



## MANUFACTURING EXPERTISE

- Over 20 years of experience with monoclonal antibody production
- Experienced in both stainless steel and single-use bioreactors
  - Operating stainless steel bioreactors since 1993
  - Operating single-use bioreactors since 2007
- Flexible manufacturing scales and technologies

# of products developed	Phase
4	1
3	2
10	3
2	Commercial products

## Manufacturing Quality From Start to Finish

### Scale-up and GMP process conversion

Our Manufacturing Team works closely with Process Sciences, Quality, Supply Chain, and Product Sponsor to successfully transfer processes from Lab-scale to Manufacturing-scale. Process SMEs (Subject Matter Experts) stay involved throughout the life cycle of the process from development to commercial manufacturing.

### Drug substance

Our cGMP facilities in Orange County, California houses manufacturing space dedicated to mammalian cell culture and is able to produce both clinical and commercial biologics. Operating both stainless steel and single use systems, we have flexibility and experience to support a wide array of projects up to 2000L.

## Experience

- Producing clinical biologics since 1993
- Commercial manufacturing since 2004
- Disposable and Hard-piped Chromatography Systems
- Disposable and Stainless Steel Bioreactors
- Extensive experience working with various cell lines: CHO, NSO, and hybridoma
- Produced more than 20 different mAbs for applications including therapeutic mAbs, imaging reagents and antibody intermediates for ADCs
- Successfully brought products from early development to market