Contract manufacturing can provide significant advantages to companies. An increasing number of Life Science Companies are looking to outsource some or all of their manufacturing processes to leverage unique manufacturing advantages around the globe and achieve greater flexibility, quicker time to market, reduced cost, lower capital requirements and access to expertise and perhaps proprietary technologies. With the benefits of outsourcing comes an increased complexity of supply chains in an industry where quality concerns are paramount and safety based regulation is ever present. These issues are relevant both to companies who undertake contract manufacturing and those who rely on it.

Risk Management concerns
- In a low margin environment, inventories are kept low and any disruption in the supply chain can leave little room for error.
- Safety and regulatory risks - Has the Contract Manufacturer (CMO) maintained compliance with GMP (Good Manufacturing Processes), ISO, FDA or other standards?
- Has the product been tainted in any way? Is the facility secure?

Typically, companies will attempt to transfer liability for product injury back to the CMO and additionally include a product liability insurance requirement. We would expect liability to be allocated contractually in some manner similar to the following:

1. Third party Liability arising from the product’s design should stay with the originator
2. Third party Liability arising from manufacturing error should go to the CMO

Although the precise allocation will vary from one contract to another, the important point is for each contract to be clear on who is responsible for what regarding products liability and for the insurance to follow the contract.

Financial loss/E&O coverage
While product liability insurance may address claims for patient injury and back some contractual indemnifications, it does not address all the risks related to what can be a critical and at times complex relationship.

The possibility of “financial” loss, unrelated to patient injury is a very real scenario and a product liability policy will not cover pure financial injury allegedly caused by a contract manufacturer.

- Many CMOs provide engineering advice alongside their contract services. They may incur liability if the materials were not engineered properly and the component part failed to perform as expected?
- If a CMO fails to adhere to GMP, the customer may initiate a recall out of safety concerns or to comply with a regulatory requirement
- A manufacturing E&O policy is available to a CMO to cover their liabilities and contractual obligations to the originator.
Non damage business interruption
A CMO may be held responsible by its clients if it is taken off line by a regulatory audit resulting in an E&O loss. However, for the Life Science Company itself, the Business Interruption Risk to their supply chain from out sourced manufacturers can be significant and outside of their immediate control. If a partner’s facility is closed down by regulators, they could face a business interruption loss not covered by Property policies which likely require physical damages. Willis Towers Watson Global Specialists can work with you to place a business interruption policy in these circumstances to cover Loss of gross margin, remediation costs and loss of market share during the indemnity period.

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Product recall
Product recalls are now a global phenomenon rather than just a North American and European issue, and a trend towards tighter regulations and government oversight means greater risk affecting all parts of the supply chain. Companies that outsource manufacturing are not immune to recall exposures - - - in fact, far from it. These are the companies holding retailer and/or consumer relationships, and typically these are the only companies identified in the media when products are recalled. What we don’t hear about, and what the general public rightfully has no concern for, are the methods for which a defective product is produced. Accountability will often fall back to the party with a brand name in the stream of commerce or with stature in their respective market. These companies need to be prepared against the risk of recalls, reputational damages and financial loss.

Life science expertise

- 350 industry colleagues in more than 100 countries including 200 in USA
- More than 500 clients in North America and 700 Globally
- The most advanced loss modeling in the industry
- A globally integrated practice that operates as a key part of your team, providing industry specialist insight and complete insurance solutions

- **Strategic** Understanding each company before we offer them tailored advice
- **Tactical** Analysis of each client’s exposure to risks. A tight supply chain, regulatory scrutiny and complex manufacturing requirements all work to heighten the exposure of a contract manufacturing failure. We will review your insurance related contractual terms and advise you on products liability, manufacturers Errors and Omissions (E&O) insurance and product recall insurance
- **Operational** Day-to-day risk management - flawless service, speedy contract reviews and a flow of insightful and relevant management to stay ahead of changes in your risk profile

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