



EQulP – Earnings Quality Insurance Protection for CDMOs

Key Features

EQulP is an innovative non-damage business interruption cover. EQulP protects CDMOs from losses arising from a suspension of manufacture due to regulatory non-compliance at Named Owned and Named Supplier Facilities.

Fully customisable dependent on client profile, but key features are as follows:

Coverage triggers

- Regulatory Order issued or instigated by a Defined Regulatory Agency (DRA*) requiring suspension of manufacture at Named Owned or Named Supplier Facilities due to irregularities in the manufacturing process
- Voluntary Suspension of manufacture at Named Owned or Named Supplier Facilities to pre-empt an order by a DRA
- An order for Prohibition of Sale or Supply applied by a DRA to a Named Facility located in a non-DRA country (optional sub-limited coverage)
- Voluntary suspension of manufacture at ANY Owned Facility due to the discovery, prior to use in manufacture, of off specification or out of specification materials received from any Named Supplier facility (optional sub-limited coverage)

Basis of indemnity

- Loss of Gross Margin
- Direct Increased Costs of Working including costs of Remediation and Start Up Costs
- Customer Recall Costs
- Liquidated Damages for failure to supply contractually payable under Customer Contract
- Extra Expense including Product Destruction Costs and Regulatory Expert Fees

Indemnity period

Commencing with the date of the Insured Event ending the earlier of:

- the date when the Irregularities that led to the Suspension of Manufacture have been rectified; or
- the Maximum Indemnity period (up to 24 months)

Key exclusions

- Products not yet approved for sale (but does cover clinical trials materials)
- Physical damage events (as covered in standard PDBI policies)
- Cyber and Network Outage Incidents (as covered in specialist cyber policies)

*DRA – authorities that are covered as standard in respect of enforcement of good manufacturing practices are the respective regulatory authorities in USA, Canada, EU (including EDQM), UK (post-Brexit), Switzerland, Norway, Israel, Japan, Australia, New Zealand.

To discuss how EQuIP
can help your clients
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