj. (Trivalent Influenza Vaccine) (for export)	Injections (Vaccine)	[A/Victoria/4897/2022(IVR-238) (H1N1)] [A/Croatia/10136RV/2023(NYMC X-425A) (H3N2)] [B/Michigan/01/2021]
SKYCellflu® Multi inj. (Trivalent Influenza Vaccine) (for export)	Injections (Vaccine)	[A/Victoria/4897/2022(IVR-238) (H1N1)] [A/Croatia/10136RV/2023(NYMC X-425A) (H3N2)] [B/Michigan/01/2021]
SKYCellflu Quadrivalent inj. (surface antigen, inactivated, prepared in cell culture) (for export)	Injections (Vaccine)	[A/Victoria/4897/2022 (IVR-238) (H1N1)] [A/Thailand/8/2022 (IVR-237) (H3N2)] [B/Michigan/01/2021] [B/Phuket/3073/2013]
SKYCellflu Quadrivalent Multi inj. (surface antigen, inactivated, prepared in cell culture) (for export)	Injections (Vaccine)	[A/Victoria/4897/2022 (IVR-238) (H1N1)] [A/Thailand/8/2022 (IVR-237) (H3N2)] [B/Michigan/01/2021] [B/Phuket/3073/2013]

SKYCellflu Prefilled Syringe (surface antigen, inactivated, prepared in cell culture)	Injections (Vaccine)	[A/Victoria/4897/2022(IVR-238) (H1N1)] [A/Croatia/10136RV/2023(NYMC X-425A) (H3N2)] [B/Michigan/01/2021]
SKYCellflu Prefilled Syringe (for export)	Injections (Vaccine)	[A/Victoria/4897/2022 (IVR-238) (H1N1)] [A/Darwin/9/2021, IVR-228(H3N2)]] [B/Michigan/01/2021]
SKYCellflu Quadrivalent Prefilled Syringe (surface antigen, inactivated, prepared in cell culture)	Injections (Vaccine)	[A/Victoria/4897/2022(IVR-238) (H1N1)] [A/Croatia/10136RV/2023(NYMC X-425A) (H3N2)] [B/Michigan/01/2021] [B/Phuket/3073/2013]
SKYCellflu Quadrivalent Prefilled Syringe (surface antigen, inactivated, prepared in cell culture) (For export)	Injections (Vaccine)	[A/Victoria/4897/2022(IVR-238) (H1N1)] [A/Croatia/10136RV/2023(NYMC X-425A) (H3N2)] [B/Michigan/01/2021] [B/Phuket/3073/2013]
SKYPneumo Prefilled syringe (Pneumococcal Polysaccharide Conjugated to Diphtheria CRM 197)	Injections (Vaccine)	Pneumococcal Polysaccharide Conjugate Serotype 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F-Corynebacterium diphtheriae cross reacting material (CRM197) protein
HEPAMUNE prefilled syringe (Hepatitis B vaccine)	Injections (Vaccine)	Purified Hepatitis B Surface Antigen (rDNA) [Host: Saccharomyces cerevisiae AB110, Vector: pYLBC-a/G-UB-HBs]
SKYZoster Vaccine inj. (Zoster Virus Vaccine (live) [Oka/SK])	Injections (Vaccine)	Live, attenuated varicella-zoster virus (Virus strain: Oka/SK, Cell line: MRC-5)
SKYVaricella inj. (Varicella Virus Vaccine (live) [Oka/SK])	Injections (Vaccine)	Live, attenuated varicella-zoster virus (Virus strain: Oka/SK, Cell line: MRC-5)
NUVAXOVID (SARS- CoV-2 Spike Protein Vaccine(Recombinant))	Injections (Vaccine)	SARS-CoV-2 Spike Protein (Recombinant) (Host: Sf9, Vector: BV2373)
SKYCovione	Injections (Vaccine)	SARS-CoV-2 Spike Protein RBD Antigen (Recombinant) (Host 1: CHO-K1 (HD-BIOP3), Vector 1: M-2560, Host 2: E. coli (BL21), Vector 2: pET296 (+))
SKYTyphoid Multi inj. (Thyphoid purified Vi Polysaccharide Conjugated to Diphtheria toxoid vaccine)	Injections (Vaccine)	Purified VI polysaccharide (strain: S. Typhi C6524)-diphtheria toxoid (strain: C. diphtheriae) conjugate

d) List of all regulatory inspections performed in the last 3 years and their outcomes:

No	Date of Audit	Name of Authority	Product/ Production Area

1.	21-25 July 2025	MFDS	SKYCellflu Quadrivalent PFS/ Suite 5 and 9, Filling line 2, Packaging
2.	11-14 October 2022	MFDS	SKYZoster inj./ Suite 8, Filling line 4, Packaging
3.	24 June - 1 July 2022	WHO	SKYTyphoid Multi inj. and NUVAXOVID / Suite 1, 4 and 5, Filling line 2 and 3, Packaging
4.	9 – 13 May 2022	MHRA*)	Novavax COVID-19 Vaccine (DS) and GBP510 COVID-19 Vaccine/ Suite 1 and 4, Suite 5, 7, and 9, Filling line 3, Packaging
5.	22 – 25 March 2022	EMA*)	Novavax COVID-19 Vaccine (DS)/ Suite 5
6.	21 February 2022	MFDS	SKYTyphoid Multi inj./ Suite 1 and 4, Filling Line 3 and Packaging

*) The EMA and MHRA inspection concerned either contract-manufactured products or products for which the marketing authorization had been withdrawn.

e) Most recent product quality review(s) (PQR)(s) of the concerned WHO Vaccine(s):

PQR for each of the Influenza vaccines were reviewed and found satisfactory.

f) Batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant Vaccine(s):

The company submitted the manufactured batch record for two product which was manufactured in 2024: SKYCellflu Multi inj., and SKYVaricella inj.

The batch records were written in Korean language. No issues were observed from the batch record. Verification of second person was conducted, printed record attached and reviewed. Deviation was recorded. Correction made to the record was managed in accordance with the Good Documentation Practice.

g) Master batch manufacturing and packaging record(s) of the Vaccine(s) of interest:

There were separate master batch records for each stage of manufacturing from the preparation up to testing and packaging. Master batch manufacturing and packaging records were available and maintained up to date. Any revision was recorded in the revision history which was part of the document. Review to the document indicated that the most recent update to the document were mostly minor updates.

h) If any of the products are sterile, the completed batch records for the most recent media fill validation that is relevant to the product(s) of interest and report on its outcome:

Protocol and Report for Aseptic Process Simulation (APS) in the Liquid Vial Line and in the Lyophilized Vial Line were submitted for review and found satisfactory.

i) Recalls in the past three years related to Vaccine(s) with quality defects:

The company submitted declaration letter signed by the Authorized Person in Quality on 10 September 2025 which stated that there were no recalls in the past three years related to any product manufactured on site.

j) Confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the Vaccine(s) has been performed and all matters dealt with:
The company submitted declaration letter signed by the Head of Quality Excellence on 10 September 2025, which stated that full self-inspection and/ or external audit dedicated to the products has been thoroughly performed. The scope of the inspection and/ or audit included all relevant quality assurance criteria and standards dedicated to the product. Any observations identified during the process had been fully addressed and resolved to ensure compliance with all applicable quality requirement

k) Copy of any warning letter, or equivalent regulatory action, issued by any authority for their market, to which the site provides or has applied to provide the Vaccine(s):
The company submitted declaration letter signed by the Authorized Person in Quality on 10 September 2025 which stated that there were no recalls in the past three years related to any product manufactured on-site.

l) Out-of-stock situations:
The company submitted declaration letter signed by the Lead of Production Planning on 22 September 2025, which stated that there were no out-of-stock situations since the last inspection in July 2022 nor are there any foreseen situations for the products within scope of the desk assessment.

m) Additional documents submitted:
The company submitted declaration letter signed by the Team Leader of Regulatory Affairs 2 on 30 September 2025, which stated that no inspection by the competent national regulatory authorities is planned or scheduled to take place within the next six months at the manufacturing facilities. In particular, the company do not anticipate any inspection specifically targeting the WHO prequalified products during this period. In the event that an inspection is conducted within the mentioned period, the relevant information shall be duly provided upon formal request by WHO.

Part 5	**Conclusion – Desk assessment outcome**

Based on the GMP evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site **SK bioscience Co., Ltd.** located at **150, Saneopdanji-gil, Pungsan-eup, Andong-si, Gyeongsangbuk-do, Republic of Korea** is considered to be operating at an acceptable level of compliance with WHO GMP guidelines.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 6	**List of guidelines referenced in this inspection report**

1. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. ***Short name: WHO GMP for APIs*** or ***TRS No. 957, Annex 2***
   http://apps.who.int/medicinedocs/documents/s20119en/s20119en.pdf

2. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eight Report. Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. ***Short name: WHO GMP Guidelines*** or ***WHO TRS No. 986, Annex 2***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

3. WHO guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report. Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 9. ***Short name: WHO TRS 1010, Annex 9***
https://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS1010annex9.pdf?ua=1

4. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-six Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2.
Short name: WHO TRS No. 970, Annex 2
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/

5. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
Short name: WHO TRS No. 929, Annex 4
http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

6. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty Second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8. **Short name: WHO TRS No. 1010, Annex 8**
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en/

7. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4.
Short name: WHO TRS No. 937, Annex 4
http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

8. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1.
Short name: WHO TRS No. 961, 957), Annex 1
http://www.who.int/medicines/publications/44threport/en/

9. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2.
   Short name: WHO TRS No. 957, Annex 2
   http://www.who.int/medicines/publications/44threport/en/

10. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6.
    Short name: WHO TRS No. 961, Annex 6
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

11. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7.
    Short name: WHO TRS No. 961, Annex 7
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

12. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9.
    ***Short name: WHO TRS No. 961, Annex* 9**
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

13. General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-First Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3.
    Short name: WHO TRS No. 943, Annex 3
    http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

14. WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2.
    Short name: WHO TRS No. 961, Annex 2
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

15. WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2.
    Short name: WHO TRS No. 981, Annex 2
    http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

16. WHO guidelines on variation to a prequalified product. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 3.
Short name: WHO TRS No. 981, Annex 3
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

17. WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14.
Short name: WHO TRS No. 961, Annex 14
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

18. WHO Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 3.
Short name: WHO TRS No. 992, Annex 3
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

19. WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4.
Short name: WHO TRS No. 992, Annex 4
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

20. WHO Technical supplements to Model Guidance for storage and transport of time – and temperature – sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5.
Short name: WHO TRS No. 992, Annex 5
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

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