

Product: Life Sciences Liability

Manufacturer Information

Product information

Life Sciences liability is a form of insurance against the risk of persons or entities incurring liabilities to third parties that can include bodily injury, illness, property damage, and financial loss.

The Life Sciences Liability market operates on (re)insurer manuscript wordings with cover specific for the Life Sciences industry.

Coverage is designed to be purchased in a modular form so that customers can attain the bespoke coverage required for their business activities. This offers the customer the ability to extend coverage when required and reduce the opportunity for gaps in coverage.

- **Product Liability** is the legal liability of the insured to pay damages and/or compensation to any party, other than the insured or employees, in respect of bodily injury and or property damage arising out of or from the insured's products anywhere within the territorial limits.
- **Professional Indemnity** is the legal liability of the insured to pay damages and/or compensation to any party, other than the insured or employees, in respect of negligent act, error or omission of the insured when providing a professional service, anywhere within the territorial limits.
- **Medical Malpractice** is the legal liability of the insured to pay damages and/or compensation for any negligent act, error or omission resulting in bodily injury committed by the insured when providing a healthcare service or as part of a Good Samaritan Act.
- **Public Liability** is the legal liability of the insured to pay damages and/or compensation to any party other than the insured or employees, in respect of personal injury or property damage, arising out of any act or default of the insured in the conduct of the business within the territorial limits.
- Clinical Trials Liability is the legal liability of the insured to pay damages and/or compensation to research subjects in respect of bodily injury arising out of any clinical trial directed by or on behalf of the insured.
- **Intellectual Property Liability** insurance protects the client in the event of an allegation of intellectual property infringement, covering representatives fees and expenses, and resulting liability, damages and/or settlement.is the legal liability of the insured to pay damages and/or compensation for any claim including associated claimant's costs and expenses and legal defence costs resulting from an action, licensing request, or circumstance.
- Cyber Liability covers;
 - Data Breach costs associated with a breach of personal data including IT forensic, notification costs, regulatory defence or fines, legal costs, and damages.
 - Extra expense and Business interruption following a computer network outage.
 - Ransomware costs including extortion payment and ensuing business interruption.

Target market

This product is suitable for Life Sciences companies that wish to insure themselves against the risk of incurring liabilities to third parties that can include injury, illness, property damage, and financial loss.

Life Sciences commercial entities that would be included in the target market would be:

- Pharmaceutical companies
- Research and Development companies
- Medical device companies
- Nutraceutical companies
- Skincare and cosmetic companies
- MedTech companies
- Laboratories
- Clinical Research Organisations and Clinical Trial Sponsors



Types of customer for whom the product would be unsuitable

This product would not be suitable for individuals, commercial entities not involved in the Life Sciences sector, or Life Science businesses domiciled in the US.

Any notable exclusions or circumstances where the product will not respond

Exclusions (available as extensions upon request and approval):

- Auto or Motor Liability offered to customers on an excess basis to protect against claims arising from injury or damage to third parties only.
- Care, Custody, and Control provides coverage to a customer in respect of non-owned property that suffered damage whilst in the care, custody or control of the insured.
- Opioids and Nitrosamine product exclusions
- Cover besides Public Liability offered on an Occurrence basis
- Employers Liability covers a business in the event of bodily injury sustained by an employee within the course of their employment.
- Medical Malpractice Liability covers the provision of medical or paramedical services or the failure to render thereof. The provision of prescription drugs, the provision of diagnostic equipment and clinical trials.
- Terrorism Liability covers bodily injury, property damage, personal injury or advertising liability arising directly or indirectly in whole or in part by Terrorism.
- Intellectual Property notable Exclusions:
 - Cyber & Data Exclusion
 - Known Circumstances Exclusion
 - TMKS will not be liable for any action or circumstance notified but that does not mature into an action or claim following 36 months from the notification.
 - Insured to not make and payments, assume any obligations, incur expenses, enter into any settlement without TMKS written consent.
- Cyber notable Exclusions:
 - Bodily injury
 - Betterment
 - Breach of contract, warranty, guarantee or promise and assumed liability.
 - Loss of funds
 - Property damage
 - Terrorism
 - Use of illegal or unlicensed programs or software
 - War or uprising
 - · Insured misconduct

Further extensions can include but not be limited to:

- Medical expenses
- Advertising Liability offers coverage to protect a company in the event that they are sued for slander, defamation, libel or copyright infringement.
- Cyber Liability covers third party bodily injury and/or property damage arising from a cyber breach.
- Medical Malpractice Liability covers the provision of medical or paramedical services or the failure to render thereof. The provision of prescription drugs, the provision of diagnostic equipment and clinical trials.
- Sudden and Accidental Pollution Liability covers a business for a pollution loss as a result of a sudden and accidental pollution event. This is not coverage for gradual pollution events.
- Product Recall covers a business for the expenses related to a withdrawal of a product from the marketplace. This can include costs for shipping and disposal.

Limits of liability:

Each section of cover, additional extra(s) and/or extension(s) will be offered with their own limit of liability (and sub-limits where applicable), as requested by the customer to reflect their exposure to risk, and as stated in the policy schedule.

Excesses

Each section of cover, additional extra(s) and/or extension(s) will be offered with their own applicable excesses and stated in the policy schedule.

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Other information which may be relevant to distributors

This product should be sold in line with FCA regulations and can only be sold by a regulated insurance distributor.

Sales journeys must identify customer eligibility and ensure that key information and choices to be made are presented to customers in a way that supports a customer through the process of understanding core cover and configuring optional elements of insurance to suit their specific demands and needs.

This product can be sold face to face, via telephone, electronic communications or a mix of these methods, as long as customers are provided with sufficient information to make an informed decision regarding the suitability of the product.

This product can be sold with or without advice in line with FCA regulations or local regulations if the distributor is regulated outside of the UK.

Commission & Fees

If there is a coverholder in the chain, they are expected to ensure that maximum commission rates do not exceed those stipulated within the Binding Authority Agreement.

The coverholder is expected to maintain oversight of all broker commissions (where applicable) and, where there may be a risk to product value, remedial action should be taken immediately including notification to Tokio Marine Kiln.

Brokers are reminded of their own regulatory obligations in relation to remuneration under PROD 4.3.6 as well as the requirements to make all necessary disclosures to the customer.

Where there are any fees charged by any member of the distribution chain these should be:

- commensurate with the service provided by the distribution.
- not have an adverse impact on customer value; and
- distributor should ensure that TMKS is made aware of the fee amount and/ or method of calculation.

How value is assessed

Value is assessed based on a number of metrics, including underwriting, claims and complaints information as well as through broker and coverholder engagement.

Remuneration paid as set out in our agreements with distributors has been considered as part of the value assessment.

If additional add-ons (including premium finance) are sold alongside this product or additional remuneration is charged, this may affect the value for the customer.

Further information on our product approval processes can be obtained on request.

Date Fair Value assessment	February 2023
completed	
Expected date of next assessment	February 2024
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