

## BioRealty vs. a CDMO

[www.biorealty.com](http://www.biorealty.com)

July 2021

Many early-stage biopharma companies engage a CDMO for manufacturing of their product, but this can create a whole host of issues:

### COMMON CONTRACT MANUFACTURING ISSUES:

Six of the most common contract manufacturing issues include:

1. **Supply chain** - Lack of complete control over your supply chain when producing a high-quality product can result cause your product to fail or otherwise expose your company to liability.
2. **Quality control** - In-house manufacturing allows you to have full control over product quality.
3. **Lacking knowledge of production techniques** – Does your product require highly specialized processes and techniques for its production? A CDMO might not have all the needed skill sets and knowledge in place.
4. **Intellectual property risks** – Providing your CDMO information on propriety processes and patented information carries with it a certain amount of risk that such information might be used improperly in the future.
5. **Poorly communicated requirements** – If your product involves a complex production processes clear communication of your requirements is vital. In these situations, it is easy for a contract manufacturer to misinterpret your requirements and get something wrong.
6. **Increased liability** – If a CDMO’s practices, procedures, or results cause harm to others in any way, you could get drawn into a rough legal situation.

### COMMON COMPLAINTS ABOUT CDMOs:

The most common contract manufacturing complaints we hear include:

1. *“We’re too low of priority in our CDMO’s manufacturing queue.”*
2. *“Our CDMO has inadequate capacity.”*
3. *“Our CDMO is not able to scale our manufacturing to a commercial scale.”*
4. *“We’re forced to change our manufacturing location post-Phase III which will add significant product-approval risk.”*

You can avoid all the above by having long term control over your own manufacturing facility (cGMP or non-cGMP). BioRealty can deliver virtually any type and size of manufacturing facility for virtually any biopharma company beyond the start-up stage.