

HYPOTHETICAL CMO PROFILES

Outsourcing Workshop

| COMPANY PROFILE | Diamond Biotechnologies | Garnet Biotherapeutics | Emerald Biologics | Opal Technologies | Ruby BioPharma | Jade Biologicals |
|----------------------------------|------------------------------|----------------------------------|---|--------------------------------|---------------------------------------|------------------------------|
| Geographic Location | San Francisco CA, USA | Cambridge MA, USA | Dublin, Ireland & San Diego CA, USA | Dusseldorf, Germany | Bangalore, India | Wuhan, China |
| # of Employees | 150 | 5000 | 10000 | 800 | 4000 | 5000 |
| Years in CMO Business | 5 | 15 | 20 | 10 | 15 | 10 |
| FINANCIAL STABILITY | | | | | | |
| % Revenue from Largest Client | 0.4 | 0.2 | 0.1 | 0.3 | 0.2 | 0.3 |
| Litigation Status | None | None | None | None | None | Yes |
| QUALITY | | | | | | |
| Science to QA Staff | 20 to 1 | 15 to 1 | 15 to 1 | 20 to 1 | 10 to 1 | 15 to 1 |
| Quality Systems | Yes | Yes - Global FDA, EMA, Client | Yes - Global FDA, MHRA, Client | Yes - Global | Yes - Global | Yes |
| Audit History | Client Audits | Audits | Audits | EMA, Client Audits | FDA, Client Audits | FDA, Client Audits |
| Audit Findings | None disclosed | 483s | 483s | None disclosed | 483s | 483s |
| CAPABILITIES / EXPERIENCE | | | | | | |
| Technology Transfer Process | Yes | Yes | Yes | Yes | Yes | Yes |
| Project Management | Yes - 2 | Yes - 5 | Yes - 10 | Yes - 3 | Yes - 10 | Yes - 10 |
| Monoclonal Antibodies | Yes | Yes | Yes | Yes | Yes | Yes |
| Recombinant Proteins | No | Yes | Yes | Yes | Yes | No |
| Viral Vaccines and Vectors | No | No | No | No | Yes | No |
| BIOREACTOR TECHNOLOGIES | | | | | | |
| Bioreactor size (number) | 2kL (1) 500L (1), 20L (1) | 2kL (2), 500L (2), 50L (2) | 6kL (2) 2kL (2) 500L (2), 20L (4) | 2.5kL (1) 250L (2), 20L (2) | 6kL (1), 2kL (4) 250L (4), 50L (4) | 2kL (2) 500L (2), 40L (2) |
| Perfusion | No | No | No | No | No | No |
| Stainless Steel | No | Yes | Yes | Yes | Yes | No |
| Single Use | Yes | Yes | Yes | No | Yes | Yes |
| OTHER CELL CULTURE TECH | | | | | | |
| Spinner Flask | Yes | Yes | Yes | Yes | Yes | Yes |
| Roller Bottle | No | Yes | Yes | No | Yes | Yes |
| Wave Bag | Yes | Yes | Yes | Yes | Yes | Yes |

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| | | | | | | |
|---------------------------------|---------------|----------------|----------------|---------------|----------------|----------------|
| DOWNSTREAM PROCESSING | | | | | | |
| Cell Homogenization | Yes | Yes | Yes | Yes | Yes | No |
| Batch Centrifugation | Yes | Yes | Yes | Yes | Yes | Yes |
| Continuous Centrifugation | No | Yes | Yes | Yes | No | No |
| Chromatography | Yes - 1 train | Yes - 2 trains | Yes - 2 trains | Yes - 1 train | Yes - 3 trains | Yes - 2 trains |
| Cold Rooms | Yes | Yes | Yes | Yes | Yes | Yes |
| Microfiltration | Yes | Yes | Yes | Yes | Yes | Yes |
| Ultrafiltration | Yes | Yes | Yes | Yes | Yes | Yes |
| RELATED SERVICES | | | | | | |
| Biosafety Testing | No | Yes | Yes | Yes | Yes | No |
| Cell Banking | No | Yes | Yes | No | Yes | No |
| Fill and Finish | No | Yes | No | No | Yes | No |
| Formulation Development | No | Yes | Yes | Yes | Yes | Yes |
| Process Development | Yes | Yes | Yes | Yes | Yes | Yes |
| Analytical Development | Yes | Yes | Yes | Yes | Yes | Yes |
| Analytical Testing | Yes | Yes | Yes | Yes | Yes | Yes |
| Stability Testing | No | Yes | Yes | No | Yes | Yes |
| Storage | No | Yes | Yes | No | Yes | Yes |
| REGULATORY EXPERIENCE | | | | | | |
| USA - FDA | No | Yes | Yes | No | Yes | Yes |
| UK - MHRA | No | No | Yes | No | No | No |
| Japan - Koseisho | No | No | No | No | No | No |
| Europe - EMA | No | Yes | Yes | Yes | Yes | No |
| ESTIMATED DURATION (MOS) | | | | | | |
| Technology Transfer | 4 | 2 | 2 | 3 | 2 | 2 |
| Process Development (USP) | 3 | 3 | 3 | 3 | 3 | 2.5 |
| Process Development (DSP) | 4 | 3.5 | 3.5 | 3.5 | 3 | 3 |
| Analytical Methods Support | 6 | 5 | 6 | 6 | 4 | 5 |
| Reg / Tox Manufacture | 3.5 | 2 | 2 | 3.5 | 3 | 3 |
| Engineering Drug Substance | 3 | 2 | 2 | 2.5 | 2 | 2.5 |
| GMP Drug Substance | 3 | 2.5 | 2.5 | 3 | 2.5 | 2.5 |

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| COST COMPETITIVENESS (\$) | | | | | | |
|---|-------------|-------------|-------------|-------------|-------------|-------------|
| Technology Transfer | \$100,000 | \$100,000 | \$200,000 | \$150,000 | \$50,000 | \$110,000 |
| Upstream Process Development | \$150,000 | \$150,000 | \$300,000 | \$190,000 | \$70,000 | \$120,000 |
| Downstream Process Development | \$140,000 | \$130,000 | \$170,000 | \$170,000 | \$90,000 | \$120,000 |
| Analytical Methods Transfer | \$120,000 | \$100,000 | \$120,000 | \$110,000 | \$80,000 | \$110,000 |
| Qualification of Analytical Methods | \$120,000 | \$110,000 | \$140,000 | \$130,000 | \$100,000 | \$100,000 |
| Reg / Tox Manufacture | \$140,000 | \$120,000 | \$200,000 | \$200,000 | \$80,000 | \$190,000 |
| Engineering DS Batch | \$1,100,000 | \$1,100,000 | \$1,500,000 | \$1,300,000 | \$600,000 | \$1,000,000 |
| GMP DS Batch | \$1,500,000 | \$1,300,000 | \$2,000,000 | \$1,700,000 | \$1,000,000 | \$1,300,000 |
| Stability (2 temps, 3 timepoints, 1,3, 6 mos per temp, and 11 assays) | \$220,000 | \$200,000 | \$250,000 | \$240,000 | \$150,000 | \$180,000 |