Munich RE

EQuIP – CDMO: Regulatory Non-Damage BI
Case Studies

These case studies are based on real events at the manufacturing plants of CDMO companies and demonstrate how Munich Re's Regulatory EQuIP Non-Damage BI for CDMO's cover would have responded.

Case I: Restriction on GMP Compliance Certificate and Prohibition of Sale or Supply of non-critical products

What happened?

During a routine regulatory inspection by MHRA, major deficiencies were found regarding cross contamination at a CDMO manufacturing facility. In particular, there was concern regarding cross contamination that could pose a risk to public health. A statement of GMP non compliance was issued. A Prohibition of Sale or Supply was also issued and clinical trials were prohibited at the site unless the company was able to demonstrate a significant benefit-to-risk ratio. All production was suspended.

Impact

The company undertook significant remediation actions and experienced lost sales due to the suspension. Supply of non-restricted products only gradually re-started. At the date of writing, the GMP compliance certificate had not been fully restored some six months after the inspection. Final licence restrictions were not expected to be lifted until a period of ca. 15 months after the inspection.

Case II: Warning Letter leading to Voluntary Suspension of Manufacture. Loss of Revenue leads to Chapter 11 Filing

What happened?

Following a routine inspection of a CDMO, the FDA issued the company with a warning letter citing poor manufacturing procedures including potential for cross contamination risk at a US site producing finished pharmceuticals. One example given was the use of the same equipment for the manufacture of both drugs and pesticides. Production was suspended and many product recalls had to be initiated across multiple sites.

Impact

Sales collapsed and extensive remediation costs of around $4m were required to rectify the problems. With limited capital resources and effectively no cashflow, the company operating the facility was forced to file for Chapter 11 protection with liabilities reaching some ten times the value of available assets.

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

- **Loss of Gross Margin** incurred by the companies as the result of the enforced or voluntary closure of their affected sites provided such voluntary closure pre-empted action by the relevant regulator
- **Liquidated Damages** where contractually obligated under failure to supply penalties
- **Extra Expense** for **Regulatory Investigative Costs**
- **Direct Associated Expenses** including **Recall and Remediation Costs** provided that such expenses and costs reduced the overall loss by enabling a faster re-start of production

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