

Parenteau BioConsultants Case Studies

Examples of where our scientific expertise and experience resulted in additional value to the product we provide our clients.

1. Data Analysis and Report Writing:

Project: Client contracted us to analyze clinical data on a biologics product for the purpose of writing post-marketing publications.

Outcome: Abstracts and manuscripts were provided on time. Publications were approved in peer review journals.

Added value: Uncovered an additional product benefit within the data that the clinician and the company had missed.

Our Approach: Rather than just writing the paper as given, we looked at the data as if it were our own and using our experience, saw things the others missed.

2. Non-clinical Assessments

Project: Client contracted us to provide a preclinical and safety summary and analysis of the clinical literature to support a European regulatory submission.

Outcome: New Class 3 product approved and CE marked without additional clinical trials.

Added value: Notified Body (BSi) was highly complimentary of documents and client adopted the format as their company standard.

Our approach: Rather than doing a job in the standard way, we looked at it from our own industry perspective and delivered something that could not only meet the minimum standards but meet the highest standards, putting the company in a very positive light.

3. Scientific Assessment

Project: Client, ready to file submission on a combination product. Last minute they needed opinion on the relevance of a new academic study that appeared to call in to question the biological safety of a component of their product for the indication they were going for. Time was at a premium. They had a 24 hr. submission deadline.

Outcome: Provided a rapid response on the scientific rationale for the irrelevance of the study to the client's product in time to meet their submission deadline.

Added value: Provided additional peer-reviewed literature that clearly demonstrated the safety of their component, evidence the client did not find on their own.

Our approach: Rather than just provide a expert opinion regarding the specific study in question; we provided additional supporting data to strength their safety claims.