

抗体などタンパク質医薬品受託 CMO サービス

組換えタンパク質医薬品の開発で、Mycenax 社はセルラインの構築から、前臨床・臨床用試料の生産、GMP 基準に基づく商業生産、IND 申請の CMC 作成まで、一貫した業務を受託いたします。

● Contract Manufacturing Service

● DRUG SUBSTANCE

Item	What We Have, Do, Provide...
Clone Construction	<ul style="list-style-type: none"> ● Provide the service of clone construction with the consideration of global requirement from the perspectives of cost and regulation.
Cell Bank Establishment	<ul style="list-style-type: none"> ● Experienced with cell banks establishment and repository control per GMP. ● GMP compliant backup storage in multiple sites. ● Contract and manage the safety and/or characterization study; experienced in cooperation with well-known GLP CROs
Upstream Process (Mammalian cell culture)	<ul style="list-style-type: none"> ● Experienced in batch, fed batch and perfusion production. ● Fed batch: ~5g/L (CHO). ● Perfusion: maintain high density ($>1 \times 10^7$ cells/ml) and high output (>500mg/L) growth over 30 days (100L/day, >3000 L/lot). ● Concentrated perfusion: ~ 10g/L (CHO). ● High density production: cell density $>5 \times 10^7$ cells/ml ● 100% single use tech. applied; the concern on clean validation and cross contamination is diminished to the utmost. ● Bioreactor: biowave (50/200L) and stir tank (50/200/500/2,000L). ● Serum free and animal source free medium used. ● Establish a design of experiment (DOE)-based medium screening platform; benefiting yield and cost control.
Upstream Process (Microbial fermentation)	<ul style="list-style-type: none"> ● Fermenters: <ul style="list-style-type: none"> ● In-house: 7.5L, 30L (7.5L x 4), and one 50L stir tank (disposable). ● 650 L with alliance. ● Conduct high density growth under animal source free and antibiotics free condition. ● Established a DOE-based medium screening platform; benefiting yield and cost control.

Item	What We Have, Do, Provide...
Downstream Process	<ul style="list-style-type: none"> ● Achieved bulk ~2.5 kg / lot. ● Experienced in process scale-up. ● Experienced in ANC, IEC, HIC, and SEC chromatography and various scale size of columns. ● Experienced in ultrafiltration/ diafiltration (TFF system), and nanofiltration. ● Experienced in design and conduct viral clearance validation.

- **DRUG PRODUCT**

Item	What We Have, Do, Provide...
Formulation Development	<ul style="list-style-type: none"> ● Established a DOE-based excipients screening platform accompanying with critical analytical parameters in stressed storage system.
Process Development	<ul style="list-style-type: none"> ● Container selection for parental use ● Experienced in lyophilization parameters development ● Experienced in process development for prefilled syringe and vial.
Liquid (vial)	<ul style="list-style-type: none"> ● Complied with PIC/S GMP. ● Capacity fitted for clinical trial. ● Validated process: 1,500~5,000 vials / lot (2R~20R vial). ● Expandable to commercial scale.
Lyophilized Powder for Injection (vial)	<ul style="list-style-type: none"> ● Complied with PIC/S GMP. ● Capacity fitted for clinical trial. ● Validated process: 3,200 vials / lot (2R vial).
Liquid (Prefilled Syringe)	<ul style="list-style-type: none"> ● Capacity fitted for clinical trial. ● Validated process: 4,000 syringes / lot (0.5~2.25 mL).

Contract Testing Service

- **LOT RELEASE TESTING (GMP)**
Methods development, qualification and validation complied with ICH Q2 and ICH Q6B
- **CHARACTERIZATION AND VIRAL CLEARANCE**
Design, executing and organizing complied with ICH Q5A, Q5D, Q6B and other int'l guidance.
- **STABILITY**
Design and execution complied with ICH Q5C and other int'l guidance.
- **ANALYSIS FOR PK, ADA AND NEUTRALIZATION**
We provide ELISA and in- vitro cell mediated bioassay methods development and do so (inclu. Validation and testing) complied with GLP regulation.

Other Services —

Item	What We Have, Do, Provide...
CMC Writing	<ul style="list-style-type: none"> ● Experienced in writing and compiling data in CTD format.
Facility Design	<ul style="list-style-type: none"> ● Own designed and operating biopharmaceutical facility.

総代理店：

株式会社 リブラメディシーナ www.lmed.co.jp biz@lmed.co.jp

東京都千代田区神田錦町 3-11 TEL: 03-3518-9708