

Threats facing life science R&D companies

Bringing life-changing drugs and medical devices to market involves a number of specialist life science companies working together to research, design, trial, manufacture and distribute new products. There are many risk factors to consider throughout the research and development life cycle, even at the early stages of product development. How these companies successfully identify and manage complex and wide-ranging risks will determine whether they succeed or fail.

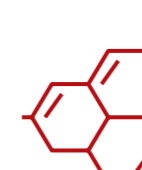
You need an insurer that delivers solutions at every stage of the R&D life cycle.



Research & Development



Specialist Service Companies



Commercialization



Research & Development

R&D companies range from small startups to universities and large pharmaceuticals. Funding and opportunities are plentiful in the R&D space, but companies face a growing range of threats.

⚠ Threats

- Reliance on third parties within the supply chain to fulfil their role on time and to specification.
- Employees working with dangerous chemicals and diseases in a laboratory setting.

✓ Solution

- We offer professional indemnity financial loss cover that protects against negligence and failure of services associated with an unintentional breach of contract, or an accidental or negligent act or omission from the providing of services.



Specialist research and development companies

Clinical research, contract research and contract manufacturing organizations play a specialist role throughout the R&D life cycle by providing expert support for clinical trials, regulatory standards, manufacturing and commercialization.



Clinical research organizations (CROs)

CROs support drug and device manufacturers on their road to discovery and eventual approval of future drugs by alleviating the burdens placed on the R&D companies (sponsors). They typically run the trial, providing expertise with regulatory framework, participant recruitment, trial management, result collection and analysis.

⚠ Threats

- Bodily injury to participants in the trial.
- Financial loss caused by trial repetition that results in delays and missed deadlines.

✓ Solutions

- We offer professional indemnity financial loss cover that protects against negligence and failure of services should the trial need to be repeated.
- We are also able to add a bodily injury extension to our professional indemnity, which covers injury sustained to the participants caused by the negligence of the insured acting as a CRO.
- Medical malpractice can also be included (not offered by many insurers) for specific exposures, with principle investigators performing medical malpractice healthcare services for the trial.



Contract research organizations

Contract research organizations typically provide outsourced R&D services such as running assays, tests or bioinformatics-type services for R&D companies.

⚠ Threat

- Delays to the research or trial phase caused by CRO negligence can result in consequential financial loss for the R&D customer.

✓ Solution

- We offer Professional Indemnity financial loss cover that protects against negligence and failure of services due to delays in the research process.



Contract manufacturing organizations (CMOs)

CMOs typically manufacture and provide products for research and development of cell cultures, proteins, antibodies and enzymes used by the R&D company.

⚠ Threats

- Manufacturing errors such as contamination may damage a customer's research batches or cell colonies. This could lead to a claim to replace the affected stock and financial loss arising out of the damage.
- Financial loss due to the delay in research caused by negligence in the manufacturing process.

✓ Solution

- We offer Professional Indemnity financial loss cover that protects against negligence and failure of services due to delays in the manufacturing process.



Commercialization

The research stage is over and product sales begin, following all necessary regulatory approvals.

Whether it's bodily injury or property damage stemming from the research, design, manufacture, distribution or marketing of the life sciences product, you need an insurance carrier that understands the challenges facing professionals and organizations dedicated to the creation, distribution or use of life sciences products and services.

Find out about our specialist life science solutions by contacting your CNA underwriter today.