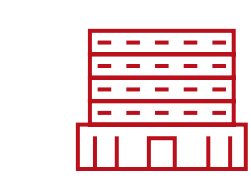


Threats facing life science R&D companies

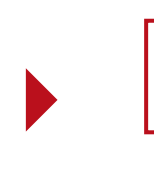
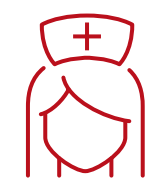


Bringing life-changing drugs and medical devices to market involves a number of specialist life science companies working together to research, design, trial, manufacture and distribute new products. There are many risk factors to consider throughout the research and development life cycle, even at the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

You need an insurer that has the **solutions** to the **threats** facing the specialist life science companies that are involved at each stage of the R&D life science life cycle.



Research & Development



Specialist service companies

Commercialisation



Research & Development

R&D companies range from small start ups to universities to large pharmaceuticals. There is a huge amount of funding and opportunities in R&D space, but also a growing range of threats facing these companies.

⚠ Threats

- Damage to temperature sensitive materials via a change in the controlled environment can delay procedures and vital delivery deadlines.
- 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 laboratory setting.

✓ Solutions

- Our package product provides comprehensive Employers, Property, Public, Products and Professional liability covers.
- Our Property damage and business interruption sections include coverage for the supply chain and temperature sensitive stock.



Specialist research and development companies:

Clinical research, contract research and contract manufacturing organisations play a specialist role throughout the life cycle by providing expert support for clinical trials, regulatory standards, manufacturing and commercialisation.



Clinical research organisations (CRO's):

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

⚠ Threat

- Bodily injury to participants taking part in the trial
- Financial loss caused by the trial needing to be repeated 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 i.e. principle investigators performing med mal healthcare services for the trial.



Contract research organisations

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

⚠ Threat

- Negligence is again a key threat. Delays to the research or trial phase that are caused by CRO undertaking incorrect services can result in consequential financial loss for the R&D customer.

✓ Solutions

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



Contract manufacturing organisations

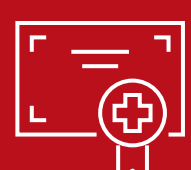
CMO's typically manufacture and provide products for research and development i.e. cell cultures, proteins, antibodies and enzymes, that are used by the R&D company.

⚠ Threat

- Property damage is a key exposure often overlooked alongside bodily injury for a R&D company. Manufacturing errors such as contamination may damage 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 is also a threat due to the delay in research caused by negligence in the manufacturing process.

✓ Solution

- Our product liability that specifically covers manufactured research material that causes property damage.
- We offer Professional Indemnity financial loss cover that protects against negligence and failure of services should there be a delay in the manufacturing process.



Commercialisation

The research stage is over and products 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 organisations dedicated to the creation, distribution or use of life sciences products and services.

Find out about CNA Hardy specialist life science solutions or contact your CNA Hardy underwriter today