

# Stakes Rise for Blown Batches

Jim Miller

The **financial vulnerability** that results from failed batches has reached new proportions.



**A**ssigning responsibility for failed batches always has been a contentious issue in contract manufacturing negotiations, but many contract manufacturers report that sponsors are becoming even more difficult than in the past. There's a good reason for the heightened sensitivity: The stakes for both sponsors and contractors never have been greater.

As contract manufacturers become an integral part of sponsors' supply chains, interruptions in product delivery and cost overruns directly affect sponsors' revenues, cost of goods, and profits. Sponsors are demanding that their contract manufacturers recognize their mission-critical position and manage their operations to ensure products are delivered on time and on budget.

At the same time, the contractors' financial vulnerability that results from

failed batches has reached new proportions. Contract manufacturers always have resisted taking responsibility for failed batches because the value of the active pharmaceutical ingredient (API) often exceeds the value added during contract manufacturing. However, with the manufacture of today's new drugs, in which the value of the API in a single batch of a biologic or a complex small-molecule product can run to millions of dollars, the vul-

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nerability of both the sponsors and the contractors has increased tremendously.

Traditionally, most contract dose manufacturers haven't taken ownership of the API; instead, they operate as a "toll" processor of the client's material. This relieves the contractor of some responsibilities. For example, if the active or finished product is destroyed in transit or by a fire in the contractor's warehouse, the client retains the loss because it owns the material. In most cases, however, the client still will require the contractor to assume some responsibility in the event the material is destroyed or rendered unusable during processing.

Some contractors say they accept responsibility for the cost of a batch blown as a result of their own negligence. Yet some say that competition in the market often requires them to take on more liability than they would prefer because there's always another contractor willing to take on the risk to get the work. Competition also may prevent contractors from charging a risk premium.

In one situation, a contractor was filling and finishing a product for which the value of the API ran to millions of dollars per batch. Asked why it didn't manage the risk by running smaller batches, the contractor said that doing so would have resulted in inefficient lyophilizer use and would have raised the cost of goods so as to make the contractor uncompetitive.

### **Managing the risk**

Negotiations over failed-batch liability have led contractors to develop approaches that aim both to make their risk exposure manageable and to reduce some of the acrimony that a failed batch can engender in the client-contractor relationship. One manufacturer includes a contract provision that provides for the appointment of a third-party laboratory to investigate the cause of a failed batch; the third-party laboratory is agreed upon before work begins. If responsibility clearly cannot be assigned to either the contractor's negligence or the client's formulation or raw material, then the contract stipulates that the contractor absorb the cost of the value added and the client absorb the cost of the API and packaging materials.

Another contractor uses an approach in which it accepts more responsibility for



## Outsourcing Resources

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each successive batch it manufactures. As the manufacturer gains more experience with and confidence in the manufacturing process, it assumes more responsibility for the outcome of the process.

A third manufacturer takes the position that it will perform to a certain yield during the term of the contract (i.e., it will produce a target volume of finished product for a given volume of API the client provides). In this approach, the success or failure of any given batch is not so important as long as the contractor achieves the target yield rate. Still another manu-

facturer holds that an equipment breakdown is an incidence of *force majeure* as long as it has maintained its equipment on a regular basis.

Plenty of situations still exist in which contractors will refuse to take on risk. Most will not accept blown-batch liability for clinical trial materials. Most will not accept liability when processes are inherently inconsistent (e.g., a coating process that does not provide a uniform coat) or when a product is sold in two or more markets with different product specifications.

### Buying insurance

Insurance is another option some contract manufacturers are considering. Coverage for failed batches is available and affordable, but contractors must look carefully.

“Some E&O [errors and omissions] forms will cover the cost of the active, but many will exclude it specifically,” says Jill Wadlund, life sciences casualty manager for the Technology Insurance Group of the Chubb Group of Insurance Companies. Currently, contract manufacturers and contract research organizations are thrown into the same risk pool, even though their activities and exposures can be very different.

The cost of an E&O policy that covers the active will depend on how the level of risk is rated. Underwriting is done on a case-by-case basis, taking into account factors such as the highest exposure at any one time, the types of products manufactured, the manufacturer’s operating history, and the liabilities the manufacturer has assumed in its contracts.

Wadlund cautions that every case is different, but figuring \$80,000 for \$10 million in coverage provides an order-of-magnitude benchmark for the cost of an E&O policy. Contractors can control the cost of the insurance by accepting a higher deductible and insuring for only worst-case scenarios, much as people do when they purchase insurance for their car or home.

Wadlund points out that the value of the insurance goes beyond simply covering the cost of the active: “Even if you are not in control of the outcome [i.e., you haven’t been negligent], you may get sued. Any contract ambiguity could trigger a lawsuit; you may be negligent just by promising more than you can deliver.” Insurance will cover legal defense costs, and a monetary settlement may be the only option if an investigation cannot pinpoint fault. **PT**