

Qualifications for James T Wagner

June 29, 2017

Jim has been involved with certification and validation of controlled environments since 1979. He has been president of Controlled Environment Consulting since 2004. His consulting includes designing and evaluation of sterile compounding facilities, containment facilities and engineering controls as well as international training on cleanroom and containment device certification.

Jim was employed at Micro-Clean, Inc. from June 1979 until March 2004. Early responsibilities included Cleanroom and Containment Device certification, providing practical applications based understanding of the issues. He served as President from 1989 to his departure in 2004. During his tenure at Micro-Clean, Jim developed an acute understanding of the compliance and maintenance issues involved with controlled environments.

He has been actively involved in the Performance Evaluation community the past 30+ years. Recent activities have involved leading the Controlled Environment Testing Association's (CETA) efforts to develop guidance documents for chapter <797>. He was the founding president of the Controlled Environment Testing Association and has served as a frequent Board member, speaker and contributor. Jim was awarded the Controlled Environmental Testing Association's Melvin First Award for outstanding contribution to the advancement of certification and testing of controlled environments through teaching, research, service, and leadership in 2017.

Involvement with NSF International includes serving on the steering committee for rewriting and maintaining NSF std. 49. He was one of the first 12 individuals accredited as a qualified individual for Certification of Biological Safety Cabinets. He also served a term on the certifier accreditation steering committee.

Involvement with the Institute of Environmental Science and Technology (IEST) includes membership on various working groups responsible for developing recommended practices for HEPA filters and Cleanrooms.

WG001 - HEPA Filters, WG002 - HEPA Filter devices, WG006 - Testing Cleanrooms
WG034 - HEPA and ULPA Filter Leak Tests

Jim is a frequent presenter at various industry forums on issues including Biosafety Cabinet design, certification, decontamination, and servicing, cleanroom design and certification, and HEPA filters. Jim has been the primary instructor since 1995 for the Eagleson Institute class; Advanced Certification (of Class II BSCs). In addition to the semi-annual class for the advanced certifiers in the United States, this course has been held internationally. Jim is the primary instructor for the Eagleson Institute class "Certification of Sterile Compounding Facilities".

Jim served on the USP sterile compounding committee for the 2005-2010 appointment cycle and has presented at many USP forums on sterile compounding. He is currently a member of the USP Compounding with Hazardous Drugs Expert Panel and has been elected to serve on the 2015-2020 USP Compounding Expert Committee.

Jim has been involved in over 250 cleanroom design projects including ISO Class 8, 7, 6, and 5 environments for sterility, containment, and combined applications.

Jim has been a member of the US Technical Advisory Group for ISO/TC 209.

Jim Wagner published articles

1. Wagner, J. Ensure Safe Use of CAIs and CACIs, *Pharmacy Purchasing and Products*. December 2014; Vol. 11, No. 12
2. Wagner, J. Interpreting Cleanroom Certification Reports. *Infusion Journal of the National Home Infusion Association*. 2014; November/December 34-42
3. Wagner, J. Meeting Regulatory Expectations for Smoke Pattern Testing. *Pharmacy Purchasing and Products*. November 2014, 42-46
4. Wagner, James T, Choosing a Certification Professional to Evaluate your Cleanroom and Engineering Controls, *Pharmacy Purchasing and Products*, 2009, 6:7
5. Kastango, Eric S, Wagner, James, T, Kastango, Kari, B, Kastango, Nicholas, E, Wagner, Terry, J, Generation of particulate matter during handling of needle and syringe packaging, *American Journal of Health-System Pharmacy*, 2008; 65:15
6. Wagner, James T, Demystifying Biological Safety Cabinets – Getting the Most Out of the Primary Engineering Controls Used in Microbiology Laboratories, *Clinical Microbiology Newsletter*, Vol. 29, No.14, July 15, 2007
7. Wagner, J. Controlled Environment Testing Association Applications Guide for the Use of Barrier Isolators in Compounding Sterile Preparations in Healthcare Facilities Part 1. *International Journal of Pharmaceutical Compounding*. 2006; 10: 128-133.
8. Wagner, J. CETA's Role Relating to the Proposed Changes in USP 797. *Performance Review from the Journal of Controlled Environmental Testing Association*. 2006; 1: 12.
9. Wagner, J. Considerations for Choosing a Primary Engineering Control for Compounding Sterile Products. *International Journal of Pharmacy Compounding Magazine*. 2005; 9: 284-289.
10. Wagner, J, Kastango ES. Understanding Cleanroom Design. *Pharmacy Purchasing and Products Magazine*. 2005; 2: 16-19.
11. Wagner, J. Does Your Barrier Isolator Isolate? *Pharmacy Purchasing and Products Magazine*. 2005; 2: 12-15.
12. Wagner, J. Choosing a Certification Professional to Evaluate Your Cleanroom Engineering Controls. *Pharmacy Purchasing and Products Magazine*. 2005; 2; 1-2.

Jim Wagner published articles

13. Wagner, J. Using Barrier Isolators for Sterile Compounding. *Pharmacy Purchasing and Products Magazine*. 2004; 1: 4-8.
14. Wagner, J. Guidelines and Standards. *Performance Review from the Journal of Controlled Environmental Testing Association*. 1995; 3: 6-7.
15. Wagner, J. High Temperature Filter Applications. *Performance Review from the Journal of Controlled Environmental Testing Association*. 1994; 1: 10-11.
16. Wagner, Chapter 4: Primary Engineering Controls, Compounding Sterile Preparations, American Society of Health-System Professionals, Third Edition, 2009.