Case study

Outsourcing manufacturing of acetic acid and benzyl alcohol solutions

INTRODUCTION

A multinational biopharmaceutical company needed excipient-grade 2M and 6M acetic acid and 3% benzyl solutions for downstream column chromatography and formulation, needed for a facility expansion in the context of a new product commercialization.

CHALLENGE

The company did not have the processing capacity to manufacture buffer solutions in the high volumes needed in-house. The solutions needed to be custom-made, so the set up required multiple-stage processing, engaging customer's manufacturing, quality and EHS department, to ensure all product and regulatory requirements will be met. Buffer solutions had to be supplied in several volumes and packing, such as glass bottles and intermediate bulk containers (IBC). In addition, the project needed to be completed within six months to meet the customer's plans.

AVANTOR SOLUTION

Avantor was able to meet the customer's needs and deadlines. To do that, Avantor developed a product sampling procedure specifically for the customer and traceability of all pack sizes to the same mixture batch was being guaranteed. Avantor supplied validation batches to the customer, while samples of the validation batches were put on stability test to initiate stability studies, in order to expedite the process. With processing, sampling, and testing methods in place, Avantor was able to commit to meeting the company's volume needs for three years.

RESULT – VALUE TO CUSTOMER

Avantor manufactured buffer solutions that met the customer's requirements for product quality and long-term availability. The customer could get all the required buffer solutions used in the same process from a single supplier from different manufacturing sites.

CUSTOMER BENEFIT

The biopharmaceutical company realized several benefits, including significant time savings because they would receive validation batches for engineering runs during stability studies. Avantor's global network of hydration facilities ensured there would be consistent manufacturing procedures and a seamless supply chain independent from location. The company would receive certain regulatory documents available from the start (RL) towards complete regulatory documentation, when GMP (R).

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