



# Risky Business?



**By Chris Tait, Life Science Account Manager at Chubb Europe**

**Chris Tait is the Life Science Account Manager at Chubb Europe, a company specialising in insurance programmes for biotech and medical devices companies. Over the last 25 years, Chris has gained a broad knowledge of the insurance industry. He started his career as a Broker before moving into underwriting, and has held a number of positions prior to joining Chubb. In this time, Chris has gained wide experience in the technology sector, particularly life sciences.**

Risk is inherent in business. This article discusses the idea that 'risk' is not always as ominous or random as the word suggests. More often than not, the risks pharmaceutical companies face can be considered, planned for and, in many cases, managed so that your business can flourish.

Building or running a business is a little like going into battle; to succeed one must have an aim, devise a strategy and be willing to take risks. While each risk has the potential to cause loss or misfortune, many of the dangers can be anticipated and controlled. This simply involves analysing the threats inherent in your business environment and taking decisions to accept exposure or reduce vulnerabilities either by mitigating the risk or applying cost-effective controls. However, risk management is more than just common sense; it requires thought and consideration.

The Institute of Directors in the UK recently carried out a survey asking businesses what advice they would most like to receive, and high on their wish list was advice on risk management (surprisingly, ahead of legal opinion). It is recognised that successful businesses are, by definition, risk takers; planning, investment and strategic decisions all involve an element of risk. This is particularly true for businesses in the life sciences arena, with its high R&D spend and high-tech activities. Organised risk management programmes provide invaluable support by identifying, evaluating and controlling areas of risk, thereby improving the integrity of decisions and maximising chances for success. Thus, in addition to governance requirements on the subject of risk assessment, it makes good commercial sense to undertake such activities.

Some areas of risk are virtually impossible to remove or control and these are generally externally driven – factors such as public perceptions of the industry as a whole, interest rates, the availability of public/private finance and local government decisions. Set aside time to consider what these may be and create contingency plans for dealing with them if they

arise. While it is impossible to anticipate every eventuality, keeping an eye on areas of potential threat will help to minimise their impact.

That said, other areas of risk can be brought under control and their financial consequences alleviated. First I will look at risks to your business operation and consider how they can be reduced, and secondly I will suggest ways to lessen the risk your business poses to third parties (including clinical trial participants).

## **YOUR BUSINESS OPERATION AT RISK**

Your business operations are exposed to many risks and all too often insurers see the results of companies failing to protect themselves. The most common areas, and they may seem obvious, but they are often overlooked in the hurly-burly of day-to-day business, are outlined below.

### **Refrigeration**

Virtually all biopharmaceutical operations store items in their freezers and the consequences of losing these could be disastrous. A master cell line stored in a -80°C freezer that fails to perform might in itself have a significant value but what about the impact of the loss of that cell line on the research being completed or on the manufacturing operation? To reduce the likelihood of putting materials in peril, complete a loss impact analysis along these lines:

- ◆ What is actually stored in each refrigeration unit and what is its material damage value?
- ◆ What are the critical temperature thresholds and how quickly might these be reached?

- ◆ What are the revenue implications if one or multiple units lose the ability to keep the contents at the desired temperature?
- ◆ What controls exist and are these adequate?

Controls to consider:

- ◆ Duplication of refrigerated contents: think about duplicating stocks between refrigeration units on site and between buildings and geographical areas.
- ◆ Loss of electrical power: claims resulting from changes in temperature tend to arise from power issues, often simply because procedures were not followed. For example, when contractors turn off the electrical power to the site, they may not realise that in doing so the refrigeration units will start to thaw.
- ◆ Alarms and emergency response: ensuring a mechanism is in place to raise the alarm in the event of unit failure.

### Smoke Contamination

A key feature of biopharmaceutical companies is the presence of highly sensitive laboratory equipment such as gas chromatographs, NMRs and protein, DNA and peptide synthesis equipment. These are all particularly susceptible to smoke damage, especially cleanrooms, which are vulnerable to a business interruption following even the smallest fire. As insurers we have had the experience of a relatively small oven fire contaminating cleanrooms. It took specialist cleaning contractors working round the clock for five weeks to get the cleanrooms back to the required standard. Only when this was done could the process of revalidating the rooms by the appropriate authority commence. Good risk management techniques, although not eliminating the exposure, can at least reduce it. Important things to bear in mind are:

- ◆ The type of building construction materials used
- ◆ Compartmentalisation of high risk areas (for example, air-conditioning systems can exacerbate spreading of smoke between laboratories)
- ◆ The proximity of sensitive and high value equipment to high risk activities
- ◆ Fire and smoke detection systems

Controls to consider:

- ◆ Construction materials: with a wide variety of materials available, make sure you take advice on the best to use. Talk to an insurance company about the most appropriate materials.
- ◆ Laboratory wall rating: aim for a minimum of one hour between risk areas.
- ◆ Separate air conditioning systems: if a separate system per room is not possible, dampers should be installed.
- ◆ Central station monitoring of an alarm signal: ensures a trained fire brigade response outside normal operating hours.

### Business Interruption Planning

What happens if a fire or disaster interrupts your business? Biopharmaceutical companies operate at the cutting edge of technology and this presents some unique planning issues. As an example, say our customer's operation shuts after the module supplying power to the computer controls fails, wiping out valuable research work in the process. Even though the facility was up and running again within 12 hours, the damage to the research samples took a lot longer to rectify. Some kind of contingency plan may well have mitigated this loss. Many businesses rely on prototype technologies and research data in many different forms, the loss of which could be devastating. It is imperative therefore to incorporate contingency planning integrally within both R&D activities as well as manufacture, rather than considering it as an afterthought.

The protection of current and future revenue sources, including funding rounds, should be the cornerstone of the planning process. Insurers see too many recovery plans written by facilities managers alone. Better plans tend to be written by a team with knowledge of the facilities, finance, science and IT requirements of the company.

It is possible to obtain insurance cover to reduce the financial impact of the above should the worst happen. Cover is available for change in temperature and smoke contamination, along with other risks to your business including the business interruption. However, given the specialised nature of the industry, insurers and brokers who understand the biopharmaceutical business will be best able to guide their clients to the most efficient method of arranging cover.

### THIRD PARTIES AT RISK

The pharmaceutical industry is among the most regulated; each country has its own regulatory bodies and requirements. Despite this, companies with drugs on the market still face problems – Vioxx and Baycol being perhaps the best known examples. While it would be impossible to provide a comprehensive analysis here of all the risk management requirements for drug management, the hazard analysis and critical control points (HACCP) provides a good starting place.

Although primarily used today in the food industry, the HACCP's guiding principles are equally relevant to the pharmaceutical business and would go some way at least to providing a defence in a product's liability action. They provide a scientific and systematic approach to minimising the impact of manufacturing processes on product safety and performance. Unlike many safety systems, which focus on finding defects during manufacturing through spot checks and by testing the end product, HACCP focuses on three key areas: identifying critical safety hazards in advance; establishing preventive measures to control hazards reasonably likely to occur; and monitoring each critical control point for the hazards identified. Its core guiding principles are:

- ◆ Conducting hazard analyses: conduct an analysis of each manufacturing process to identify potential product safety hazards, biological, chemical or physical and develop preventive measures to control them.
- ◆ Determining critical control points: these refer to those points in the manufacturing process where product safety could be compromised. They are also points at which potential hazards can be controlled or eliminated. There will be many possible control points, so focus on those that are considered critical and for which preventive measures can eliminate the hazard or reduce it to an acceptable level.
- ◆ Establishing critical limits for each control point: critical limits are parameters, such as maximum or minimum values, used to ensure that a process is working properly or that the product meets a safety specification.
- ◆ Establishing procedures to monitor each critical control point: continuous or frequent monitoring of critical control points is essential to ensure that processing systems are working properly and that critical limits are not breached.
- ◆ Establishing corrective actions: corrective actions must be defined in advance and must be taken when monitoring reveals that a critical limit has been compromised. This may involve removing defective materials from production to get the control point back within the critical limit.
- ◆ Establishing verification procedures: in addition to monitoring, establish procedures, such as an audit, to verify that the HACCP system is working correctly.
- ◆ Establishing record-keeping and documentation procedures: keep records of hazards and control methods, monitoring data for critical control points, actions taken to correct potential problems, and verification activities and results.

The following incident involving two companies will illustrate the above: one of which had an efficient risk control system; the other did not. Company 1 supplied a product to Company 2, which was to be part of a vaccine manufacturing process. Due to a mis-formulation by a lab technician, the product supplied by Company 1 was found to be lacking an amino acid, which caused the product, produced by Company 2, to be defective. Although this was spotted by Company 2 before sale, they made a substantial claim against Company 1. The checking system in place by the second company saved them significant financial and reputation loss, while the first company suffered severe consequences as a result of the absence of adequate quality control.

Precautionary steps are especially important when it comes to clinical trials. Since the introduction of the Clinical Trials Directive into EU law last year, insurers have seen more requests to cover trials than ever before. The disparate nature of the rules governing insurance around Europe has

made the administration of this issue confusing, but with the local insurance variances in today's litigious climate, companies should ensure that every step has been taken to avoid the possibility of a liability suit, especially one brought in the US.

Certain key risk mitigation factors remain true, no matter where a trial is taking place. Typically there are three key issues that are often overlooked in the race to get the trial authorised by an ethics committee:

1. Research protocol: the bedrock of any clinical trial, it is vital to have a comprehensive and well-designed protocol. The information must be easily understood, ethical and support the goals of the research. Once established, it must be adhered to closely.
2. Reaching the subjects: as the number of clinical trials increases, so does the demand for subjects. However, industry estimates suggest that of all patients eligible for a trial, only 5-10 per cent actually become involved. Accessing those individuals presents an enticing challenge for recruiters, as well as a temptation to be 'creative' in the sign-up procedure.
3. Informed consent: once the subjects have been enrolled, it is the clinical investigator's responsibility to ensure they fully understand the informed consent form. The consent document must be easy to read and understand, so that a 14-year-old could comprehend it. It is worthwhile making informed consent an ongoing process throughout the trial. For example, ask the subjects to reconfirm in writing their consent after any significant event occurs that has safety implications – such as the death or serious illness of a participant in that trial or a similar one.

Clinical trials are not the low risk environment they used to be – just defending an allegation ties up valuable resources and time. Mitigation of risk is essential and your insurer can take on some of the burden of ensuring your world is a little less risky. It is important to choose an insurer carefully so that the potential financial impact can be passed to a knowledgeable and professional partner. When considering an insurer it is important to choose one that has the experience, knowledge and ability to deal with trials cover.

Returning to my opening battle analogy, American General George S Patton (1885-1945) is claimed to have advised: "Take calculated risks. That is quite different from being rash". Building a business is about taking the risks you need to as an entrepreneur; it is not about being imprudent with the results of your efforts or your investors' capital. ◆

*The author can be contacted at christait@chubb.com*