Volt Pharma Associates - Case Studies

Pharmaceutical Science (PHARM SCI) Services

CASE STUDY 1

SITUATION

The client had developed a new manufacturing process for a biotech drug substance, which improved the yield, reduced the cost of goods and removed the raw materials of animal origin. However, a lengthy regulatory approval process needed to be avoided.

SERVICE

Through careful assessment of the whole manufacturing process and its regulatory implications, restricting the changes only on critical process steps, maintaining the control tests and specifications and eliminating the need for additional clinical studies, the improved process was validated.

RESULT

The client had a clear regulatory strategy of how to present and submit the manufacturing process improvement successfully as a minor regulatory process modification only. As a result, it was approved in short assessment time by all major health authorities leading to the implementation of an improved process significantly earlier than anticipated.

CASE STUDY 2

SITUATION

The client had a novel drug delivery platform, however, the process introduced degradation and the client was unable to discover where.

SERVICE

Using the twin Quality by Design tools of Risk Assessment and Knowledge Management, a facilitated process was used to completely map the process for all areas that may produce degradation.

RESULT

The client had a clear strategy for refining the process to reduce the risk of degradation as well as a much greater understanding of their process and technology platform.