GMP

GMP and GLP DATABASE – Version 34 (May 14)

GLP

CONTENTS : Part A : GMP & GLP GUIDELINES ....Covering more than 50 countries

1. US FDA : 21 CFR part 210 & 211, Process Validation and OOS draft guidance 1997, *21 CFR 58*.on GLP
2. WHO TRS : 822, 823, 834, 863, and 902 (GMP, Sterile, Biological Standardization, Excepients, Validation packaging)
3. TGA : Australia : Guideline dated August 28, 2002, effective from September 28, 2003, Drafts 2005
4. PICS GMP (basic GMP guide and 18 annexes), Checklist on HVAC, Validation & Computer systems.
5. MHRA (EU GMP - Volume 4, and 18 annexes), The Qualified Person (QP) code 2010
6. MCC South Africa : GMP guide dated February. 15, 2004 and all associated guides
7. HPFB Canada - (all GMP guidelines 10+ latest 2011 amendments)
8. HSA, Singapore - GMP (20 Guidance Documents)
9. ANVISA Brazil (2010) and the Swiss GMP guide
10. Schedule M India - December 11, 2001, Schedule U, and the D&C Act 2006
11. ICH - all guidelines - (Q1 – Q11) – Jan. 2014
12. GMP guidelines China (2011), Thailand, Hong Kong, Korea
13. The New Zealand GMP guide for human and veterinary products
14. Pakistan GMP guideline, Biologicals GMP checklist, Bangladesh Biosafety
15. Guidelines on Technology Transfer – Japan & MRC Good Research Practice
16. Saudi Arabia GMP & Radiopharmaceuticals, Baharin GMP guide, GCC (Gulf) GMPs, Arab & Palestine GMP,
17. GMP guide : Japan, Philippines, Malta, Iceland, Ireland, Ethiopia and Egypt
18. Sudan GMP checklist, Turkey GMP guide, Tanzania, Israel GMP inspection manual
19. GMP guidelines : Czech, Virginia, Malta, Macedonia, Bulgaria, Croatia, Estonia, Uganda and Zanzibar
20. The OECD GLP guidelines, principles and check lists, and GLP guides of other countries

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UPDATES

CONTENTS : Part B : GMP CHANGES : 2003 – 2014 (Second Quarter Updates)

1. INDIA - Schedule M - 2005, D & C Rules 2005 and 2010 – Schedule L1 (GLP), GDP, Recall (updates Jan 2013)
2. WHO : TRS 908 (all annexes), Oct. 2003. TRS 917 , TRS 926 (*Biological Standzn.) TRS 929 , TRS 937. (Validation, HVAC for non-steriles, Transportation), Stability, Reference substances, Quality terms, QC labs qualification, TRS 943 – International Chemical Reference Substances & registration submission details, counterfeits management guide, TRS 948, TT guide, Hormone & Stability, TRS 953, GMP - sterile medicinal products, GLP, TRS 957, QRM R1, HVAC, Water Systems & GMP revisions, GLP Micro Labs, TT guide, TRS 961, GMP, Tech Transfer, Risk, Water Systems, TRS 970, 981, QRM R2, GMP prop rev, bulk hold time studies R2 & GDP, Hold time & PV NS (updates April 2014).
3. MHRA (EU and EMEA) : Annex 1- S.M.P.Ch. 1 – P.Q.R., Ch. 6 - Lab Controls, Annex 19 - Control Sample Mtgt, GMP for starting material - part 2, Ch. 8, ,Q b D & QRM, annex 7, Herbals, Site Master File for overseas manufacturers (MHRA), G. D.P., Inspection procedures of EU, Chapter 1- QRM, Q10, annex 2, Biologicals, GDP version 8, stability guide, Medical gases, Annex 11, QP study guide 2008, Herbal GMP, ICH Q4, Parametric release, QRM., Plasma products, Risk based Inspection MHRA, SMF guide, Ch. 2 - Personnel, concept papers on RTR and validation, Ch 7, Production controls, Lab controls, Genotoxic impurities, storage conditions, OOS, Annex 11 Electronic Systems, Ch. 4, Ch. 8 MCR, PV, Final ver. Ch. 1. P.Q.S., Ch. 7 Outsourced activities, An. 2 Biologicals, PV, Ch. 3,5,6,8, GDP API. Execip, Inspn. findings and new Annex 15 Qualification and Validation, Chapter 6, QC (updates - April 14)
4. MCC - South Africa - 19 GMP guidelines added after Feb 2004, January 2006, June 12 (updates - June 2012)
5. US FDA - Quality Systems for GMP, PAT, Aseptic Processing, GMP combination products, Computerised systems in clinical trials (Sept. 29, 2004). Inspection process for API manufacturers (Feb. 2006), Adoption of QbD and QRM (May 2006), Quality systems for GMP final guide (September 2006). OOS (November 2006). IND GMP, Addition, Final 21 CFR Part 211, PV guide rev 1, Dedicated facilities, Audits, Method validation (update Feb. 2014).
6. HPFB Canada : new process validation Guideline, 2004/05. GMP risk observation classification 2006, Temperature control of drugs during storage and transport, Validation of FFS, dosage forms, Sterilization, GMP guide draft 2007 (December. 2006), Implementation guide 2009 and updates June 2010. Current Version (updates March 2011)
7. PICS GMP : Checklists – inspn. of HVAC, Q C Labs, Biotech, Medical gases, API & Packaging. All revisions - till Sept. 09. QRM Implementation - Jan 2010, SMF 2011, Risk based inspections, GMP ver. 10 (Updates Feb 2014)
8. HSA Singapore : Revision of 20 GMP guides Dec. 2008, Dec 2010, Oct 2012 and Feb 2013

SUPPORT

CONTENTS : Part C : OTHER USEFUL GMP GUIDES

1. STABILITY GUIDELINES : 11 COUNTRIES (ASEAN, GCC, ANVISA, PANAMA, WHO & likes)
2. GMP for PACKAGING MATERIAL : Basic 2011, Glass, Plastic, Boxes, Adhesives, Sealants, Alloys & Printing inks, Tissue
3. GOOD STORAGE AND DISTRIBUTION PRACTICES GUIDELINES – 28 documents
4. ANIMAL USE GUIDELINES - 4 & 2 POLLUTION guides for the Pharma Industry !
5. MEDICAL DEVICE GUIDELINES, DIETARY SUPPLEMENTS, BLOOD PRODUCTS GMP
6. GMP : Herbal Medicinal Products : Good Agriculture & Collection Field practices , IUPAC Documentation & Protocols
7. GMP for COSMETICS (Malaysia, Singapore, CFTA, BIS and ASEAN) & GMP for EXCEPIENTS IPEC guide
8. FOOD GMP GUIDELINES – PFA India, USFDA, Tanzania, Australia, SQF & more. New – STEMCELLS / BIOSIMILARS !

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