

Six Factors for Biotech Companies to Consider When Choosing Next-Generation Contract GMP/CMC Laboratories

Continued expansion in the biotech and pharmaceutical industries drives the need for companies to partner with good manufacturing practices (GMP) / chemistry manufacturing and controls (CMC) contract laboratories. When choosing a next-generation contract GMP/CMC laboratory, six factors should be considered.

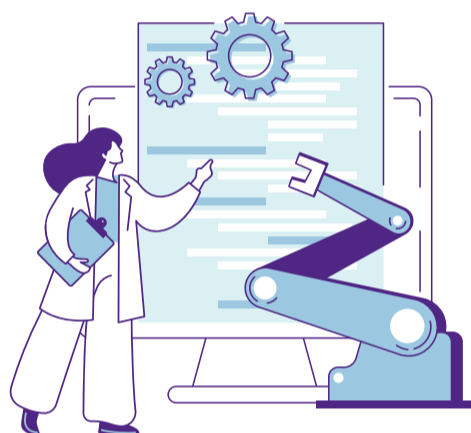


1. PROVEN TRACK RECORD

- A proven history of on-time delivery, efficient project management and the ability to meet goals and timelines.
- The goal: projects completed on time and on budget, or with cost reduction.

2. EXTENSIVE SUITE OF LABORATORY INSTRUMENTS

- A contract laboratory that possesses a diverse range of equipment ensures seamless transition of assays with more cohesive results.
- Cost and time savings negate the need to redesign and troubleshoot assays.

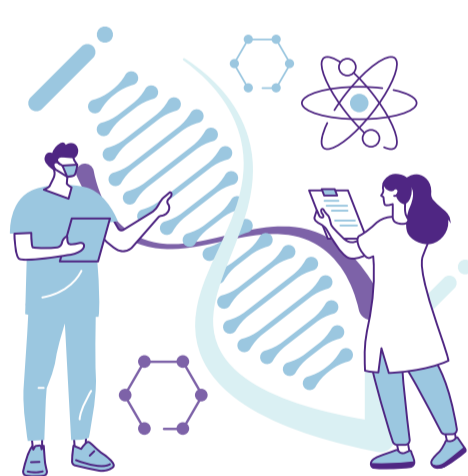


3. EXPERIENCE IN AUTOMATING AND EXPANDING PLATFORMS

- Many laboratory tasks are repetitive and time-consuming and may leave room for human error.
- Automation brings consistency of technique and method performance over time and will help drug developers increase the speed of regulatory filings, improve data accuracy and free up highly skilled staff for more complex tasks.

4. DATA GENERATION AND SELECTION, SECURE DATA MANAGEMENT AND STORAGE

- Regulatory bodies require specific data sets with strict access and storage requirements.
- A drug development team will benefit from rapid access to refined laboratory data sets that are compliant with government regulations.



5. KNOWLEDGEABLE AND EXPERIENCED SCIENTISTS

- Staffing shortages have affected the industry, and finding qualified and highly trained personnel with knowledge of assays and current regulatory guidelines remains challenging.
- Forecasting needs for expansion of laboratory space, equipment and data management requires forethought for recruitment and retention of highly qualified personnel.

6. FORWARD-THINKING AND HOLISTIC STRATEGIC APPROACH

- Strategic planning positions a GMP/CMC laboratory for future needs with respect to equipment, technology and staffing.
- Forward-thinking assay design requires abundant knowledge of and experience with regulatory requirements.



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