

Case study

A custom formulation solution including an animal-origin element

INTRODUCTION

A leading biotech company that focuses on developing and manufacturing vaccines wanted to outsource a multi-component solution that contains an animal-origin element in the finishing step of its vaccine production.

CHALLENGE

One component of the solution used by the customer is not compendial, so a specific agreement for its use was needed. Other components in the solution contain a certain percentage of animal-origin substances. The stability of the formulation was unknown.

The solution would need to be in custom packaging, including ports and aseptic connectors, and transported in temperature-controlled conditions in a dedicated truck and a single-use temperature data logging device.

AVANTOR SOLUTION

Avantor manufactured the solution in a closed manufacturing process at a GMP site, using customer-approved raw materials

and Water For Injection (WFI) quality water. Avantor was able to provide the required custom packaging, as well as samples of validation batches that met the requested quality requirements. Based on development studies, longer starting product shelf life could be provided.

RESULT – VALUE TO CUSTOMER

The formulation solution was manufactured in a customer-designed process and met the customer's quality and availability requirements. It could be delivered within the requested timeline for customer's commercialization.

CUSTOMER BENEFIT

The biotech company received a custom solution that met its specification, testing, packaging, and regulatory requirements. The longer shelf life means the company can order the solution in larger volumes, and the company is able to enter into a long-term supply agreement with Avantor.