



November 1, 2004

Jeffrey Gassman  
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To Whom It May Concern:

Jeffrey Gassman has worked as a Quality Consultant for Astralis starting in April 2004. Astralis is a small Biotech company with therapeutics in early stages of development for immune disorders and skin diseases. Mr. Gassman was introduced to our company thru Compli, a validation and regulatory compliance services company.

The first phase of Mr. Gassman's work here was to carry out an assessment/audit of Astralis' current Quality Systems at the time. Included in this scope was to be a written report outlining his observations, making recommendations for completing and implementing the required Quality Systems, and provide a plan for a phased approach for completing and implementing the recommendations. Mr. Gassman performed the audit in a very timely and unobtrusive matter. He was always punctual and pleasant, and the written report was submitted very shortly after the audit was performed. Included in the report was an extremely comprehensive appendix listing cGMP policy requirements by department, i.e. Quality, Materials Management, Clinical, Production, etc., by what Phase of Development that requirement needs to be met, (Phase 1, Phase 2, etc), and whether Astralis had fulfilled the requirement or not.

After the audit, Mr. Gassman was then contracted to write Master Batch Records and SOP's that reflected our manufacturing processes. This involved him working hand in hand with the manufacturing personnel, and adjusting his schedule accordingly. Mr. Gassman was always extremely flexible in regards to scheduling, making every effort to accommodate the manufacturing team. Again, he was always punctual and pleasant to work with. The Batch Records and SOP's were written in a timely manner, and submitted for review very quickly.

I would recommend Mr. Gassman as a Quality Consultant to any Biotech or Pharmaceutical Company. He has in depth knowledge (both theoretical and practical) of cGMP, and Quality requirements, and is an efficient and capable worker. He is also extremely warm and polite and was very pleasant to work with.

Sincerely,

Linda Scheiner