

### Aseptic processing for pharmaceuticals

The aseptic cleanroom is a mission-critical facility in the pharmaceutical discovery and production processes.

Avoiding contamination is essential to aseptic cleanroom operations. In an ISO Class 5 aseptic cleanroom, no more than 10,200 particles larger than  $0.3\mu\text{m}$  are permitted per cubic meter of air. (ISO Standard 14644-1, Cleanrooms and Associated Controlled Environments, International Organization for Standardization.) Given that moving any part of the human body generates 500,000 such particles per minute, maintaining aseptic cleanroom conditions is a significant challenge:

**Of the many potential sources of contamination in cleanrooms and other clean manufacturing environments, none is more persistent, pervasive or pernicious than the human beings who occupy them...**

**Of the many elements of cleanroom operations and processes, humans are the easiest to control, yet contribute the most contamination.** ("Human Contamination," Jan Eudy, *A2C2 Magazine*, April 2003.)

The costs for cleanroom mistakes—in both regulatory and financial terms—can be high. A single interruption of operations can have costs as high as \$1 million. ("The Many Faces of Risk Management," Bob Predmore, *A2C2 Magazine*, June 1999.) With this in mind, the training for cleanroom operators in aseptic techniques is critical. Current Good Manufacturing Practices (CGMPs) issued by the US Food and Drug Administration (FDA) call for both initial and ongoing training for cleanroom operators:

Appropriate training should be conducted before an individual is permitted to enter the aseptic processing area and perform operations. For example, such training should include aseptic technique, cleanroom behavior, microbiology, hygiene, gowning, patient safety hazards posed by a nonsterile drug product, and the specific written procedures covering aseptic processing area operations. After initial training, personnel should be updated regularly by an ongoing training program. (*Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice*, US Food and Drug Administration.)



### The training challenge

The very nature of cleanrooms makes training difficult. Given the potential cost resulting from an interruption of operations due to a simple mistake, training in aseptic procedures within the cleanroom itself is impossible. Students are typically expected to observe cleanroom operations from outside and imitate the aseptic techniques they have seen upon cleanroom entry. In practical terms, this is equivalent to having a student pilot observe a seasoned aviator and then solo without ever having taken the controls.

### The process simulation learning solution

*Simulation learning* provides a solution to this critical problem. Simulation learning includes e-learning solutions based upon computer simulations of real-world facilities, equipment, and processes, and is based on the simple idea that people learn best when they *learn by doing*.

**3Dsolve** specializes in creating advanced simulation learning products for government and private industry. Now 3Dsolve is applying these same principles to the mission-critical problem of training the pharmaceutical industry workforce in proper aseptic techniques for cleanroom operations. Using standard, off-the-shelf desktop personal computers, pharmaceutical firms can train their employees using learn-by-doing methodologies, enabling them to practice aseptic techniques before ever setting foot in a cleanroom. This virtual approach also eliminates the need to use real manufacturing facilities to train employees.

## 3Dcleanroom overview

Using 3Dcleanroom, **3Dsolve**'s product for aseptic cleanroom training, students can perform the most common aseptic techniques in a safe, simulated environment, including cleanroom behavior, gowning procedures, personal hygiene, and working in a laminar flow hood.

Specific tasks to be performed within the aseptic environment are part of the simulated training, including antimicrobial effectiveness testing, endotoxin testing, environmental monitoring, microbial identification, product sterility testing, and water testing. Within the simulated environment, students interact with a complete range of aseptic cleanroom equipment, including air showers, airlocks, autoclaves, filling machines, laminar flow benches and hoods, particle counters, pass-throughs, shoe cleaners, and steamers.



3Dcleanroom also includes narrative information and presentations on important topics, such as basic microbiology techniques, basic volumetric techniques, environmental monitoring techniques, the safety hazards posed to patients by non-sterile drug products, and other relevant background information.

A well-defined model of instruction ensures that the learner is always provided with the best mode of learning for the subject matter being covered. 3Dcleanroom utilizes the FAPV model: Familiarize, Acquire, Practice, and Verify.

3Dcleanroom includes not only the ability for students to practice aseptic techniques, but to be evaluated on them as well. For organizations that operate Learning Management Systems (LMS), 3Dcleanroom communicates with the LMS to store and retrieve student progress information. This enables management to instantly determine training progress across an organization, as well as demonstrating regulatory compliance on short notice.

## Conclusion

Hands-on training is key to proper cleanroom operations. With a controlled cleanroom environment, pharmaceutical manufacturers can expect improved regulatory compliance and increased profitability:

A thorough, comprehensive training program detailing all aspects of cleanroom management will empower the cleanroom operators to control the degree of contamination during the production process...

[T]he key to controlling human contamination within a balanced cleanroom management program lies in the combination of knowledgeable, empowered employees, working in a meticulously controlled cleanroom environment, using quality-assured processes. When such a system is in place, manufacturers can expect a substantial decrease in product rejects and a corresponding increase in profitability. ("Human Contamination," Jan Eudy, *A2C2 Magazine*, April 2003.)

Simulation learning is the best tool for creating a knowledgeable and effective cleanroom workforce.

## About 3Dsolve

**3Dsolve**, The Simulation Learning Company, creates collaborative simulation learning solutions for government, military, and corporate applications, a market estimated to reach \$6.1 billion by 2006. **3Dsolve**'s simulation learning products use realistic, interactive 3D graphics, based upon industry standards, enabling users to learn by doing. **3Dsolve** has been named as one of *Military Training Technology* magazine's Top 100, the "companies that have made a significant impact in the military training industry." **3Dsolve**'s headquarters are in Cary, North Carolina, near world-renowned Research Triangle Park.

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