

Can you **see** a biomedical and life sciences risk?

Biomedical and life sciences companies are not limited to those high profile pharmaceutical giants such as Pfizer and GSK. We see the driving force behind the growth of this sector being SME organisations that design, develop, manufacture and distribute products.

Take a closer look...

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Example risks we will write:

- Precision engineer of medical devices
- Distributor of medical consumables
- Manufacturer of lab equipment
- Manufacturer of drugs
- Contract research (clinical trials)
- Laboratory

Some risks aren't so obvious

- **Raw ingredient manufacture / processor**
For example, a company breeding algae for use in a therapeutic drug
- **Contract manufacturer of medical device components**
For example, a precision engineer manufacturing valves for an anaesthetic device

Why is specialist cover needed?

Organisations involved in biomedical and life sciences products or services require specialist cover. They face more complex exposures which may not be covered under a standard policy, as illustrated by the following examples:

- **Efficacy:** A manufacturer of sutures creates a defective product by using material of insufficient strength. The suture fails and the patient suffers an injury. Some insurers may consider this product to have failed to perform its intended function. Markel provide efficacy cover as standard.
- **Contractual liability:** A research company undertakes work on behalf of a client. The work is defective and the customer suffers a financial loss. If the research company's insurance excludes contractual liability (as most standard liability policies do) their policy might not respond but they may still be legally liable. Markel have seen this potential problem and include contractual liability for financial loss as standard.
- **Deviations in controlled environments:** A biotechnology company stores their research samples within a freezer in a lab. The samples would be destroyed if the temperature raises by a few degrees Celsius. In the evening a contractor unplugs the freezer to plug in a vacuum cleaner and forgets to reconnect the freezer after they have finished. When the technicians arrive in the morning and although the door has not been opened the temperature has risen a couple of degrees and the research samples are destroyed. Some insurers would exclude this damage from a change in temperature. Markel have seen this potential problem and include deviation in controlled environments as standard.

How to identify a biomedical and life sciences risk

If you can answer 'yes' to any of the following questions you should consider placing the risk on a specialist biomedical and life sciences policy:

1. My client designs, develops, manufactures or distributes:

a. Medicinal products or medical devices that diagnose, prevent, monitor, treat, alter, supplement or alleviate: disease, handicap, physiological process, conception, appearance or dietary need in humans or animals.

Examples include:

- Hip implants
- Dental implants
- Anaesthetic devices
- Therapeutic drugs

b. Components or ingredients used in medicinal products or medical devices

These risks can be harder to identify. The component or ingredient that your client is dealing with may seem 'standard' but you should consider the end use for their product as this could mean that they require specialist cover.

Examples include:

- Pins for hip implants
- Screws for dental implants
- Valves for anaesthetic devices
- Algae for therapeutic drugs

2. My client offers a service relating to the discovery, development or regulation of a biomedical and life sciences product

Examples include:

- Research and development
- Clinical trials
- Product design
- Diagnostic services