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Commentary

The outlook for peptide drugs and the intricate relationship between the Active Pharmaceutical Ingredients manufacturer and their sponsors¶

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Abstract: As research laboratories discover an ever-increasing number of peptides of pharmacological interest, there is an increased need for Good Manufacturing Practices (GMP) services, as these drugs candidates undergo clinical trials. It is therefore essential to understand the importance of the relationship with the Active Pharmaceutical Ingredients (API) manufacturer and its implications in the development and commercialization of the future peptide drug. Copyright © 2005 European Peptide Society and John Wiley & Sons, Ltd.

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This is truly an exciting time for peptide drug development. Many viable peptide leads are generated daily to potentially treat all sorts of diseases, from diabetes to multiple sclerosis to various cancers or even Alzheimer's disease. The general lack of peptide toxicity at therapeutic doses adds to their appeal.

The first wave of peptide drugs, such as Salmon Calcitonin, Desmopressin and Leuprolide, are fast becoming successful generic drugs. New high-profile peptide drugs, such as Fuzeon to prevent HIV fusion or Pramlintide for Type 1 diabetics, only further enhance the confidence of investors to sponsor peptide drug development.

Drawbacks of peptides, such as the short half-life and the difficulty of getting them to target organs, have been largely overcome by half-life-enhancing methods and by drug delivery technology. These are readily made available by specialized biotechnology companies with strong intellectual property franchises.

Last but not least, proficient and specialized contract manufacturers combined with large-scale manufacturing improvements has made peptides relatively accessible and affordable to companies lacking the skills and costly infrastructure required to produce peptide drugs.

The drug development timeline typically extends over a decade. Marketing of the successful drugs then extends for several decades thereafter. Hence, the relationship between the manufacturer and the sponsor is a long-term affair.

Key issues affecting both parties crop up at different points in time and must be dealt with to mutual satisfaction. This is essential to guarantee timely delivery of API, scale-up and validation services, as well as relevant regulatory documentation. The time spent by both the sponsor and the supplier in managing the various interrelated projects to expedite the experimental drug through the development pipeline generally makes it impractical to abort the partnership in mid-stream. Hence, a deliberate wise choice of partners needs up-front consideration.

Critical factors worth contemplating are the capability to effectively communicate and understand each other's critical path-related issues. Technical and regulatory prowess, as well as adequate financial resources are paramount for both the sponsor and the supplier.

Having made peptide drugs since the 1970s, Bachem is well versed in managing complex projects in-line with our sponsor's requirements. We find that a true partnership approach, maintaining mutual accessibility and working toward clearly defined commitments works best. Both parties must have a high level of competency and experience in their respective fields of expertise. Time spent early on in delineating responsibilities is time well spent.

Core values, such as safety, environmental, compliance and economic considerations should be shared. Project timelines and critical paths need to be discussed, particularly as they relate to scale-up and validation issues. These activities tend to be costly and time consuming. Without mutually clarified tasks and commitments, one could end up derailing the drug development and commercialization effort.

Hence, joint project teams from the sponsor and manufacturer need to understand process and

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analytical considerations fully and follow through as the projects evolve and mature. An ensuing alignment of vision to further the process and compliance documentation, hand in hand with clinical milestone achievement, is the only guarantor of success. For projects with large volume requirements, scale-up and validation can take several years. To secure commercial supply, appropriate staffing and plant expansion measures need timely attention.

Although there are many manufacturers of peptide APIs, relatively few have the capabilities to follow through from start to finish. The vendor selection process is therefore critical and should not be guided solely by short-term considerations.