

## **Anne Marie Dixon**

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### ***Career Summary***

Owner and President of Cleanroom Management Associates, Inc., a consulting firm based in Carson City, NV that specializes in competitive benchmarking, training, and auditing of clean and aseptic operations and management.

Actively engaged in the field of contamination control for over 30 years with extensive experience in the areas of cleanroom operations, training, technical writing, strategic consulting, facility start-up, construction protocols, and process optimization. Has trained over 750,000 cleanroom technicians and managers.

### ***Major Accomplishments***

- ✓ 1978 Developed and tested cleanroom sanitization protocols
- ✓ 1979 Developed initial clean build protocols for the cleanroom industry
- ✓ 1980 Developed the first Cleanroom Management Training and Manuals
- ✓ 1983 Chairman of Institute of Environmental Sciences – Recommended Practice on Cleanroom Housekeeping and Sanitization Procedures, testing and equipment. In this committee the techniques and testing of 1978 were incorporated and proven.
- ✓ 1983-present – Developed aseptic gowning techniques
- ✓ 1984-present – Developed equipment move-in procedures
- ✓ 1985 Developed undergraduate course in Cleanroom maintenance and equipment installation techniques. Used today at 5 major universities in the USA.
- ✓ 1986 Chairman of Institute of Environmental Sciences – Recommended Practice on Cleanroom Operations. In this committee the techniques for equipment move-in were incorporated and proven.
- ✓ 1988 Developed and expanded clean build protocols to include 3,5 and 8 phases
- ✓ 1990 Chairman of conference on Particle Detection Methodology and Control
- ✓ 1991-1992 President of Institute of Environmental Sciences
- ✓ 1992 Chairman of conference on Mini-environments and Isolators
- ✓ 1993-present – Chairman of the United States Technical Advisory Group to ISO Technical Committee 209

- ✓ 1993-present – Head of the United States Delegation to ISO Technical Committee 209 on Cleanrooms and Associated Controlled Environments
- ✓ 1995 Chairman Biocontamination Control Symposium - IEST
- ✓ 1998 Chairman of Symposium on Cleanrooms for the Healthcare Industry (PDA and IEST)
- ✓ 1998 Headed research to develop new techniques for sanitization and cleaning of walls and floors in cleanrooms and controlled environments
- ✓ 1999 Chairman of PDA Special Scientific Forum on Environmental Monitoring
- ✓ 2000 Keynote address – PDA Training Conference
- ✓ 2001 Keynote address – Barnett International – conference on Environmental Monitoring
- ✓ 2001 Updated Institute of Environmental Sciences Recommended Practice on Housekeeping and Sanitization Procedures. Included new techniques and methods as developed in 1998-2000.
- ✓ 2002 Updated IEST Recommended Practice on Cleanroom Operations.
- ✓ 2007 Update IEST Recommended Practice on Housekeeping and Sanitization
- ✓ 2008 Co-Chair of ISO TC 209 – Nanotechnology Cleanroom and Controlled Environment – WG-10.

### **Awards**

- 1993 James P. Agalloco – “Excellence in Education”
- 1997 Diploma in Validation – Pharmaceutical Association of Mexico
- 1998 Fellow of the Institute of Environmental Sciences
- 2007 Fred Hermann Award

### **Education**

- BS in Finance – University of Illinois
- MBA – University of Chicago
- BS in Engineering – University of Nevada
- Certified ISO 9000 Auditor – University of Nevada – Reno

### **Publications**

#### Books

- Cleanroom Management Manual – 1980, revised 1988
- Cleanroom Management chapter – Noyes publication, Handbook of Contamination Control in the Microelectronics Industry - 1988
- Cleaning and Sanitization of Cleanrooms and Materials – Marcel Dekker publication, Validation of Pharmaceutical Processes – 1998

- How to Write A Training Manual –Micron Video International – 1999
- Personnel Training– A cleanroom must – Interpharm Press – Sterilization of Medical Devices – 1999
- 2006 – Editor - Environmental Monitoring for Cleanrooms and Controlled Environments – Informa USA
- 2007 – Confronting Variability, editor R. Prince, chapter 2 – “People, Training and Variability”, DHI International.
- 2009 – Aerosol Science and Technology – Particle chapter – to be published
- 2010 – Cleaning Validation – Informa USA – 11/09

### Technical articles

Over 335 technical articles have been published in the following areas in the following journals or publications:

Management  
Quality  
Personnel Training  
Garments  
Cleaning and Sanitization  
Auditing  
Cleanroom supplies – validation and testing  
Cleanroom cost and budgeting  
Design/testing and validation  
Environmental monitoring  
Gowning techniques  
ISO Standards  
Risk

### **Public Courses**

University of California – Irvine  
PDA

Cleanroom Management  
Design and Start-up of Cleanrooms  
Aseptic Operator Certification  
Auditing for Compliance, CAPA's and Investigations  
Controlling Cost of Operations  
Risk Mitigation

CCE

Design, Validation and Operations of Cleanrooms  
Isolator, Cleanroom and Controlled Environments  
A Practical Approach to Cleanroom Management

IEST

Cleanroom Operations  
ISO Standards  
Risk Assessment

Cleanrooms International

Introduction to Cleanroom Management

Pharma Net

Understanding Risk and GMP

***Professional Organization – Memberships***

PDA  
ISPE  
IEST  
ASQ  
AMA