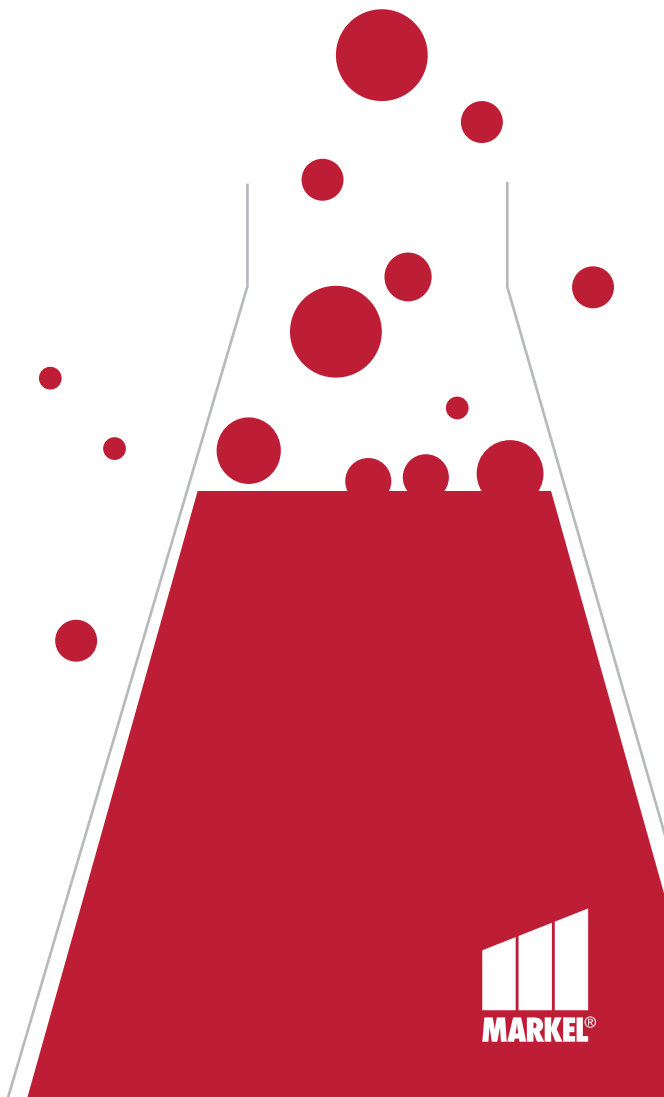


Biomedical and life sciences insurance

Frequently asked questions



Risk appetite

What do you mean by biomedical and life sciences?

Companies that design, develop, manufacture or supply products or provide supporting services to the following industries:

- Pharmaceutical
- Biotechnology
- Medical device
- Food supplements and dietary products
- Laboratory instruments and equipment
- Cosmetics

What do you mean by biomedical and life sciences products?

Medical products are products used to diagnose, prevent, monitor, treat, alter, supplement or alleviate; disease, handicap, physiological process, conception, appearance or dietary need in humans or animals.

Food supplements and dietary products are used to provide nutritional or health benefits, but cannot claim to treat, prevent or cure a disease or medical condition.

Cosmetics are used to change appearance, cleanse or beautify.

What type of risks do you want to insure?

- From start-up, through research and development and clinical trials, to product manufacture and worldwide sales
- UK domiciled (with possible overseas ancillary offices)
- SMEs with sales of up to £50m (we can consider larger companies)

What types of premises can you insure?

Offices, wet and dry laboratories, manufacturing, associated storage and clinics (other than healthcare providers).

What is your target business?

- Research and development
- Producers of medicinal products
- Producers of medical devices
- Producers of food supplements and dietary products
- Producers of cosmetics
- Contract research organisations
- Contract manufacturing organisations
- Sponsors of UK clinical trials
- Importers / wholesalers / distributors

Do you have some examples of risks you would write?

- A new therapeutic drug in clinical trial
- Contract manufacturing of drugs
- Orthopaedic implant manufacturer
- Contact lens manufacturer
- Contract manufacturer of dental implants
- Distributor of medical devices
- Raw ingredient manufacturer / processor
- Start-up research and development company
- Food for special medical purposes
- Total diet replacement for weight control
- Manufacturer of health food supplements
- Distributor of sports nutrition
- Supplier of herbal products
- Manufacturer of natural hair and skin care products

What risks will you not insure?

- Healthcare providers e.g. hospitals, doctors, dentists or pharmacists
- Blood, tissue or cell banks i.e. facilities for storage and future use
- Products used to increase animal yield or weight
- Agricultural or environmental products e.g. GM crops, pollution prevention or mitigation
- Non-approved panel construction (PD / BI)
- Large chemical plants

Can you cover risks domiciled outside the UK?

Yes, but only overseas ancillary offices e.g. sales offices.

Can you insure exports to the USA and worldwide?

Yes. We can insure exports worldwide.

Do you insure clinical trials?

Yes. The policy wording has a specific insuring clause and separate limit of indemnity available. This cover is designed for sponsors of clinical trials. Due to regulatory restrictions in the sector, we are unable to offer clinical trials cover outside the UK.

Are there any clinical trials you won't insure?

We do not insure clinical trials outside the UK.

Can you insure prototypes?

Yes. Our definition of products includes prototypes.

Do you insure implantable medical devices?

Yes. We can insure active (e.g. pace makers) and non-active (e.g. orthopaedic implants) including transient invasive, short term and long term invasive products. NB we do not insure metal on metal implants.

Do you insure medical malpractice?

No. We do not insure medical malpractice.

Can you insure products targeting agricultural or aquaculture or designed for treating pollution?

No. We do not insure products intended to increase yield or performance of animals or crops.

Policy coverage

Do you offer directors' and officers' liability?

Yes, including cover for start-ups and companies in research and development.

Do you offer professional indemnity?

Yes. Liability arising from breach of professional duty is provided under insuring clause 2 professional liability and products liability (financial loss).

Do you offer contractual liability?

Contractual liability is included under insuring clause 2 professional liability and products liability (financial loss) (other than in respect of penalties and liquidated damages). Contractual liability is excluded under insuring clause 1 (public liability/products liability).

Do you include efficacy cover?

Yes. Efficacy (failure to perform) is not excluded under our contract, although we do exclude the cost of defective workmanship, product recall and the like in respect of products.

Do you cover intellectual property?

We cover unintentional breach of copyright, trademark or registered design under insuring clause 2 professional liability and products liability (financial loss). This is subject to an inner limit (usually £1,000,000).

Do you offer no fault compensation?

Yes. Under insuring clause 3 'clinical trials' we offer to pay injured research subjects in line with the clinical trial compensation guidelines agreed by us.

Can you provide an extended reporting period?

Yes. Under most insuring clauses we offer a standard 30 days with an option to increase this under certain classes, from 90 days to 5 years.

Do you offer machinery breakdown?

Yes. We include an element of cover within the standard wording, higher limits are available.

Do you offer computer breakdown?

Yes. We include an element of cover within the standard wording, higher limits are available.

What about computer viruses?

We cover damage to computer equipment arising from a computer virus.

Can you provide full theft cover?

Yes. Our standard theft cover is on a full theft basis other than with regard to outbuildings, property in the open and unoccupied buildings.

Do you offer a flexible first loss basis under business interruption?

Yes. We offer an option to purchase a flexible first loss limit across revenue, profit, R&D expenditure, rent receivable, ICOW and ACOW.

What coverage extensions can you provide?

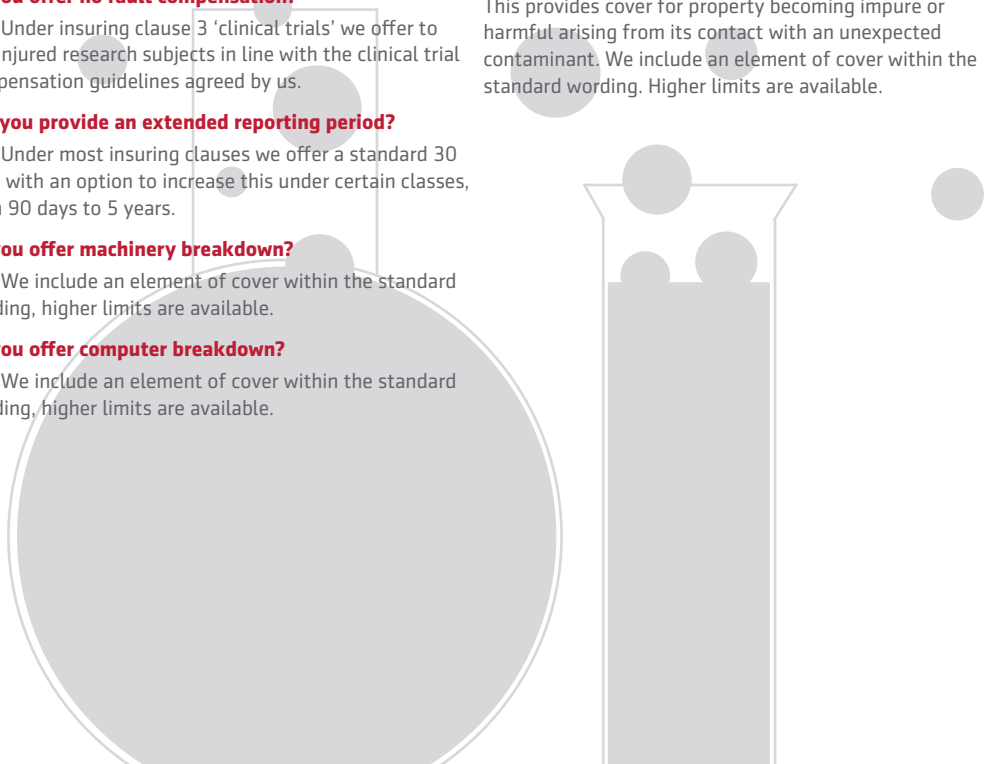
We can provide denial of access, public utilities, restrictions to premises, customers extension, suppliers extension and product withdrawal expense. We include an element of cover within the standard wording. Higher limits are available.

What is controlled environment deviation?

This is where cover is provided for damage to property arising from a change in an environmental condition in an artificially controlled environment. We include an element of cover within the standard wording. Higher limits are available.

What is a contamination event?

This provides cover for property becoming impure or harmful arising from its contact with an unexpected contaminant. We include an element of cover within the standard wording. Higher limits are available.



Technical

What cover can you provide?

1. Public liability/products liability:
 - a) Public liability: occurrence, any one claim / costs inclusive - up to £10,000,000 limit
 - b) Products liability: claims made, aggregate / costs inclusive – up to £10,000,000 limit
2. Professional liability and Products liability (financial loss): claims made, aggregate / costs inclusive – up to £10,000,000 limit
3. Clinical trials: claims made, aggregate / costs inclusive - up to £10,000,000 limit
4. Employers' liability: occurrence, any one claim / costs inclusive - £10,000,000 limit
5. Entity defence: claims made, aggregate / costs inclusive - £1,000,000 limit
6. Directors' and officers' liability: claims made, aggregate / costs inclusive - £5,000,000 limit
7. Property damage
8. Business interruption
9. Specified all risks
10. Money and personal assault
11. Transit

Do you require a proposal form?

Yes, although we can consider a competitors proposal form during quoting stage we will still require our own form to complete the binding process. Our proposal form is available to download from our website.

How do you calculate the value of research and development (R&D) property?

R&D property is not easy to replace and often needs time and expertise to recreate. The value of the property sum insured needs to reflect the cost of this recreation, not just the value of the raw ingredients.

What is R&D expenditure?

An R&D fund is a pot of money intended to be spent over a fixed period of time to reach a desired point in the research and development process. Normally this fund is a finite amount. In the event of a loss that interrupts the R&D process, the advancement of the R&D is delayed whilst the property is reinstated. However during this time the assured has to maintain certain fixed costs and expenses. In the absence of other sources of income, these payments are made from the R&D fund. This depletes the amount in the fund whilst no recognisable advancement is made in the research. The R&D expenditure cover is designed to cover these fixed costs and expenses until such time the property loss is resolved or other policy conditions are met.

What are R&D payments?

Research and development is often funded by milestone payments or collaborative agreements. These payments are normally paid periodically when certain pre agreed stages have been reached. In the event of a loss and the subsequent interruption caused by the time to reinstate the property, the assured may not trigger the payment at the expected time. This cover indemnifies the assured against the loss of this income.

This is not a policy document and contains only general descriptions and illustration. Policyholders must refer to the actual policy issued for the binding terms, conditions and exclusions of cover.

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