



Medical &
Commercial
International

Coverholder at

LLOYD'S

Life Science Product Contamination and Recall Insurance

Consultancy Services

Control Risks

Product Recall Consulting Services

In today's complex business climate, crises and incidents can derail even long-established companies. In the pharmaceutical sector, product recall—including extortive demands and cyber threats—presents the kind of predictable crisis that resilient companies can actively prepare for. To support your company in responding to, or preparing for product recall, Control Risks offer our combined strategic and technical experience.

What we offer our clients

- A unique and unparalleled suite of services for product recall consulting and response
- Industry-leading sector-specific strategic and technical expertise
- An integrated, seamless solution that gives our clients the best of both organizations to assist with critical needs
- An unmatched depth and breadth of support from our vast network of global offices

Your strategic advisor – Control Risks

Control Risks is a specialist global risk consultancy that helps create secure, compliant and resilient organizations. With 37 offices around the world, we help our clients implement their strategies and solve complex problems wherever they arise. Resolving critical issues and crises is a core part of Control Risks' DNA, forged over 40 years during which we have helped more than 5500 clients in nearly 150 countries. Control Risks has been working in the life sciences sector since its inception and continues to work with the sector as a strategic advisor relying on our experts and their diverse backgrounds as technologists, lawyers, aid workers, investigators, cyber experts, political scientists, soldiers, strategy consultants, intelligence officers and a host of other professions. Our global reach combined with the depth of our expertise makes Control Risks relevant and distinctive.

What if?

Hypothetical cyber incident involving an implantable medical device:

- Public health concern
- Crisis management
- Product recall deployment

SITUATION

In this fictional scenario, Control Risks are contacted by a medical device company following a cyber incident on some of their implantable medical devices. The company had been informed of an incident at a center for the deaf involving cochlear implants, wherein patients with the implants were rendered incapacitated due to increased pitch and tone signals being transmitted.

APPROACH

Control Risks are approached to:

- Advise and support the crisis management team
- Assist the client with identifying customers who had purchased the product, consumer notifications, health department and regulator reporting requirements as well as media relations and brand issues
- Work with the company and the health department and regulator to deploy a field-fix campaign for all individuals who had the cochlear implants installed
- Work with the implant company, the health department and regulator to develop a root cause analysis.

OUTCOME

In response to the scenario, we work together to manage the regulatory issues nationally and create a blocking device to prevent future incidents. As a result the client develops resilient software/firmware updates. Under our consultation, the company works cooperatively with the police, the health department and the regulator. A person of interest is identified and legal action is taken. Ongoing support from the Control Risks team helps the client to resolve the situation quickly, implement a solution and work on corrective and preventative measures to protect the company's customers.

Control Risks

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