Regulatory Non-Damage BI
Case Studies North America

These case studies are based on real events at the manu-facturing plants of pharma companies and demonstrate how EQuIP, Munich Re's Non-Damage BI cover would have responded.

Case I: Pre-emptive suspension resulting in product shortages, substantial remediation costs and loss of revenue

What happened?

A US manufacturing site suspended production at a site voluntarily to remedy problems after a number of unsatisfactory FDA inspections and the subsequent issuance of a warning letter. The warning letter listed manufacturing and testing issues. The site produced oral tablets that the FDA noted failed size specifications and also cited problems with the dissolution rate for slow release versions.

Some production re-started approximately a year later followed by a slow ramp up back to normal volumes. An FDA close-out letter was issued roughly two years after the final failed inspection.

Impact

Product shortage risk was reported to the FDA and listed on the FDA website. The company experienced an initial $20.6m (33%) half year decline in sales, in part because of additional compliance work at the affected site.

The site posted an annual loss in the first year of suspension instead of a forecast break even. The company also spent circa $45m on remediation.

Case II: Suspension of distribution due to faulty contract manufacture resulting in product recall and loss of revenue

What happened?

A US pharmaceutical company was forced to initiate a countrywide voluntary recall of one of its injectable drugs as a result of potential contamination with glass particles. Distribution of the product was also halted whilst the problem was investigated.

A third party contract manufacturer produced the product which was then distributed by the pharmaceutical company. The facility used subsequently received a warning letter following an FDA inspection citing GMP failures in producing drugs to specification and preventing microbial contamination.

Impact

Sales of the injectables were suspended whilst the problem was investigated, although no adverse events were reported. This incident demonstrates impact of regulatory quality issues on key suppliers where the company itself had no direct oversight.

Another pharmaceutical company was also forced to recall products manufactured at the same facility.

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Case III: Suspension of establishment licence following inspection due to GMP concerns

What happened?

A Canadian manufacturing facility producing injectable drugs had its establishment licence suspended by Health Canada. The company at the time supplied 80% of the Canadian market and offered the most cost effective drug available.

The licence was suspended due to significant concerns regarding the manufacturing process. The licence was partially reinstated within months but prohibited manufacturing prior to the installation of new equipment which was subject to inspection and re-approval.

Impact

The suspension of the establishment license meant that no product could be sold from the Canadian site, which had the potential to take down the company as it only produced this one product. There were also available competitor products that risked major contracts and would have an ongoing impact on market share.

What EQuIP, Munich Re's Non-Damage BI solution would have covered in these examples:

- **Loss of Gross Margin** incurred by the companies as a result of loss of establishment licence, or pre-emptive closure of the affected sites provided such closure pre-empted action by the relevant regulator

- **On-going Loss of Market Share** once production was re-established at the affected site (up to maximum indemnity period of Policy)

- **Direct Associated Expenses** including **Remediation Costs** provided that such expenses and costs reduced the overall loss by enabling a faster re-start of production