

Stakes Getting Higher for Contractors



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As outsourcing services become a more integral part of pharmaceutical processes, **drug companies are taking a harder line** on consequential damages.

Pharmaceutical companies are taking a harder line on the sticky issue of consequential damages in the event of a contractor's failure to perform. Resolving such discrepancies could be expensive for both parties.

Consequential damages are the losses suffered by the client when the contractor fails to perform, above and beyond the cost of the service being provided. Examples include the loss of profits resulting from a supply shortage caused by a manufacturing failure or from the rejection of an NDA filing because a CRO failed to notice that an investigator falsified documents. Less draconian, but still expensive, consequential damages might include the lost value of the active pharmaceutical ingredient (API) as a result of a "blown batch" in dose manufacturing or the costs of having to delay or forego a clinical trial.

Consequential damages have always been among the most contentious issues in contract negotiations. Contractors have usually taken the position that they will not pay consequential damages for a variety of reasons, among them

- their margins are not big enough to allow for consequential damage payments and clients are not willing to pay higher prices to reflect them
- there are many parts of the process of which they have no control (e.g., the characteristics of the API shipped to the dose manufacturer)
- certain performance problems such as blown batches are inherent in the manufacturing and development process and can occur even when the client is doing the work in-house.

However, according to Jill Wadlund, vice-

president and life science casualty manager at **Chubb Commercial Insurance** (Whitehouse Station, NJ), drug companies have begun pushing back harder on the consequential damages issue as outsourcing has become a more integral part of their business processes, "Pharmaceutical companies are less willing to go along with absolving CROs and contract manufacturing organizations from responsibility for consequential damages," says Wadlund, who has been very active in developing insurance policies for pharmaceutical companies and contract service providers. Wadlund says that drug companies cannot get contractors to take on unlimited liability for consequential damages. However, the two sides often settle on some multiple of the contract value that is not too burdensome to the contractor but still enables the client to recover more than just direct damages.

Wadlund says that if the trend continues, contractors can expect to see higher premiums on insurance coverage for errors and omissions and a lowering of coverage limits (i.e., the amount the insurance company will pay per claim). The determining factor is the degree of exposure to loss. For instance, if a manufacturer is the sole source of the API, the potential for consequential damages in the event of a problem is greater than if alternative sources exist.

If contractors' insurance premiums start rising, drug companies will feel it through price increases. The best way for clients and contractors to control the cost of consequential damages is to follow good risk management practices. "The better the risk management practices, the lower the chance of a bad event happening," says Wadlund.

Tough times in pharmaceutical chemicals

News from the Informex 2004 trade show in late January was not very upbeat. Conditions remain bad in commercial-scale contract manufacturing, as they have for several years now. Contract API manufacturers do not expect to see conditions improving much before 2006, if



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Outsourcing Outlook

by then. Much depends on what happens in Big Pharma, whose own capacity utilization remains relatively low.

Difficult conditions have spread to the early-stage process development and clinical-scale manufacturing segments of the pharmaceutical chemical business. Despite some growth in activity during 2003, pricing has become cut-throat there too, with discounts of 30–40% below normal levels. Furthermore, companies are finding they can no longer charge for process development work that is part of commercial scale-up. A number of factors were cited for the intense competition including

- the establishment of clinical-scale manufacturing units by the large commercial manufacturers. Commercial-scale manufacturers traditionally stayed away from early-stage projects, but they are now using clinical manufacturing as a way to establish client relationships they hope will yield commercial projects.

- tough purchasing practices by Big Pharma companies, which are not reluctant to use their buying power
- growing competition from chemical companies in India and China, which

(because monitors can be hired on contract), major CROs have substantial infrastructures in place to support large, global Phase III trials. The need to cover those fixed costs can result in price com-

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have substantial cost advantages and are aggressive competitors.

Pharmaceutical chemical companies are not the only ones feeling price pressure. Clinical CROs are reporting aggressive pricing for large Phase III studies and several report losing large contracts because they have tried to hold the line on price.

Although clinical CROs are usually thought to have a flexible cost structure

petition in the clinical business just as it does in the chemical business. In addition, the principal buyers of Phase II CRO services are the Big Pharma companies that are adept at using their buying power. **PT**