

**DEPARTMENT OF MECHANICAL ENGINEERING**  
**Purdue School of Engineering and Technology**

**FALL 2008 SEMINAR SERIES**

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**Date: Thursday, November 20, 2008**

**Time: 10:30 am – 12:00 pm**

**Room: SL 165**

**Everyone is invited**

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**Thesis Seminar**

**Computation Fluid Dynamics Modeling of Pharmaceutical Isolators**

**Cai Shen, Graduate Student, Purdue School of Engineering and  
Technology, IUPUI, Indianapolis, IN**

**Abstract.**

Isolators which provide aseptic barrier environments for drug filling operations have gained popularity during recent years in the pharmaceutical industry as a relatively new technology for environmental control of various parenteral operations. While this technology offers greater sterility assurance when compared to cleanrooms, because the operators of the system remain outside the aseptic environment, there are still several unanswered questions about the operational effectiveness of isolators. Therefore, a computational model has been combined with experimental research to investigate and understand the behavior of the decontaminant vaporized hydrogen peroxide (VPHP) diffusion in pharmaceutical isolators, and also to improve the design and operation of the isolators. This project was conducted in three different phases. Phase 1 focused on the air-flow modeling in isolators and its experimental verification. Phase 2 concentrated upon the VPHP concentration predictions and measurements together with the modeling of VPHP absorption, and desorption characteristics of different isolator materials. The VPHP absorption and desorption during the decontamination and aeration phases have been investigated using tubing experiments conducted at Eli Lilly and Company. Phase 3 was devoted to extending the isolator CFD model to calculate the temperature distribution and comparing the model predictions to isolator bulk and surface temperature measurements. This CFD model of the pharmaceutical isolators has been verified by experiments. This model can provide an improved methodology for assessing the operation of isolators and the proposed modifications, and developing validation protocols. It can also be used to advance isolator technology in the pharmaceutical industry in a way that supports the Food and Drug Administration (FDA) Quality-by-Design directives.

**About the Speaker.**

Cai Shen is a graduate student in mechanical engineering at Purdue School of Engineering and Technology and a Research Assistant at the Computational Fluid Dynamics Laboratory at IUPUI. She received her bachelor's degrees in thermal engineering at Tsinghua University, Beijing, China, 2006. She has been a Research Assistant at the CFD Lab of IUPUI since September, 2006. Her academic advisor is Dr. Hasan U. Akay and committee members are Dr. Sivakumar S. Krishnan, Dr. Razi Nalim, and Mr. Willis V. Bell.