

Executive Summary

Injectable CTM Manufacturing Market Report (10/2008)

It wasn't so long ago that capacity for manufacturing Phase I/II clinical trial materials (CTM) for injectable products seemed to be in short supply. Five years ago, a relative handful of CROs and CMOs were manufacturing clinical batches of injectables, and many of these were suspect from the standpoint of expertise and GMP compliance.

These days, the capacity problem seems to have been resolved. We count at least 43 CROs and CMOs offering to manufacture early phase (Phase I and Phase II) clinical supplies in our PharmSource Advantage database. That number includes 19 contract biomanufacturers that offer fill/finish services to their cell culture and microbial fermentation customers, and it excludes commercial-scale injectables CMOs that manufacture Phase III clinical supplies for their commercial clients.

Is all that capacity necessary? To answer that question, PharmSource's experts completed an analysis of the supply/demand balance for injectable CTM manufacturing. We interviewed several injectable CTM manufacturers to understand typical client requirements as well as key manufacturing practices, then applied our knowledge to the development pipeline and supply base to calculate the supply/demand balance.

Report length: 7 pages

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