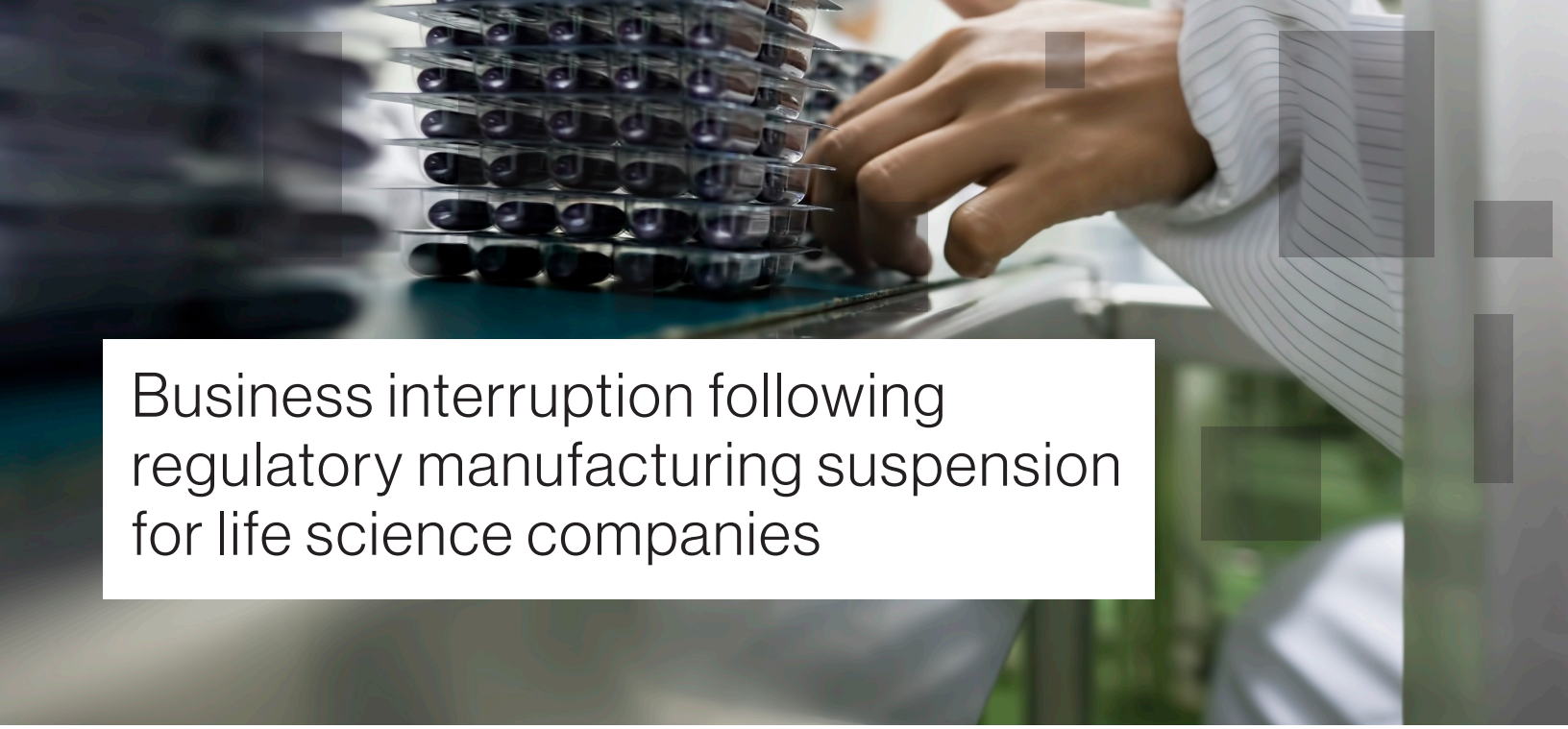

Business interruption following regulatory manufacturing suspension for life science companies

Balance sheet protection

Expense reduction

Decision support through analytics

Our unique perspective

Is your current broker providing you with in-depth trends and insights on the life sciences industry and insurance marketplace? How about information on emerging risks in the industry?

Are they assisting you with evaluation and analysis of your risks in order to minimize your total cost of risk to enable you to achieve the goals of your life sciences organization?

Are they providing direction and consultation regarding risk mitigation improvement opportunities to enhance your life sciences organization's performance? Do they offer a full range of solutions to address your people, risk and capital issues?

Does your broking team include product specialists who are Life Science experts? D&O, Cyber, Product Liability, Workers' Comp, Cargo, Property and Risk Control?

Since 2000, life science companies have incurred over $13 billion in business interruption losses caused by regulatory actions arising from manufacturing issues , 600% more than losses incurred from traditional property related business interruption. The FDA and other regulators around the world are scrutinizing life science companies more closely than ever to ensure latest Good Manufacturing Processes (cGMP) are being followed. Regulatory inspections can result in a suspension of manufacturing, either voluntary by the company or enforced by a regulator.

The ever-increasing complexity of companies' supply chains only adds to their potential exposure. More companies are relying on third parties to supply key elements of their products or to provide manufacturing capacity to supplement or even replace what they provide in-house.

The impact of regulatory inspections can be far reaching:

- Regulatory non-compliance can lead to 483s, warning letters, withdrawal of marketing authorization and ultimately enforced suspension of manufacturing by the regulatory agency
- Suspension at a key supplier or manufacturer can lead to suspension of product manufacture and loss of sales if no alternative is available.
- Regulatory suspensions can be lengthy and the approval process to re-start production is often complex.

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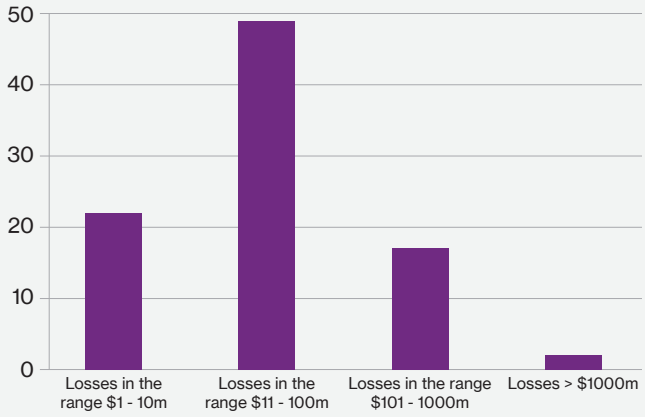
Figure 1. **Business interruption following regulatory suspension 2001-2016**



Non damage business interruption insurance (NDBI)

Insurance can respond to the following events which are a direct result of significant manufacturing deficiencies or irregularites, withdrawal of regulatory approval or license suspension, or a voluntary decision to suspend operations due to these cGMP violations (which may cause a subsequent recall). Covered loss can include loss of gross margin and direct expenses, such as remediation costs, extra expenses such as destruction costs, regulatory investigation costs, recall cost and direct loss of market share. The life science company can choose to insure its own and/or supplier facilities ('mission critical locations').

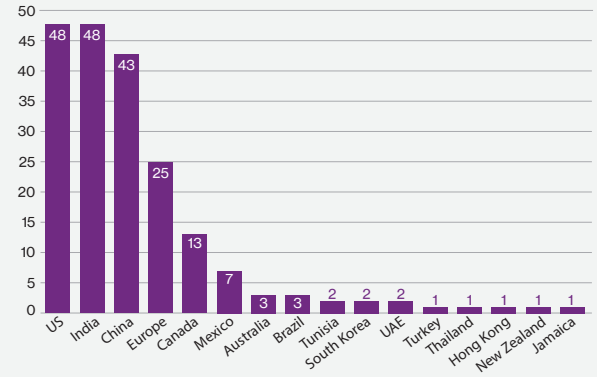
Key coverage events are:

- Total or partial suspension of manufacture by or on behalf of the insured as a direct result of
  - An order by a defined regulatory authority (DRA) to suspend manufacture, or
  - Voluntary suspension of manufacture by the Insured or supplier to pre-empt a DRA order to suspend manufacture as a direct result of irregularities in the manufacturing process
- Covered sites can be the Insured's own sites and/or those belonging to supplier
- Coverage can be applied to scheduled sites

In addition, coverage can be negotiated to include:

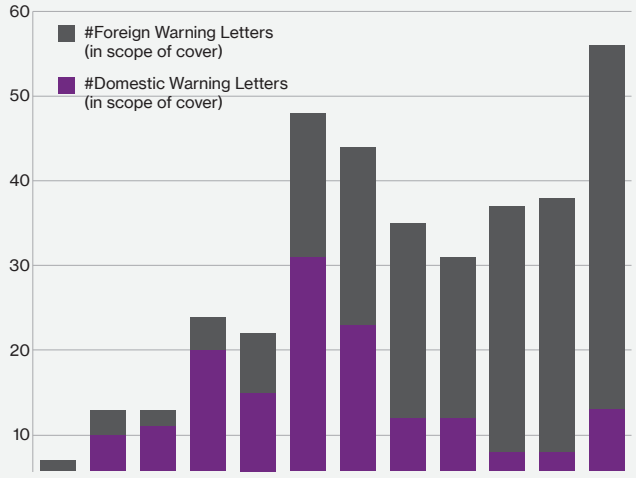
- Import ban in respect of products manufactured at sites situated in non-DRA countries following action by a DRA
- Off-specification, faulty or contaminated materials received from a supplier discovered prior to incorporation into the manufacturing process
- Loss of royalty income or liquidated damages not received as the result of DRA or pre-emptive action

Figure 2. **FDA shutdowns (incl. voluntary shutdowns) + Import bans (2009-2017)**



Source: MunichRe

Figure 3. **FDA foreign and domestic cGMP related warning letters**



Source: MunichRe

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- In-Country regulations
- Insurance limits
- Medical professional liability
- Certificate protocols
- Specific Information requirements

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About Willis Towers Watson

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