

A significant number of articles are available on the subjects of USP <797>, regulatory compliance, and related issues. Below is a summary of key reference articles recommended by experts in USP <797> training and compliance.

"Understanding Pharmaceutical Cleanroom Design" written by John Zhang, P.E. in **ASHRAE Journal**, September 2004. <http://www.ashe.org/ashe/codes/epa/pdfs/JournalSept2004PharmacyDesign.pdf>

"Microbial Monitoring of Controlled Environments and Alert and Action Limits" written by Gregg A. Mosley and Matthew A. Hansen. **A2C2**, Vol. 7, No 6, pp. 9-11 June 2004. Request reprint at <http://www.biotestlabs.com/reqs.html#pubform>

"CETA Certification Guide for Sterile Compounding Facilities", **CETA**, CAG-003-2006, June 7, 2006. <http://www.cetainternational.org/reference/CETAasepticCompoundingCertificationGuide.pdf>

"Guideline for Hand Hygiene in Health-Care Settings" prepared by John M. Boyce, M.D. and Didier Pittet, M.D. and published by **MMRW**, October 25, 2002/Vol. 51/No. RR-16. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5116a1.htm>

"Preventing Occupational Exposures to Antineoplastic and other Hazardous Drugs in Healthcare Settings," published by **NIOSH**. www.cdc.gov/niosh

"Cosmetics in cleanrooms...again? (Part 2)" written by Ken Goldstein, PhD. **CleanRooms**, March 2001. http://cr.pennnet.com/articles/article_display.cfm?section=archives&subsection=display&article_id=95074&keyword=people%20and%20particles

"Surface Cleaning Training Session: Overlooked Protocol" written by Howard Siegeman. **CleanRooms**, April 2003. http://cr.pennnet.com/articles/article_display.cfm?section=archives&subsection=display&article_id=173753&keyword=cleanroom%20mops

"Antiseptics and Disinfectants: Activity, Action, and Resistance" written by Gerald McDonnell and A. Denver Russell. **Clinical Microbiology Reviews**, Jan. 1999, p. 147-179. http://cmr.asm.org/cgi/content/full/12/1/147#SEC2_3

"Transmission of infection with multi-dose vials" written by Barbara DeBaun, RN, MSN, CIC – **Infection Control Resource**, Vol. 3 No. 3 http://www.infectioncontrolresource.org/Past_Issues/IC11.pdf

"Exophiala Infection from Contaminated Injectable Steroids Prepared by a Compounding Pharmacy" published by **MMWR Weekly**, December 13, 2002/51(49); 1109-1112. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5149a1.htm>

"Environmental Monitoring Practices and Regulations for the Sterile Manufacturer" written by Anne Booth and published by **PMPS**. <http://www.samedanltd.com/members/archives/PMPS/Autumn2003/AnneB.htm>

"A Practical Guide to Aseptic Technique Verification: Policies and Procedures that Meet USP Chapter <797> Requirements" written by Eric S. Kastango, RPh, MBA, FASHP and published by **PP&P Magazine**. http://www.pppmag.com/index.php?option=com_content&task=view&id=243

“Design Your Cleanroom to Ensure Easier Use, Cleaning, and Maintenance” written by Kate Douglass and published by **PP&P Magazine**. http://www.pppmag.com/documents/V3N2/PPP_V3N2_pp10-14_cleanroomdesign.pdf

“Does Your Barrier Isolator [Isolate]? The Importance of Eliminating Contamination in Your Barrier Isolator” written by James T. Wagner and published by **PP&P Magazine**. http://www.pppmag.com/index.php?option=com_content&task=view&id=152

“Establishing Sound Practices for Cleaning Your Cleanroom: Cleaning Products and Procedures for <797> Compliance” written by Kate Douglass and published by **PP&P Magazine**. http://www.pppmag.com/index.php?option=com_content&task=view&id=194

“Understanding Pharmacy Cleanroom Design Requirements” written by James T. Wagner and Eric S. Kastango, RPh, MBA, FASHP and published by **PP&P Magazine**. http://www.pppmag.com/index.php?option=com_content&task=view&id=253

“Using Barrier Isolators for Sterile Compounding” written by James T. Wagner and published by **PP&P Magazine**. http://www.pppmag.com/index.php?option=com_content&task=view&id=263

“Guidance For Industry - Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice” published by **US Dept of Health & Human Services - FDA** <http://www.fda.gov/cder/guidance/5882fnl.htm>