## Publications

### Hydrogen Peroxide Gas Decontamination

Rickloff, J.R., *in* Advanced Aseptic Processing Technology, Informa Healthcare, London, England, **2010**.

This chapter provided an overview on the basics of $H_2O_2$ gas decontamination and on how the sterilant should be applied to isolator systems. In addition, the latest in validation techniques and sterilant monitoring requirements were discussed from a user and regulatory perspective.

### Chemical and Biological Aspects of Hydrogen Peroxide Gas

Grignol, George[1], Don Eddington[1*], Ph.D., Dave Karle[1], and James Rickloff[2], ISPE Barrier Isolation Technology Conference, Arlington, VA, June 5-6, 2000.

The interactions of hydrogen peroxide concentrations and surface temperatures are studied in an isolator using chemical and microbiological techniques. These tests verify commonly accepted theories of the gaseous properties of flash vaporized hydrogen peroxide that have recently been challenged.

### Key Aspects of Validating Hydrogen Peroxide Gas Cycles in Isolator Systems

Rickloff, J.R., Journal of Validation Technology, 5:61-71, 1998.

The purpose of this paper is to revisit some essential validation aspects of sanitizing isolators with hydrogen peroxide gas in order to assist the industry in demonstrating reproducibility of the process under worst-case conditions.

### Hydrogen Peroxide Gas Sterilization Trials Performed on A Prototype Enclosed Vial Filler

Rickloff, J.R. and D. Eddington, PDA/ISPE Conference, January 17-18, 1995.

Testing was performed on a prototype vial filler isolator at TL Systems Corp. in Minneapolis, MN, to determine the feasibility of incorporating hydrogen peroxide gas sterilization into the system. Carrier sterilization, isolator aeration, and water fill residual data was presented.

### "Modern Trends in Sterilization of Enclosures"

Rickloff, J.R. and L. M. Edwards, Chapter in Isolator Technology: Applications in the Pharmaceutical and Biotechnology Industries, edited by Carmen Wagner and James Akers, Interpharm Press, 1995.

### "Engineering and Project Management Issues for a Hydrogen Peroxide Sterilized Filling System"

Rickloff, J.R. and L. M. Edwards, Chapter in Isolator Technology: Applications in the Pharmaceutical and Biotechnology Industries, edited by Carmen Wagner and James Akers, Interpharm Press, 1995.

### Hydrogen Peroxide Gas Sterilization: A Review of Validation Test Methods

Rickloff, J.R., J. Dalmasso, and L.W. Lyhte, PDA Annual Meeting, 1992.

The importance of performing temperature distribution studies, the use of chemical and biological indicators in optimizing and verifying proper gas distribution, a technique to easily perform square-wave D-value determinations, and a means to quantitatively monitor aeration efficiency when using a prototype VHP1000 was reviewed.

### Resistance of Various Microorganisms to Vaporized Hydrogen Peroxide in a Table Top Sterilizer

Rickloff, J.R. and P. Orelski, ASM Annual Meeting, 1989.

A great deal of information is available in the literature on the relative resistance of microorganisms to aqueous hydrogen peroxide; however, the same cannot be said for hydrogen peroxide in the gaseous state. *Bacillus stearothermophilus* spores were found to be the most resistant to the sterilant, and the presence of organic soil did not affect the ability of hydrogen peroxide gas to sterilize stainless surfaces.

## The Use of Nitrogen Dioxide Gas for Isolator Decontamination Applications

Rickloff, J. R., PDA Global Conference on Pharmaceutical Microbiology, October 22-24, 2012.

A new decontamination technology is being developed and a review of preliminary breadboard testing on an isolator was presented.

## Historical Perspective on the Decontamination of Isolators Using Hydrogen Peroxide Gas

Rickloff, J. R., ISPE Barrier Isolation Technology Conference, June 6-7, 2005.

A 15-year look back at how hydrogen peroxide gas generators were developed and implemented into isolator systems was provided along with a synopsis on how to properly validate the decontamination process and how variable BI resistance can affect the revalidation of such systems.

## The Use of Abbreviated Decontamination Cycles to Prevent False Negative Sterility Test Results

Rickloff, J. R., PDA SciTech Summit, March 10, 2004.

Reviewed the current methods and past data involved in the validation of sterility testing isolators and discussed the value of using abbreviated decontamination for some product containers to prevent sterilant penetration.

## Implementing Validation Strategies for Isolator-Based Systems

Rickloff, J. R., Barnett International's 4th Annual Isolator Conference, January 27-28, 2003

This workshop thoroughly reviewed the overall strategies and basic validation methodologies for isolator system validation utilizing gaseous decontamination methods. Facility design and qualification, equipment qualification, performance qualification, and process simulation testing was reviewed, with practical examples and demonstrations of key methods and techniques.

## $H_2O_2$ Gas Decontamination Cycle Comparisons Between Rigid and Flexible Wall Isolators

Rickloff, J.R., Ia Calhène AUDITS 101 Conference, October 3-4, 2002.

This presentation provided an overview on the decontamination cycle and regulatory expectations for the process. Past flexible wall data and its' implications are reviewed and how new trends in validation techniques are implemented to reduce them. The benefits of rigid wall isolator construction are also discussed.

## Microbiological Monitoring in Isolators

Rickloff, J.R., bioMerieux Industrial Microbiology Seminar, September 18, 2002.

This presentation reviewed the principles of microbial monitoring in isolators, current US and European regulatory requirements for monitoring, and the means to achieve and maintain a germ free environment. The current means to monitor the air and surfaces in isolators is also touched upon.

## Practical Validation Strategies for Isolated Sterility Testing Labs - Part I

Rickloff, J.R., Barnett Isolator Conference, June 13-14, 2002

This workshop thoroughly reviewed the overall design process and equipment qualification methodology for isolator systems utilizing gaseous decontamination methods. Key learning objectives included determining your capacity requirements, developing a validation master plan, facility classification requirements, and qualifying your isolators and related process equipment.

## Practical Validation Strategies for Isolated Sterility Testing Labs - Part II

Rickloff, J.R., Barnett Isolator Conference, June 13-14, 2002.

The second part of the Workshop focused on the Performance Qualification studies that are needed to properly validate the gaseous decontamination method in sterility test isolator systems. Practical examples, a discussion of acceptance criteria, and the demonstration of test methods were included. Key learning objectives included determining a D-value for your BIs, developing and qualifying decontamination cycles, isolator aeration, sterilant ingress methods, and creating a meaningful process simulation (no false negative) study.

## Current Trends in Controlled Environments

Rickloff, J.R., AAPS Annual Meeting, October 29, 2000.

An overview of conventional aseptic processing was presented, and it addresses the key issues that corporate decision makers are faced with when implementing isolation technology, such as regulatory requirements and equipment validation focus areas.

## Isolator Sterilants: Common Issues and Differences

Rickloff, J.R., PDA Conference, October 16-17, 2000.

This presentation discussed the similarities and differences of the current chemical germicides used for isolator decontamination in the pharmaceutical industry with emphasis placed on validation issues and safety considerations.

## Current Trends and Concepts in Validating Sterility Testing Isolators

Rickloff, J.R., Serentec Workshop for Sterility Testing, May 25-26, 2000.

Past practices & current trends in validating sterility testing isolators were reviewed with an emphasis on productivity. Although the key validation criteria remain the same, i.e. no false negatives, improvements to the overall system design have permitted the optimization of the decontamination cycle.