เอกสารอ้างอิง

1. http://autoclaves.globalspec.com/LearnMore/Labware_Scientific_Instruments/Thermal_Processing/Autoclaves_Sterilizers
2. http://www.cdc.gov/oralhealth/infectioncontrol/faq/sterilization_monitoring.htm
3. http://www.ehs.neu.edu/autoclave/frame.htm
4. http://www.orcbs.msu.edu/biological/programs_guidelines/autoclave/a_01toc.htm
5. http://web.missouri.edu/~muehs/
6. http://www.systec-lab.de/
7. http://www.thaidental.com/dentist/a16.htm
8. http://www.uottawa.ca/services/ehss/docs/autoclave.pdf
9. http://www.validation-online.net/performance-qualification.html
10. คณะทำงานย่อยเพื่อศึกษาวิเคราะห์การพัฒนาอุตสาหกรรมยา “การพัฒนาอุตสาหกรรมยา” ในระบบยาของประเทศไทย, 303-370. สุวิทย์ วิบุลผลประเสริฐ, บรรณาธิการ. กรุงเทพฯ: อรุณการพิมพ์, 2537.
11. คณะทำงานศึกษาวิเคราะห์การพัฒนาอุตสาหกรรมยา “อุตสาหกรรมผลิตยาแผนปัจจุบัน” ในระบบยาของประเทศไทย, 449-496. สุวิทย์ วิบุลผลประเสริฐ, วิชัย โชควิวัฒน และศรีเพ็ญ ตันติเวสส, บรรณาธิการ. กรุงเทพฯ: ชุมนุมสหกรณ์การเกษตรแห่งประเทศไทย, 2545.
12. แนวทางการตรวจสอบความถูกต้องของกระบวนการทำให้ปราศจากเชื้อด้วยความร้อน (Guide to Validation of Heat Sterilization Process), จัดพิมพ์โดย กองควบคุมยา สำนักงานคณะกรรมการอาหารและยา. (Thai FDA) มิถุนายน 2546.
13. สำนักงานคณะกรรมการอาหารและยา, กองควบคุมยา 2550.
14. “หลักเกณฑ์และวิธีการในการผลิตยาแผนปัจจุบัน”, 2554.
15. ปกรณ์ ทวีโชติภัทร์. เอกสารประกอบการสอนวิชา Microbiological analysis. กรุงเทพมหานคร: ภาควิชาจุลชีววิทยา คณะเภสัชศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย, 2540.
16. A Practical Approach to Steam Autoclave Cycle Delopment, Journal of Validation – Technology, by Victor Tsui, P.E. and Ward Wiederhold, B.S.M.E.
17. American National Standard Institute (ANSI), Association for the Advancement of Medical Instrumentation (AAMI), International Standards Organization (ISO), ISO 11138
18. (2005) Sterilization of health care products – Biological Indicators – Part 1 General.
19. ANSI/AAMI/ISO 11138 (2005) Sterilization of Health Care products – Biological Indicators – Part 2 Biological indicators for ethylene oxide sterilization.
20. ANSI/AAMI/ISO 11138 (2005) Sterilization of health care products – Biological Indicators – Part 3 (1995) Biological indicators for moist heat sterilization.
21. ANSI/AAMI/ISO 18472 (2006) Sterilization with Health Care Products - Biological and Chemical Indicators – Test Equipment.
22. 3M™ Technical Product Profile: 3M™ ATTEST™ Biological Monitoring System, 1994

23. 3M™ Technical Information Sheet: 3M™ Comply ™ (SteriGage™ Steam Chemical Integrator, 1999, 70-2009-0710-6 (29.5) DPI
24. Bacteriological Analytical Manual, US. FDA., 18 1998.
25. “Baseline Guide: Risk-Based Manufacturer of Pharmaceutical Product (Risk-MaPP)”, ISPE, 2010.
26. “Baseline Guide Volume 5: Commissioning and Qualification”, ISPE, 2001.
27. British Pharmacopoeia 2013.
28. Butsumyo, A and SA Velasco. Refrigerators and Freezers, pp. 12.18.1 – 12.18.9. In Isenberg HD, P Della-Latta and EM Vellozzi (ed.), Clinical Microbiology Procedures Handbook. American Society for Microbiology, Washington, DC. 1992.
29. Clarke J. Save power: build these heat controllers. Electronics Australia 1984;76-85.
30. EMEA; Decision tree for the selection of sterilization method (CPMP/QWP/054/98). 5 april 2000
31. Frederick J. Carleton, James P Agalloco. Validation of Aseptic Pharmaceutical Process. Marcel Dekker, Inc. Newyork. Basel 1986.
32. Fundamentals of an Environmental Monitoring Program, PDA Technical Report No.13 Revised 2001.
33. “Guide to Good Manufacturing Practice for Medicinal Product Part II”, PIC/S, 2009
34. International Standard 17665-1, Sterilization of health care products – Moist heat – Part1: Requirements for the development, validation and routine control of a sterilization process for medical device. First edition, 2006-08-15
35. IEC 60068-3-6, Environmental testing-Part 3-6: Supporting documentation and guidance-confirmation of the performance of the temperature/humidity chambers, 2001.
36. ILAC-P10:2012 Policy on Traceability of Measurement Results.
37. Ira R.Berry, Robert A.Nash. Pharmaceutical Process Validation Second edition,Revised and Expanded,Marcel Dekker, Inc. New York. Basel. Hongkong 1993.
38. ISO/IEC 17025-2005: General Requirements for the Competence of Testing and Calibration Laboratories.
39. ISO/IEC 17020-Conformity assessment: Requirements for the operation of various types bodies performing inspection.
40. Kenneth E. Avis, Herbert A. Lieberman, Leon Lachman. Pharmaceutical Dosage Forms:Parenteral Medications Volume 3 Second Edication, Revise and Expand . Marcel Dekker, Inc. Newyork. Basel. HongKong
41. Knezek KH, Dorn GL, Fleming WH. Is your incubator really calibrated Lab Med 1983;14:366-71.
42. Le, R.N., et al, Autoclave Testing in a University Setting. *Applied Biosafety*, 2005;10(4):248-252.

43. Limulus Amebocyte Lysate, PYROGENT ™ PLUS manual (Lonza Group Ltd.)
44. Mosley, G. A., “Estimating the Effects of EtO BIERVessel Operating Precision on D-Value Calculations,” MD&DI, 24 (4), 46-56 (April, 2002).
45. Mosley, G. A. and Gillis, J. R., “Operating Precision of Steam BIER Vessels and the Interactive Effects of Varying Z Values on the Reproducibility of Listed D Values,” PDA Journal of Pharmaceutical Science and Technology, Nov-Dec, 56 (6), 318-331 (2002).
46. Nigel A. Halls. Achieving Sterility in Medical and Pharmaceutical Products. Marcel Dekker, Inc. Newyork. Basel. Hongkong 1994.
47. Oxborrow, G. S., Twohy, C. W., and Demitrius, C. A., “Determining the Variability of BIER Vessels for EO and Steam,” MD&DI, 12 (5), 78-83 (1990).
48. PDA Journal of Pharmaceutical Science and Technology; Technical Report no.1Revised 2007 Validation of moist Heat Sterilization Process: Cycle Design, Development, Qualification and Ongoing Control. Supplement volume 61 no. S -1.
49. Parametric Release of Pharmaceutical Terminally Sterilized by Moist Heat, PDA Technical Report No 30.
50. PhillStunell, “FMEA for Engineers: How to improve productivity in design and development”, Stunell Technology Limited, 2003.
51. PUWER 1998: Provision and Use of Work Equipment Regulations 1998. Open1 learning guidance (Second edition) HSE Books 2008 ISBN 978 0 7176 6285 2.
52. Practical Guide to Autoclave Validation, PHARMAEUTICAL ENGINEERING. JULY/AUGUST 2002 by Raymond G.Lewis, PE.
53. “Quality Risk Management (ICH Q9)”, EMA, 2011.
54. Remington :The Science and Practice of Pharmacy , Mack Publishing Company Easton, Pennsylvania 18042, 1995.
55. Safety of pressure systems. Pressure Systems Safety Regulations 2000. Approved Code of Practice L122 HSE Books 2000 ISBN 978 0 7176 1767 8.
56. Safe work in confined spaces Leaflet INDG258 HSE Books 1997 (Priced pack ISBN 978 0 7176 1442 4).
57. Sharp, J. QualityRules in Sterile Products Manufacture Interpharm Press Inc., Buffalo Grove,II.1992
58. Scharff R. Refrigeration, air conditioning, range and oven servicing. New York : Mc Graw-Hill Book Company, 1976.
59. Stoecker, W.F. and J.W. Jones. 1982. Refrigeration and air conditioning, 2nd ed. McGraw-Hill, New York.Construction Completion Pre-commissioning & Commissioning Dossier: Purified Water System, MWZ/526143/ M-009, Volume 1 of 1, April 2009.

60. TLAS G-20, Guidelines for Calibration and Checks of Temperature Controlled Enclosures, 2008.
61. United States Pharmacopoeia version 36.
62. VALIDATION of PHARMACEUTICAL PROCESSES, Sterile Product, Second Edition, Revised and Expanded. Edited by Frederick J.Carleton and James P. Agalloco. Validation of steam sterilization in Autoclave; page 413.
63. Validation of Steam Sterilization ,PDA Monograph No.1 2002 Revision November 2001 Draft 12.
64. "WHO Guideline on Quality Risk Management", World Health Organization, 2010.
65. Written schemes of examination: Pressure Systems Safety Regulations 2000. Leaflet INDG178 (rev1) HSE Books 2002 (Priced pack ISBN 978 0 7176 2269 6).
66. Yamamoto Y, Hanafusa T, Nagamatsu T, Okada S. Experimental incineration of low level radioactive sample. Health Phys 2000;79:25-32.