



ControlledEnvironmentConsulting

Qualifications for James T Wagner

January 2007

Jim has over 28 years experience assuring the performance of critical environments. He has been involved with certification and validation of controlled environments since 1979. As President of Controlled Environment Consulting, Jim puts his experience with engineering controls to use consulting with users as well as manufacturers of Cleanrooms and associated engineering controls.

Employed at Micro-Clean, Inc. from June 1979 until March 2004, he continues to serve Micro-Clean as a contracted consultant. 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 over the past 28 years. Recent activities have involved leading the Controlled Environment Testing Association's (CETA) efforts to develop guidance documents for chapter 797 of USP27-NF 22. This includes drafting a general overview as it applies to Environmental Control, a guide for Barrier Isolators, a Cleanroom guide, and a Testing guide. Collaborating with registered pharmacists, Jim has developed a team to assist those in need of guidance in complying with the USP guidelines. Jim serves on the board of the Controlled Environment Testing Association (CETA), including a stint as the first president from 1992 to 1994 and again in 2005.

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 served a term on the certifier accreditation steering committee as well.

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. In addition to the semi-annual class for the advanced certifiers in the United States, this course has been held internationally.

Jim was the primary instructor for a class that Micro-Clean provided to both the Center for Drug Evaluation and Research (CDER) and the Center for Biologic Evaluation and Research (CBER) of the Food and Drug Administration (FDA). This class was conducted at Micro-Clean's Techcenter to develop a consistent understanding of Cleanroom issues for the decision makers of both influential groups.

Jim has been elected to serve on the USP sterile compounding committee for the 2005-2010 appointment cycle and has presented at many USP forums on sterile compounding.

Jim is a current member of the editorial advisory committee of Cleanrooms magazine and Pharmacy Purchasing and Products.