Munich RE

EQuIP – Medical Devices: Regulatory Non-Damage BI Case Studies

These case studies are based on real events at the manufacturing plants of Medical Devices Companies and demonstrate how Munich Re's EQuIP for Medical Devices solution would have responded.

Case I: Enforced suspension by Regulator resulting in substantial remediation costs and loss of revenue

What happened?

The manufacturing and shipping of all products from one Class III product range were suspended by a Consent Decree, covering two manufacturing facilities in the US, which are owned by a multi-billion dollar technology company. The Consent Decree was issued because a range of devices were made in violation of current Good Manufacturing Practice (cGMP) based on non-compliance with Quality Systems Regulations (QSR). The non-conformances included failure to establish and maintain adequate processes to manage corrective and preventative actions, design verification and validation controls.

Impact

Significant remediation costs were incurred across both facilities, and whilst some products could be substituted with alternatives, predicted revenue growth was suppressed and EBITA impact was assessed at approximately €60m on an annualized basis. The manufacturing suspension has been in force for >1 year at time of writing.

Case II: Voluntary Suspension of distribution following Regulatory Warning Letter resulting in product recall and loss of revenue

What happened?

A multi-billion dollar US medical technology company voluntarily suspended supply and recalled a wide range of its Class I devices in response to an FDA Warning Letter issued to a recently acquired business unit following a GMP inspection of its third party supplier. The root cause was potential cross contamination from non-pharmaceutical grade products. The company suspended production at the supplier and brought the manufacturing in house. A wider range of products were also put on hold to address further concerns about product testing raised in the Warning Letter.

Impact

50% of all products from the acquired Business Unit were suspended for 2 months, with resumption of full production only achieved after 4 months of supply interruptions. This incident represented a significant impact to a business with their financial forecast restated at the lower end of original estimates.

Case III: TGA Delisting and Suspension of CE Mark due to inadequate Quality Management Systems

What happened?

The Mark for an implantable medical device was suspended, meaning that the device could no longer be sold in the EU. The reason for suspension was non-conformances in the company's Quality Management System (QMS) under European Union regulations (ISO 13485:2003 and 93/42/EEC). This action followed Australia's TGA delisting of the product from its Register of Therapeutic Goods, due to a lack of "adequate evidence of compliance with certain provisions of the TGA Essential Principles".

Impact

The small, single product R&D company lost its only revenue stream when the product was pulled from the European and Australian markets. Stock fell over 16% following the announcement. A year later the company appointed a new Notified Body to support re-certification. However the suspension looks likely to be in force over at least a 2 year period.

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 suspension or loss of establishment licence, or voluntary closure of the affected sites due to non-compliance with cGMP including QSR or QMS failures provided such voluntary closure pre-empted enforced 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** and On-Site Repair Costs provided that such expenses and costs reduced the overall loss by enabling a faster re-start of production
- **Extra Expenses** including Destruction Costs and Regulatory Expert Fees
- **Recall Costs as** a direct result of an enforced or pre-emptive suspension of manufacture

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