Due Diligence Considerations

Providing a thorough evaluation of the development process and marketing possibilities for drugs and biologics of interest

I. General Approach

BCR&DS is capable of performing due diligence on the following information usually provided in secure datasites:

- Chemistry, Manufacturing, Controls (CMC)
- Intellectual Property
- Regulatory Correspondence
- Preclinical Development
- Clinical Development
- Pharmacovigilance
- Competitive Environment and Marketing Potential

The interested party should also arrange for an on-site audit to determine the company's adherence to GLPs and GMPs. BCR&DS can assist and direct an on-site audit by examining specific manufacturing records, testing procedures, CAPAs and others. Such documentation is usually placed in the secure data sites. A summary of this information may provide valuable information to the on-site inspection team.

II. Detailed Approach

There are specific approaches. These are detailed below:

A. CMC

Usually, CMC falls outside the purview of the due diligence performed by BCR&DS. However, BCR&DS will examine information on quality such as specific CAPAs or customer complaints that may have an impact on clinical development and/or the safety profile of the drug/biologic. In the same manner, it will review such information if concerns were expressed by regulatory authorities. BCR&DS will also examine analytical methods to determine if these methods have been validated appropriately and if they possess the sensitivity, selectivity, reproducibility, and robustness required for the development program. Such analytical methods will include potency determination, and, in the case of biologics, determination of immunologic response both to the treatment agent and to host cell proteins.

B. Intellectual Property

BCR&DS will examine all claimed intellectual property and provide a detailed assessment. BCR&DS will also try to determine competing or conflicting intellectual property held by third parties. In that context, BCR&DS will be able to facilitate a more accurate assessment of the validity and extent of the intellectual property held by the company that addresses the product in question by the assigned IP law firm. BCR&DS has worked with various IP Law firms in a variety of due diligence assessments. In the process, it has been able to provide a full assessment while minimizing costs.

C. Regulatory Correspondence

BCR&DS will examine all regulatory correspondence that is connected to the product in question, and all submissions to the FDA and summaries of any meetings held with regulatory agencies. It will especially focus on specific requests by the regulatory agencies and the response/actions of the company to these requests. Due diligence efforts will define possible gaps, and provide remediation suggestions, if these are possible.

D. Preclinical Development

BCR&DS will examine all the reports (if available) of preclinical testing to verify that preclinical development has been performed in accordance with the regulatory precedent in the chosen indication and for the appropriate class of compounds. BCR&DS will identify any gaps (especially in the context of regulatory precedent) and identify likely remedies for these gaps.

E. Clinical Development

BCR&DS will examine (a) all clinical study reports (CSRs) for studies performed and (b) all protocols or study concept sheets for planned development. It will compare the clinical development – or proposed clinical development- with that of the regulatory precedent and current clinical practice. It will also compare the analyses and data produced by the clinical development to the FDA's (or other regulatory body) requests and comments made in meetings or in regular correspondence. It will identify any issues that may potentially derail a successful BLA/NDA if present and propose remedies. In addition, BCR&DS will evaluate if a proposed development is likely to meet the timelines presented by the drug's sponsor.

In the same vein, for approved products, BCR&DS will examine in detail all periodic and expedited safety submissions to regulatory agencies as well as the relevant literature on the drug to identify any potential issues in the future.

F. Competitive Environment

BCR&DS will provide full information of all development efforts for the therapeutic agent under consideration and the targeted indication. It will assess their probabilities for success. It will also determine the likely market share of competing compounds under development.