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Biotechs and Service Organisations: What are the insurance exposures during the R&D process?

There are numerous types of life science companies involved in the research and development of medical devices and new drugs.

In general, biotech firms develop the device or drug and service organisations bring these products to the market. The exposures both business types face evolve during their lifecycle and the duration of the stages can vary depending on their product. Some of the main exposures can be summarised as follows during their stages of development.

LIFECYCLE STAGE 1:

Start-up / Discovery

Exposures are limited in the start-up phase, as there is limited dependency on supply chain partners and there are only a small number of employees, as well as property R&D equipment. At this stage, the key exposures include:

- Public and Employers' Liability
- Directors' and Officers' Liability, particularly if receiving funding or seeking investment or to satisfy new investor requirements.
- Cyber Liability can protect businesses in respect of loss of data or privacy breaches and provide business continuity support in the event of an incident.

→ Consultants offering services to biotech firms will also need to consider their professional liability covers.

LIFECYCLE STAGE 2:

Development & Pre-Clinical Testing

The product may be developed at a third-party pre-clinical testing laboratory. At this stage, the exposures can include property and business interruption, losses and stock. Biotech firms may also engage the services of Contract Research Service (CRS) firms to carry out testing and gain approval to conduct human clinical trials.

→ CRS firms will need to consider their professional indemnity exposure.

$500bn

Scale of the global biotech market

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PROTECTING YOUR BUSINESS FROM THE UNPREDICTABLE

Risk and exposure are constantly changing

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LIFECYCLE STAGE 3:

Manufacturing

The biotech firm will require products to facilitate the clinical trial and may outsource to a Contract Manufacturing Organisation (CMO). The risks in this process relate to the movement of stock, often temperature-controlled and a business interruption loss.

→ CMOs will need to consider exposures relating to:

- errors in the production
- manufacturing errors
- product recall
- damage to stock in their custody
- contamination

All of these exposures could lead to bodily injury to participants in the trial or a financial loss to the biotech firm.

LIFECYCLE STAGE 4:

Testing - Clinical Trials Phase

The primary exposure during this phase is bodily injury risk. They may engage a Clinical Research Organisation (CRO) to run the trial.

→ The CRO needs to consider the financial loss exposure due to mismanagement of the trial or bodily injury.

LIFECYCLE STAGE 5:

Approval of Product

The clinical trial data is collated into a report and passed to regulators for market approval.

In conclusion

Throughout all phases, whether you are a biotech firm, contract manufacturer, supply chain partner or consultant, given the wide range of exposures that can be faced, you may need to consider some of the following insurance covers:

Cyber Liability Insurance: First-party and third-party losses – damages due to breaches of privacy, system downtime, business interruption and cybercrime.

Intellectual Property Rights (IPR) Cover: Defence of IPR/patent trade secret allegations.

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Directors' and Officers' (D&O) Liability: Including entity cover and employment practices liability. Directors and Officers in the management of their companies face increasing exposures in view of the liability that could arise from decisions made in relation to the operation of the company and given the extent of regulation, in relation to corporate behaviour and reporting.

Financial Loss/Errors & Omissions, Provision of Services**:** Breach of contract negligent, provision of services.

Products' Liability: Any material, finished drug product, laboratory consumable or equipment used for research purposes.

General/Public Liability: Third-party property damage (not product or service related).

Clinical Trials: Injury to the subject.

It is important to ensure that you have the correct risk management tools in place along with a suite of insurance policies to protect your exposures, with adequate policy limits and worldwide jurisdiction.

Contract wordings

Contract wordings should be carefully reviewed to ensure that the indemnification provisions and insurance obligations are carefully understood in context of any insurance policies arranged.

Please contact a member of our specialist team should you wish to discuss Life Science insurance solutions for your organisation.

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