



Doing business in America?

Matthew Clark of La Playa examines some critical insurance implications

UK businesses can reap huge rewards when they break into the US market. But it's not easy. And it's certainly not without risk. You need to understand American business culture as well as the myriad federal and state regulation, taxation, accounting, legal and financial systems. Understanding the insurance implications is important too.

What additional risks need to be considered? Are you with the right insurer? Do your existing policies provide the requisite cover already? If not, can they be easily extended? How much is it all likely to cost? Some of the risks faced by UK entrepreneurs enticed by the promise of the US marketplace can be mitigated and controlled with intelligent insurance planning.

La Playa are experts in the design of insurance and risk management programmes for small and medium-sized science and technology firms. We have prepared this document to give some general information to life science entrepreneurs contemplating doing business in America. We've set out some key elements that we believe merit attention, but it's not an exhaustive examination, since different businesses will have different needs. Most of the comments appearing here may also be applied to those contemplating trading in Canada.

We're not lawyers, so no legal advice is given or implied.

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What insurance policies should be considered?

To help tackle this question, we will explore it under two headings; tangible and intangible risks.

1. Tangible Risks

Asset Protection & Consequential Loss



Perhaps it's just a laptop accompanying you on a one-off conference to Las Vegas, or maybe you're taking several staff, product prototypes, research data and materials on a month-long demonstration of your technology in several cities across America. Either way, you must ensure that the Material Damage section of your Commercial Combined Insurance policy provides coverage on equipment taken outside the UK.

Some policies restrict coverage to property taken around the UK/EU and insurers will charge more for equipment taken to America. So it's important to verify the territorial limits under your current policy before you travel. Insurers will already be applying strict security conditions – such as you taking electronic equipment on board aircraft as cabin baggage rather than checked luggage, not leaving property in vehicles overnight or unattended at any time during an exhibition or conference. Cover should extend to all company property taken with you, including electronic items like laptops, PDA's and cellphones. It's an unfortunate fact of life that UK firms typically insure their assets for 60% less than their true value. It's always important to maintain adequate insured values and to communicate the security conditions to staff before travelling.

If you plan to have property permanently located in America, you will need to provide all relevant underwriting information to your broker to enable the UK insurance policy to be endorsed to insure the stateside property. Some insurers may not be able to accommodate this and you may have to consider changing insurer. If such coverage is required it is preferable to insure with a multinational insurance company which has the ability to provide global coverage and local support in the event of a claim. Always insure against Acts of Terrorism. In America, such cover is provided by US insurers with federal government support in the form of the Terrorism Risk Insurance Act (TRIA), the ultimate insurance backstop.

It may also be necessary to consider extending your Business Interruption ("Consequential Loss") protection to insure against increased costs, lost revenue or lost profit resulting from damage to property abroad. But be prepared to accept more limited coverage for certain perils, such as hurricane, windstorm and flood – which may be part of the standard package in the UK but aren't always readily insurable overseas.

Travel

Emergency Medical Expenses & Related Benefits

Perhaps the most worrying scenario for anyone travelling in America is to suffer illness or injury requiring medical attention – while having no insurance to cover the treatment costs. The provision of medical care in America follows a very different model to that of the UK and adequate insurance against emergency medical costs and medical



repatriation is an absolute prerequisite. Excellent travel insurance products are now widely available for UK firms sending staff abroad and it is often more cost effective to insure under a 'group' policy rather than on an individual-trip basis. Some policies will even cover the cost of flying out a replacement member of staff to conduct the work that would have been carried out by the person who has fallen ill. This could be very useful if a director falls ill days before he was due to sign a new contract to supply your company's product. You need a policy that will take care of your valuable employees and enable you to still complete deals. Such policies will also provide additional travel contingencies, including benefits in respect of cancellation or curtailment expenses, loss of personal money, repatriation, loss of luggage, cash and travel documents, personal liability and legal expenses. Most insurers provide credit card style ID cards for each member of staff which provides emergency assistance contact numbers. Policies can usually be extended to include dependent children and spouses travelling with an employee and can provide holiday cover which is incidental to a business trip, e.g. for a skiing trip following a business meeting.

Personal Belongings of Staff

Members of staff who travel abroad on business should insure their personal possessions under their own Household Insurance policy. Most group travel insurance policies arranged by companies provide some level of benefit for personal belongings, but the policy limits may be insufficient to cover, for example, an employee's jewellery or wristwatch stolen during a business trip.

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Personal Accident



Under a “PA” policy insurers will pay pre-agreed sums to the firm should an employee suffer death or serious personal disablement. The PA cover is customarily offered as an extension to a group travel insurance policy and may include Personal Illness benefits too. This can be a very cost-effective way of providing

tangible employee benefits, or to help the firm meet certain costs in the event that a member of staff is killed or seriously injured. It is advisable to check the “aircraft accumulation limit” under your policy to ensure that adequate coverage is provided when larger groups of employees are sent abroad on the same flight. Where key people travel on the same business trip, it is often advisable that they travel on separate flights.

Cargo Insurance



When shipping finished product or stock to America under terms of trade that require you to insure it, you are strongly advised to establish a Cargo Insurance policy. It can be dangerous to rely upon a freight forwarder, courier or other carrier to arrange the insurance for you; they in turn will often rely upon legislation that limits their liability for loss or damage to sums far lower than the true replacement values of the property in their custody. Insurance policies can be tailored to your specific needs, e.g. including transshipment &/or temporary storage. If you insure with an American insurer, you should be aware that your policy will exclude any cover for goods held in temporary storage in countries which are subject to US trade embargoes, e.g. goods being shipped via Cuba. Insurers will expect your product to be professionally packed for shipment, which may involve the use of expert couriers if the product requires specialist care in transit (e.g. for temperature sensitive materials).

2. Intangible Risks

Employers’ Liability

Mandatory for most UK companies, so you must have it. The policy is designed to provide an indemnity against liability for an employee who is injured or becomes ill arising from the work he or she is doing for the firm. Most Employers’ Liability (EL) policies issued in the UK will cover events arising during temporary

business trips abroad, but it’s always advisable to check your policy. For UK domiciled workers who are on secondment to America, refer to your broker, don’t assume secondees are covered by your existing EL policy. For staff permanently placed in America, it may be necessary to arrange local “Workers’ Compensation Insurance” to comply with State legislation. In general, EL policies should provide an indemnity limit of at least £10 million.

Public Liability & Product Liability Insurance

These forms of insurance are designed to protect your company, its staff and management against claims from third parties alleging negligence in the conduct of business activities, or in the provision, manufacture, sale or distribution of products that causes third party bodily injury &/or property damage. In American parlance, Public Liability is often referred to as “Comprehensive General Liability” or just “CGL”, while Product Liability is known as “Completed Operations Liability”.

A third party should be considered as being anyone who is not an employee and can therefore include customers of your customers. You need policies that cover your legal defence costs, claimants’ costs and compensation awarded against you. It’s no secret that America leads the world in both the volume and cost of litigation. So even if you’re just attending a seminar, exhibition or business meeting adequate Public Liability protection is a prudent basic level of cover. If your business is pre-revenue and has yet to ship completed product, the establishment of Product Liability coverage might ordinarily be deferred to a later date. However, early stage Life Science firms are often engaged in R&D activity which involves the creation, manufacture, handling and use of R&D materials/stock, thus creating a de facto Product Liability Insurance exposure for which insurance should be established.

Professional Indemnity Insurance

Also commonly referred to as “Errors & Omissions Liability”, Professional Indemnity Insurance (PI) is designed to protect you against the consequences of your professional negligence, a breach of contract or a failure in the provision of services causing a financial injury to third parties. Such policies may also protect you against allegations of breach of privacy/confidentiality and defamation or disparagement. There may also be limited protection for allegations that you have infringed third party intellectual property, though disputes concerning US patents are usually excluded from cover. Even if you do not perceive there to be a need for this type of insurance, it may be imposed upon you under contract.

Directors of small companies often lament that, because they are small, a large American customer has the potential to ‘squash them like a bug’ in court, rendering insurance moot. But consider this - if you have adequate PI cover it won’t just be you they see sitting in the courthouse, but your phalanx of lawyers, all paid for by your insurer, which is likely to be a multi billion dollar financial services organisation with a duty to defend you. This lends credibility and security to you, your company, its staff and investors and can avert ruin.

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Territory & Jurisdiction Clauses

Most standard UK liability insurance policies (including the relevant sections of Commercial Combined Policies) contain strict “Territorial” and “Jurisdiction” limits that could limit or exclude coverage for liability claims occurring in America or brought against you in a US court – so it’s imperative that you check your policy and extend the limits as appropriate. Again, it may be prudent to insure with an insurance company that is established in America, since such companies may be more easily able to provide local support and legal defence.

Policy Limits



It is hugely important that you review your policy indemnity limits before doing business in America. You should remember that Products Liability and Professional Indemnity policies customarily provide cover on an aggregate basis, meaning that the policy limit applies to the aggregate of all claims, (compensation and legal costs) brought during the policy year. It is therefore critical to review policy limits to ensure they remain sufficient and take account of exchange rate movements.

Directors’ & Officers’ Liability

The directors of a company, be it a small private firm or a large quoted multinational, risk considerable personal liability simply by holding office. Directors’ & Officers’ Liability (D&O) Insurance has long been a critical element of corporate insurance portfolios - to guard against potentially ruinous personal liability falling on directors. The risks are magnified when doing business in America. The US judiciary has of late seen fit to pursue directors for the wrongdoings of their employees – seeing little difference between the two in the face of aggrieved plaintiffs. American prosecutors have used anti-terror legislation to pursue and extradite foreign businessmen to face charges in American courts. Therefore, when doing business in America, and even if you have no assets there,

you are strongly advised to carry appropriate levels of D&O protection. Such a policy should be configured to provide coverage for US court actions and extradition proceedings. For larger firms, it may be necessary to tailor coverage to meet specific exposures and specialist advice from your broker is crucial.



Clinical Trials held in America

Put simply, Clinical Trials Liability Insurance protects you against the cost of settlement or liability where a clinical research subject suffers bodily injury. There is a well-established insurance market for this type of insurance but you should bear in mind that it takes time to prepare quotes. If you’re conducting a trial in the USA, a good deal of documentation and information is required in order to arrange the insurance. Insurers will need to consider issues as diverse as trial funding, CRO reputation, the claim potential of the subject group, the clinical protocols, patient documentation and consent issues. Insurers need time to study this material and it can take up to a month to prepare insurance quotes. This isn’t due to inefficiency - it can genuinely take that long to read through the material and prepare the quote!



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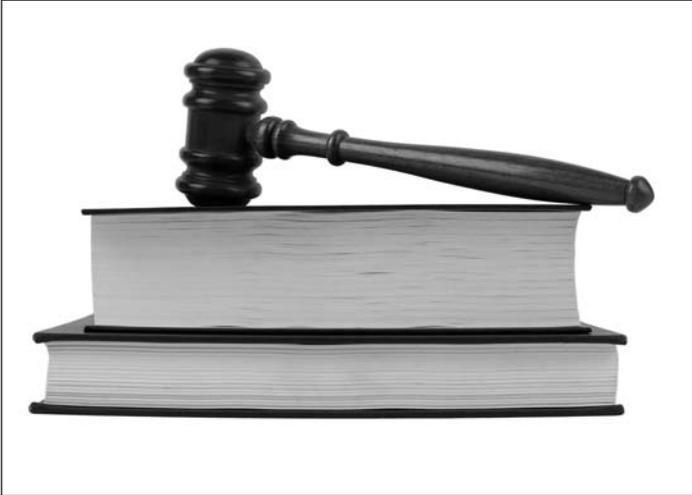
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American Contract Language



It is highly likely that any agreements or other legally binding contracts entered into in America in the normal course of business (collaboration agreements, joint venture agreements, distributor agreements, licenses, partnerships, franchise agreements, terms of sale agreements, memorandums of understanding, co-operation treaties, leases, etc.) will necessitate close scrutiny by your insurance broker before you sign them. Elements to be mindful of include;

- **Contractual jurisdiction** - what law applies to (and shall govern the interpretation of) the contract? In this respect, a contract may specify a particular State as constituting contract jurisdiction;
- **Contractual liability** - that is, liability assumed by your firm which is greater than that which would normally apply – at the very least, this may require the negotiation of specific extensions to the basic policy, or it may comprise additional liability that is not insurable at all, e.g. contractual fines and penalties for late performance;
- **Specific insurance requirements** - the contract may demand that you establish (for example) specific Professional Negligence (also known as “Errors & Omissions Insurance” in America), Public &/or Products Liability (also known as “Comprehensive General Liability” and “Completed Operations Liability” in America) and even “Automobile Liability”, relating to the use of vehicles. American contracts may also refer to “Advertising Injury”, “Libel & Slander” and “Umbrella Liability”. It is important to consult with your broker in each case to identify exact requirements.
- **Indemnity Limits** – in addition to prescribing the specific types of insurance policy you must establish, American contracts will typically also impose minimum policy indemnity limits (usually expressed in US Dollars) with which your policies must comply.

- **Insurer Security clause** - some contracts will specify minimum acceptable “Insurer Financial Strength Ratings” that your insurance companies need to meet. These are typically expressed in terms of Standard & Poor’s, A.M. Best or Moody’s ratings.
- **Joint Names clause** – this is roughly the equivalent to an “Indemnity to Principals” clause under a UK liability policy and effectively demands that your policies be extended to indemnify the American company with whom you are contracting against claims they may incur arising out of real or alleged contract breaches by your firm. On the face of it this may appear reasonable; it’s only fair that the American organisation should be protected from the consequences of your negligence. But consider the implications for a moment. If you are a small firm, contracting with a multi billion dollar



American pharmaceutical giant, you are effectively asking your insurer to indemnify this much larger firm in addition to your company. Not all insurers may be willing or able to do this.

- **Sub-contractors** - If you use freelancers or subcontractors you will usually be held responsible for their actions, errors or omissions, so it’s crucial that your policies extend to insure you against this eventuality. Otherwise, you should verify that subcontractors have their own coverage in place that mirrors that required by your American contract.
- **Other onerous liability conditions.** Professional Liability policies will often contain conditions that exclude claims arising from contracts you entered into unreasonably – that is, where you knew (or ought to have known) that your firm would encounter serious difficulty in fulfilling your contractual responsibilities. You must be sure that you can deliver on your promises; the insurance policy cannot be treated as a guarantee.

Your insurance broker will be happy to review all such documents on your behalf in order to ascertain any insurance implications.

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Am I with the right insurer?



Businesses operating in Life Science present some unique risk exposures to insurers. Research and development operations, the storage and use of materials that may be susceptible to changes in controlled environments and the way in which investment is spent and income is generated are all areas in which Life Science firms can differ greatly from other types of enterprise. For those firms doing business in America these exposures are exacerbated due to the nature of the liability environment.

Off-the-shelf insurance products simply won't provide the cover you need; specialist advice and insurance is therefore critical to your commercial well-being. There are relatively few insurers who offer products and services designed for Life Science companies. Fewer still who are able to provide cover for firms planning to trade in America.

If your firm is insured with a non-specialist, composite insurer, you're running the risk of significant underinsurance. During a recent meeting with a drug development firm based at a university science park, it was apparent from an initial discussion with their management that the company's R&D assets were underinsured to the tune of £500,000. In addition, there was effectively no coverage for Business Interruption. The firm was paying a significant premium to a non-specialist insurer in return for largely irrelevant insurance coverage. Even a moderate fire or flood at their premises would likely have proven terminal.

As an independent, specialist insurance broker La Playa is well-placed to advise on insurer suitability. We only conduct insurance business with companies that are knowledgeable and experienced in Life Science. And we use insurers that enjoy excellent reputations in North America. Typically, these insurers are American multinationals, easily able to absorb North American liability risk on behalf of UK policyholders, and well-versed in American insurance and legal best-practice.

How much is it all likely to cost?



Unsurprisingly, there's no simple answer to this question, since each company must be considered according to its own individual set of circumstances. It should also be born in mind that policy indemnity limits may need to be scaled-up to take account of the heightened risk exposure when final product enters the market. It's unusual for an insurer to offer policy limits of more than £10 million (or US\$15 million) and your broker may need to approach several other insurers to obtain quotes for "excess layer" liability policies that increase the overall level of cover. Insurance programmes providing tens, or even hundreds of millions of Pounds/Dollars in coverage limits aren't uncommon.

It's safe to say that doing business in America will involve significant additional premium cost. You should reckon on it adding at least 100% to your liability insurance costs, but it could be very much higher if the level of your American sales constitutes a significant (i.e. above 50%) proportion of your overall sales, or if insurers view your product as representing unusual risk.

You should also be prepared to accept policy excesses ("deductibles") on certain policies, making you responsible for paying a proportion of each claim arising from your activities in America. For property claims this may be relatively low, perhaps a thousand pounds (or Dollars) per claim. But for liability claims this may be much higher; \$15,000 to \$25,000 excesses for Directors' & Officers' Liability claims brought in US courts are not unusual.

As with most things, advanced planning is important if you are to avoid problems in establishing the insurance that you need. You should talk with your broker as early as possible, informing them of your plans so that relevant underwriting material may be collected, presented to insurers and quotations prepared. This all takes time and it's possible that the insurer may want a face to face meeting before giving you cover. The insurer is being asked to shoulder significant levels of your business risk, so they will expect full disclosure in return. Refusing to provide information because "it's confidential" won't get you very far with your insurers. Most American contracts contain non-disclosure or privacy clauses, so you should ask your lawyers to prepare your own NDAs or Confidentiality Agreements for your broker to sign.

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General Tips & Advice

- Don't let staff travel abroad without adequate Business Travel insurance.
- Ensure that all members of staff travelling to America have Emergency Assistance Cards to help them access their insurance benefits if they fall ill or suffer injury.
- To avoid disappointment, advise staff to insure any especially valuable personal effects under their own household policies. Otherwise, communicate to staff the specific benefit limits provided by your Travel/PA insurance policy.
- Check the adequacy of "accumulation limits" under your Personal Accident policy, when you have several people travelling together.
- When taking computers and data abroad, ensure that it's all duplicated back in the office before you travel. Unless it's absolutely necessary, consider leaving confidential data off your laptop altogether.
- If something is stolen, inform the local Police. If baggage is lost by the airline, hold them responsible and fill out a report before leaving the airport.
- Check draft contracts for "Insurance" or "Indemnity" clauses and let your broker see them. If the American party isn't insisting on a contract, make sure they have your standard Terms & Conditions of Trade on file.
- Make sure your standard Terms & Conditions of Trade exclude or at least limit your liability for consequential losses.
- Review the adequacy of the Indemnity Limits under your liability policies – especially in relation to US Dollar exchange rates.
- Check that the "Territory" & "Jurisdiction" limits under your liability policies include America.
- Remember, no insurance is available for contractual fines or penalties, so avoid them when negotiating contracts.
- Maintain full product traceability at all times and never surrender rights of recovery against suppliers.
- Avoid onerous contract conditions and resist the temptation to sign up to deals that you know will be very difficult to complete. Don't go out on a limb making representations your firm can't honour.
- Identify warranties and conditions in your insurance policies which could void coverage where you have signed up to "Hold Harmless" or "Waiver of Subrogation" clauses.
- Know the limitations of your insurance policies. Make the time, find a quiet corner, have a stiff drink and read over your policy documents – or at least the EXCLUSIONS sections - to understand what you're not insured for. Don't rely solely on the broker's register since this is only a summary.
- Be prepared to change insurer if it proves necessary.
- Produce your own Confidentiality Agreement now – they're almost always necessary so it saves time later.
- Keep your broker fully informed of your plans. He'll only be able to help you if he knows about your activities in America. Never assume. Always question.
- Act early. The more time you have to review your insurance arrangements before committing to trading in America, the better. It may be necessary to get quotes, change insurer and prepare Insurance Certificates – this all takes time. This is particularly important if you are conducting clinical trials in America. Even if insurers have all relevant documentation and information, it can still take a month for insurers to produce a quote.
- Get relevant insurance certificates from your broker, where required by contract, and send them to the American party - ideally before contract commencement if possible.
- Once you're in the American market, conduct regular reviews with your broker. The ongoing duty to declare all material facts rests with you not your broker – so keep your broker fully informed of changes in products, processes, materials and other key facts. If you're unsure if something is relevant, declare it anyway. Record everything. Diary ahead for policy renewal negotiations - don't wait for your broker to remind you.
- Have your broker's direct dial number on your cell phone memory – you may need to call him when you're in contract negotiations in America.
- If something goes wrong, tell your broker immediately, even if it's unclear if a claim will result. This includes circumstances where clients withhold payment alleging some deficiency in your product or service. The earlier you involve insurers the better – and policies often require that insurers are informed of such circumstances within tight timeframes – check your policies.
- Don't leave home without Directors' & Officers' Liability Insurance.

'Take calculated risks - that is quite different from being rash'

General George S Patton

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Useful links:

Foreign & Commonwealth Office

Travel advice by country
www.fco.gov.uk

US Embassy, London

Visa & travel advisory
www.usembassy.org.uk

UK Trade & Investment

USA Country Report & Analysis
www.uktradeinvest.gov.uk

BIO

USA biotechnology trade association
www.bio.org

US Federal Drug Administration

Bio/Pharma import advisory
www.fda.gov/ora/import

BritishAmerican Business Inc.

US/UK trade networking forum
www.babinc.org

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Need more help?

Remember, our advice is always free - so let's talk.



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