



### **Advanced Aseptic Compounding**

Three factors make up a quality program to assure patient safety reducing the potential of contaminating preparations during compounding.

Important in understanding these three factors is the fact that the exterior of components commonly used in compounding such as vials, syringes and IV bags are likely contaminated. The source of the bio contamination is touching the exterior of the packages or particulate accumulated on the packages while stored both in the pharmacy and during the handling along the supply chain.

Current practices of wiping down the exterior of components does reduce bio contamination but still leaves contamination. The impact of the transfer of the touch contamination to the final patient preparation ranges from 0.1% to 5.0%. The USP<797> revisions that became effective in June of 2008 introduced the concept of using 'sterile' gloves as a means of reducing touch contamination. While this approach offers an initial solution, it does not provide a consistent or repeatable solution after initial contact with non-sterile surfaces.

The CTG approach of advanced aseptic compounding results in over a 30% reduction of bio burden in our conventional MIC units when compared to isolators with dynamic airlocks. The reduction of bio burden is the result of a combination of factors created by the MIC design. The airflow technology increases contact residency time of decontamination agents inside both the airlock and interior chamber of the MIC. Plus a more consistent spray down of components in the static airlock. The 30% overall reduction in bio burden has been verified by validation techniques that use a known population of challenge organisms.

The MIC-EDU with automated decontamination capabilities is CTG's next step in advanced aseptic compounding. This advanced technology provides a consistent and repeatable delivery system for VHP (Vapor Phase Hydrogen Peroxide) that has been validated to provide a six log reduction of microorganisms.

The second factor is the design of a system that delivers unidirectional airflow in the critical zone of the MIC, which maintains ISO class 5 conditions during compounding activities. This has also been validated per the requirements described in the USP<797> revisions effective in June of 2008.

The third factor is the ergonomic design of the MIC that allow for 100% interior surface cleaning and sanitizing. The membrane technology allows both cleaning and decontamination of the HEPA filtered air inlets.

The MIC's ability to provide an advanced aseptic environment for compounding sterile products increases your ability to provide preparations having the highest sterility assurance level.