Centre for **Biopharmaceutical** Excellence

# CBE provides technical and scientific due diligence support to companies looking to make or attract major investments in the Biopharmaceutical industry.

Fundamentally the due diligence process can be divided into 3 distinct categories:

- Commercial
- Legal
- Technical

CBE's focus is on Technical and Scientific due diligence and aims to determine if the company's technologies, facilities, manufacturing processes, quality systems and R&D portfolio are aligned with commercial forecasts and assumptions. CBE may also support the legal due diligence – particularly in the area of intellectual property and its robustness in relation to prior art and freedom to operate, or ability to license technologies.

## The Technical and Scientific Due Diligence Process

The team works to gain a deep understanding of management's view on the business drivers, competition in the market place and points of differentiation from competitors, principally from a technical and scientific perspective, and then validating this through the due diligence process.

## We work in 3 phases:

1. The discovery and planning phase where the scope of the due diligence is determined and agreed. During this phase we review in detail any commercial and legal due diligence work that may have been undertaken and assumptions or technical dependencies assumed in meeting objectives.
2. The due diligence phase during which agreed areas are reviewed and reports prepared.
3. Oversight of any implementation programs arising from the due diligence, as appropriate.

## Technical and scientific areas covered typically include:

- Quality Systems, GMP, GLP compliance assessments
- Manufacturing processes and improvement plans
- COGs analysis
- Facility design
- Regulatory status
- R&D portfolio
- Key risks and risk mitigation strategies
- Prior art reviews assessing freedom to operate, and/or ability to license out technologies, or need to license in technology, to operate successfully.

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## Key questions are addressed in the process.

For example:

- **Is the technology used:**
  - Competitive?
  - Robust and reproducible?
  - Compliant with international regulatory standards?
  - Protected either through know how and complexity or intellectual property?
  - If there are questions relating to the above, what is being/should be done to rectify it? What is the timing and cost/benefit of rectifications?
- **Is the product pipeline aligned with the commercial strategy?**
  - Will it be front line therapy or generic?
  - Is the R&D program viable with respect to skill base and funding to meet milestones?
  - Do clinical programs meet regulatory requirements in target markets?
  - Is the clinical strategy for products in development appropriate?
  - Are there ways to expedite getting the product to market?
  - Are the target markets accessible?
  - Are there regulatory or legal barriers to entering the targeted markets? If so how can these be resolved?
- **Does the company have in place sound governance systems?**
- **Manufacturing and process development**
  - Has the process development been well documented?
  - Are the facilities compliant with regulatory standards?
  - What are product batch failure, reject and recall rates and what are the reasons for these?
  - Are costing systems and structures appropriate?
- **Supply chain**
  - Is the supply chain robust and are there alternative suppliers for critical materials?
- **Regulatory Affairs**
  - What are the regulatory issues facing the company?
  - What regulatory findings have there been from inspections, how have they been addressed and what issues are open?
- **What gaps are there in the management team and how are they/should they be addressed?**
- **What training programs are in place and do they meet current standards to ensure ongoing compliant manufacture?**

**CBE has a strong team capable of covering areas outlined above. CBE also draw on trusted affiliates to further support programs as required. For further details on CBE services and the CBE team please visit our website:**

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