

Case study

Meeting local regulations with ready-to-use buffer solutions

INTRODUCTION

A leading international manufacturer of plasma-derived biopharmaceutical products was opening a new facility and needed a source for ready-to-use buffer solutions for pH adjustment in column chromatography.

CHALLENGE

The customer's manufacturing facility was not designed to produce buffer solutions in-house, so they had to look for an outside source.

Buffer solutions must be prepared in ISO Class 8 cleanrooms under controlled and repeatable conditions for quality and consistency. Each batch must include two pre-equilibration buffers and one elution buffer, all packaged in custom-size containers. In addition, each container must have a connector that adapts to the manufacturer's production tool. All buffer solutions must be delivered in controlled temperatures according to Good Distribution Practices (GDP), and each drum must be supplied with a side sample to meet local regulations.

AVANTOR SOLUTION

Avantor reviewed the customer's needs and developed a plan to offer buffer solutions in a higher concentration to reduce

the quantity needed in each batch. That allowed Avantor to supply the buffer solutions in standard drums and containers with approved material compatibility. Each packaging (drum/container) will be sampled, with packaging and sample being supplied as one unit. Avantor supplied own validation batches for the customer's engineering runs to expedite the process. This process allowed Avantor to meet the customer's expectations for the timely delivery of ready-to-use buffer solutions.

RESULT – VALUE TO CUSTOMER

Avantor's custom solution capabilities met the customer's timeline expectations with product and packaging specification according to customer needs, with side samples, while meeting specific local regulatory requirements.

CUSTOMER BENEFIT

The customer received several benefits, including reduced costs because of lower quantities per batch of solutions and less time spent on quality control testing due to delivery of satellite samples. Further time savings could be achieved with the supply of validation batches during process development and engineering runs. In addition, the customer gained supply chain security due to Avantor's European production site and backup capabilities in other regions.