

## **CAPS Quality Assurance Program**

### **Comprehensive Environmental Monitoring**

The CAPS comprehensive environmental cleanroom and employee monitoring program ensures that preparations are compounded in a controlled environment that minimizes the potential for introduction of microbial contamination and particulate matter. Weekly dynamic testing consists of gloved fingertip bioburden, sterile sleeve cover bioburden, air bioburden testing, particulate matter air counts, and surface bioburden testing.

### **Media Fill Verification**

CAPS aseptic process and individual media fill verifications demonstrate objective evidence that the compounding staff, equipment, and controlled environment and microbiological controls used in the CAPS compounding processes are capable of producing sterile products. Three media fill verification runs are performed initially to evaluate each process and individual. Low, medium and high risk individual media fills as well as medium and high process media fills are conducted at intervals that at least meet and in some cases exceed USP <797> standards.

### **Barcode Automation**

CAPS order entry software and barcode systems ensure a high degree of safety from order placement through compounding. CAPS uses bar code systems that scan orders and automatically program a compounding pump with a bar code safety check on each source ingredient. CAPS also uses a Manual Additive System (MAS) bar code to match the source ingredients with the additive syringe to ensure manual additives are correctly compounded.

### **Beyond Use Dating (BUD) based on stability indicating data and maintenance of sterility**

Room temperature, refrigerated, and frozen beyond use dating is assigned to low- and medium-risk CAPS products in the absence of batch level finished product sterility testing. The combination of the CAPS stability extension studies, periodic compounding process sterility testing, container closure integrity testing over the shelf, extensive individual and process media fill verifications, comprehensive cleanroom and employee environmental monitoring, and enhanced process controls provide the foundation for CAPS' BUD Program.

### **Container Closure Integrity Testing**

BUD studies by CAPS utilize Container Closure Integrity ("CCI") testing using a severe microbial aerosol challenge following worst case aseptic manipulations and shipping/handling conditions to demonstrate both the container and closure maintain a sterile barrier throughout the shelf life of the preparation. Containers such as IVPB, syringes, and elastomeric devices are first filled with a sterile growth media and then exposed to an aerosolized microbial challenge for a specified amount of time. Containers are removed from the challenge, rinsed, incubated, and then examined for growth. A successful CCI test shows that the container maintains the sterility of the preparation throughout the duration of its shelf life.

### **QC Reporting**

The CAPS pharmacy process is supported by an extensive documentation system comprised of computerized and hard copy record keeping for tracking incoming orders, the materials and supplies consumed in their preparations, as well as the process and product control testing records that document the quality, accuracy, purity, strength, safety and content of the final product. Quality indicator summaries are provided to customers for their quarterly records.