**WATER – REFERENCES**

1. WHO Technical Report Series, No. 929, 2005. Annex 3 - WHO Good Manufacturing Practices: water for pharmaceutical use.

http://apps.who.int/prequal/info\_general/documents/trs929/who\_trs\_929.pdf

1. TRS 970 Annex 2 WHO good manufacturing practices: water for pharmaceutical use. 2012 ®

http://apps.who.int/medicinedocs/en/m/abstract/Js19832en/

1. TRS 937, Annex 4 Supplementary guidelines on good manufacturing practices: validation. 2006.

-Appendix 2: Validation of water systems for pharmaceutical use ®

http://apps.who.int/prequal/info\_general/documents/TRS937/WHO\_TRS\_937-Annex4.pdf

1. FDA GUIDE TO INSPECTIONS OF HIGH PURITY WATER SYSTEMS.1993.

http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074905.htm

1. ASME BPE-2009 (Revision of ASME BPE-2007) Bioprocessing Equipment.
2. ISPE Baseline – Pharmaceutical Engineering Guide for New and Renovated Facilities – Vol. 4 – Water & Water Systems.2001
3. ISPE Baseline Guide, Volume 5, Commissioning and Qualification. 2001.
4. USP <1231> WATER FOR PHARMACEUTICAL PURPOSES. ®
5. PI 009-X Inspection of Utilities- Aide Memoire- PICS (*PI 009-3, September 2007*). ®

http://www.gmp-compliance.org/guidemgr/files/PICS/PI%20009-3AIDEMEMOIREONUTILITIES.PDF

1. Practical guidelines for qualifying purified water systems. Dec 01, 2007. A. Hultqvist. Pharmaceutical Technology Europe. Vol. 19, Issue 12. ®http://www.pharmtech.com/practical-guidelines-qualifying-purified-water-systems?id=&sk=&date=&pageID=4

**HVAC - REFERENCES**

1. WHO Technical Report Series, No. 937, Annex 4. Supplementary guidelines on good manufacturing practices validation. 2006. –Appendix 1: Validation of heating, ventilation and air-conditioning systems. ®

http://apps.who.int/prequal/info\_general/documents/TRS937/WHO\_TRS\_937-Annex4.pdf

1. WHO technical report series; no. 961. Annex 6 WHO good manufacturing practices for sterile pharmaceutical products. ®

http://apps.who.int/prequal/info\_general/documents/TRS961/TRS961\_Annex6.pdf

1. WHO technical report series; no. 961. Annex 5. Supplementary guidelines on good manufacturing practices for heating, ventilation and air conditioning systems for non-sterile pharmaceutical dosage forms.

http://apps.who.int/prequal/info\_general/documents/TRS961/TRS961\_Annex5.pdf

1. ISPE, Good Engineering Practices for clean room design and construction for Pharmaceutical Industry.
2. ISO 14644-1. Second Ed. 2015-12-15. Cleanrooms and associated controlled environments.Part 1:Classification of air cleanliness by particle concentration ®
3. PDA Technical Report No. 13 (Revised). Fundamentals of an Environmental Monitoring Program. 2014.
4. FDA Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice. September 2004. Guidance for Industry.

http://www.fda.gov/downloads/Drugs/.../Guidances/ucm070342.pdf

1. WHO Environmental Monitoring of Clean Rooms in Vaccine Manufacturing Facilities Points to consider for manufacturers of human vaccines. November 2012. ®

http://www.who.int/immunization\_standards/vaccine\_quality/env\_monitoring\_cleanrooms\_final.pdf

1. USP <1116> MICROBIOLOGICAL CONTROL AND MONITORING OF ASEPTIC PROCESSING ENVIRONMENTS. ®
2. PI 009-X Inspection of Utilities- Aide Memoire- PICS (*PI 009-3, September 2007*). ®

http://www.gmp-compliance.org/guidemgr/files/PICS/PI%20009-3AIDEMEMOIREONUTILITIES.PDF

**AUDIT – REFERENCES**

1. PHARMACEUTICAL INSPECTION CONVENTION PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME. AIDE-MEMOIRES - INSPECTION OF BIOTECHNOLOGY MANUFACTURES. PI 024-1. 16 December 2005. ®

http://www.picscheme.org/pdf/15\_pi-024-2-aide-memoires-on-biotech.pdf

1. Parenteral Drug Association. “Elements of a Code of Conduct for Data Integrity”

### ISO 19011:2011(E). Guidelines for auditing management systems.

### International Conference on Harmonization, *Q10*, “Pharmaceutical Quality System,” June 2008. ®

http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html

### Auditing as a Component of a Pharmaceutical Quality System. T. Fields. *Journal of GXP Compliance. Autumn 2008 Volume 12 Number 5.* ®

http://www.ivtnetwork.com/sites/default/files/AuditingComponent\_01.pdf

1. Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 1: General Requirements. GHTF/SG4/N28R4:2008. ®

<http://www.imdrf.org/docs/ghtf/archived/sg4/technical-docs/ghtf-sg4-guidelines-auditing-qms-part-1-general-requirements-080827.pdf>