

Build or Buy Challenge:

6 advantages of using a pre-qualified,
fully customisable GMP environment





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As global patient populations increase, there are a growing number of challenges and demands faced by pharma and biotech companies to ensure product is delivered in a timely and cost effective way. When capacity is at a premium, significant investment decisions must be made to ultimately determine the expansion of existing facilities, headcounts and technology choices necessary to maintain supply.

With so many elements to consider, a clear strategy must be defined to ensure any potential investment can be maximised for the long term. However this is not always possible due to changes in business objectives and requirements.

An alternative solution to the 'build or buy' decision is the use of readily available, pre-qualified GMP facilities which can be fully tailored to suit individual needs and provide reassurance that product will be delivered on time and on budget.

Engaging with an established CMO to deliver valuable drug product, manufacturing and packaging of all dosage forms offers a range of clear advantages.

The following are just some benefits our clients have experienced thus far:

1. Flexibility

Pre-qualified, customisable space can be configured as required and can be scaled up and down as necessary.

Set-up and implementation of all equipment, technology and processes will be defined and agreed prior to commencement of operations to suit individual requirements.

2. Elimination of study delays

Often there is immediate demand which can add pressure to the product development programme therefore, as time is of the essence, it is crucial to enable delivery of drug on time.

If capacity is maximised in existing facilities, plans to expand can often be challenging which will undoubtedly adversely affect timelines for supply of valuable drug product.

By utilising pre-qualified GMP capacity via an established and experienced CMO, clients can avail of dedicated resource and equipment train(s) enabling operations to commence much quicker. As a result, less time is required for planning agreements, construction, validation and approval - effectively providing a 'turnkey' solution solely for your product.

3. Minimise costs

Depending on short term and long term requirements, constructing, or alternatively, purchasing a new facility to expand capacity can be extremely expensive. Additional capital investment of this nature could potentially require years of planning prior to approval which will have an effect on crucial timelines.

An agreed partnership with a suitable CMO can save significant cost to enable investments to be made in other areas of the business as appropriate.

4. Guaranteed compliance

By utilising pre-qualified GMP space at a credible CMO facility, full traceability is provided relating to validation, manufacturing and quality procedures.

Additional services including power, compressed air, purified water, RH control and Class 10,000 / 100,000 rooms will be available on demand to ensure a suitable environment to accommodate specific drug product.

Full auditing and inspection can be carried out prior to commencement. This offers reassurance that all operations will be performed to the highest specification throughout the entire product development programme.

5. Autonomy

Whilst equipment and technology are housed in a third party's facility, the sponsor's control will be guaranteed in order to ensure individual requirements are met throughout the project's lifecycle.

Unplanned adjustments and revisions to agreed operations will be supported with authorised access available, as required, to enable continual review and supervision throughout.

6. Access to skilled employees

A reputable CMO will have a wealth of technical expertise which can be leveraged, as required, to perform some or all operations.

A wide range of highly skilled engineering, scientific and operational employees can be contracted to dedicate agreed time on individual projects. This option enables the company's own existing employees to focus on core manufacturing activities and other key projects as determined by the business.

Partnering with a reputable and experienced CMO to extend current capacity, and accommodate existing proprietary manufacturing and packaging processes, will prove beneficial in a variety of ways and will present an opportunity to significantly improve productivity and supply.



