**ABSTRACT**

Buffer and excipient screening studies are important to formulation development of biopharmaceuticals. Preparation of protein drug substances into suitable liquid formulations is often accomplished by buffer exchange using a variety of methods that are both time consuming and labor intensive. In this poster, we describe a novel and automated high throughput system based on UF/DF technology for buffer exchange of liquid protein formulations. In addition to the buffer exchange module, the different modules for formulations and the analytical integrated instruments will be discussed. Example of automated workflows and case studies are presented to demonstrate the utility of the new product.

**THE CMS 3 BIOLOGICS FORMULATION SYSTEM**

Freeslate’s CMS3 for Biologics Formulation System (BFS) shown below automates formulation development from start to finish and can be configured with a variety of elements for a variety of workflows.

The BFS consists of two robotic systems connected by a carousel. The robot on the right side, or Analytical side, of the system has multiple arms and tools that perform liquid handling and vial and plate transfers. It also has various elements such as heating, cooling, and mixing stations along with analytical tools including visual inspection, pH, and viscosity. The robot on the left side, or Formulation side, of the system can be physically integrated with a variety of instruments for incubation and analytics.

**AUTOMATED STABILITY CASE STUDY**

A formulation study was designed to evaluate the stability of a mAb in 12 different formulations at two different protein concentrations. The study design was created in LEA (Lab Execution and Analysis Software) and then executed on the BFS.

**How it Works**

Stress conditions are captured and linked to formulation composition and downstream analytical data.

**RESULTS AND CONCLUSIONS**

With the BFS system a formulation team can complete a 24-vial 3-month DOE stability study with less hands on time. This complete study, fully inclusive of analytical setup, automation execution, data analysis, and reporting, required only 0.25-0.5 FTE (Full Time Employee) over the three months.