

Mike Parkes is COO for  
Regulatory Compliance Associates Inc.  
m.parkes@rcainc.com  
Jon Cammack is President of  
The Science Cooperative, LLC.  
Cammack@sci-coop.com  
Published in January 2012 issue  
of Medical Design Briefs



# Crisis Playbook: “Lessons learned” from real investigations of product failures

When a medical or pharmaceutical product fails in the field, everyone suffers – not just the patient, but also the manufacturer and its employees, investors, suppliers, and even competitors. No one wants a product failure, least of all the company liable for its safety. Faced with a crisis, the manufacturer has three priorities: 1) protect patients; 2) resolve the problem as quickly as possible, and 3) prevent the problem from recurring.

Any product failure threatens a huge loss of value, above and beyond liability, to the manufacturer. If investors lose confidence and share price falls, enterprise value is destroyed. Then, as the company dedicates resources to resolving the problem, their other jobs – such as new product development – don't get done (or, at best, don't get done as quickly). Since innovation is the beating heart of the medical products and pharmaceutical industries, any delay of a new product launch can cost a manufacturer millions; in these industries, time really is money. All the more reason that speed is so important in fixing any product problem.

Yet, many – maybe most – companies are not really prepared for product failure because they lack a crisis playbook. Without a scenario-based guide, they begin and often conduct an

investigation in a somewhat helter-skelter fashion, wasting valuable time figuring out what to do first, and next, and after that. The optimal time to answer those “what to do” questions is before a crisis, not in the middle of one. In our work, helping companies investigate and resolve product failures, Regulatory Compliance Associates and The Science Cooperative have gained the following insights about what works (and what doesn't) in managing a product crisis.

## **“First responders”: Be ready to act without all the facts**

A problem is identified as serious when field events reach some specified tipping point that indicates a trend beyond isolated incidences. At that time, the company's leadership team has to make a few decisions: Should an official notice be released? Should the product be recalled? If yes, which markets? Should production of the product be stopped? In multiple or select plants?

Prompt action generally contributes to good will and positive publicity. The challenge at this stage is a deficit of facts since the forensic investigation itself hasn't started.

In putting together a crisis playbook, a company should begin with guidelines and policies to direct the first responders in evaluating the size of the threat and the appropriateness of various options for response depending on the apparent scope and severity of the problem. For example, if a product is one component in an assembly, perhaps the best response is for multiple supply chain owners to work together to find the optimal fix for the problem. The “point man” for making that happen could be decided in advance.

Of course, a crisis playbook would also help business leaders evaluate the cost of alternative responses. Scenario-based planning provides a context for weighing alternatives and options. Above all else, the first responders would want to stop patient harm. Every manufacturer we have worked with has agreed: protecting the safety of the patient population comes first.

### Functional teams: divide and conquer

After the first responders have reviewed the situation and decided there is cause for escalation, it is time to identify a crisis manager, an investigation leader and the functional forensic team(s). In our experience, an attorney or senior executive with strong project management skills is a good choice for crisis manager. Also, each team needs at least one member with strong organizational skills.

The crisis playbook should cover roles and responsibilities – including potential action checklists – for multiple functional teams. It is feasible that a crisis might require teams in R&D, sciences, manufacturing, distribution, supply chain, human resources, legal, regulatory, quality, environmental, sales/marketing, and communications, as well as sub-teams for representatives from affected countries and from government affairs. What expertise would each team require? What would be each team’s scope and focus? Most important, how should the teams interact, coordinate activities, and measure progress toward milestones and a final resolution? A crisis playbook should provide answers, which would vary case-by-case. (See the sidebar, “Functional Crisis Planning: Roles and Responsibilities for the Crisis Team”)

<b>Functional Crisis Planning:</b>	
<i>Example Roles &amp; Responsibilities for the Functional Team</i>	
<b>Quality</b>	Corrective and preventive actions; regulatory agency communications; investigation support; field action plan
<b>Regulatory</b>	Formal agency reporting, as appropriate
<b>Manufacturing</b>	Investigation support; replacement product planning
<b>Legal</b>	Support and advice for all crisis teams, as appropriate; review of external communications; coordination with external counsel
<b>Marketing</b>	Customer communication, if needed, and coordination with communication and legal teams
<b>Sales</b>	Coordination with manufacturing and distribution to facilitate product replacement; communication with customers
<b>Distribution</b>	New product deliveries and recall activities, if applicable
<b>R&amp;D/Sciences</b>	Analytical support for investigation
<b>Investor Relations and Communications</b>	Communications strategy; messages, Q&A fact sheets, press release(s) and other materials for media outlets and others
<b>Country Representatives</b>	Strategy execution, consistent with global plans
<b>Crisis Manager</b>	Investigational plan, including use of outside resources; functional updates for each crisis team meeting; daily updates to appropriate senior executive(s)
<b>Crisis Management Team</b>	Daily meetings to ensure clear, timely cross-functional communication
<b>Supplier Management</b>	Coordination of supplier investigation efforts and support for new product replacement

Good project management skills are fundamental to managing the investigation process effectively and efficiently. Although the teams are all working on the same problem, each has its own agenda and requires its own plan and milestones. Role-based accountability for project and team-specific organization, documentation, schedules, data management, and reporting can be decided well in advance of a crisis. In our experience, it is a best practice for the leaders of the crisis management team to meet daily and assure clear, timely, cross-functional communication, as well as to agree on next steps.

### **Resources: Look for knowledge and “know how”**

If valuable resources are taken away or distracted from their jobs to any significant degree, real and measurable enterprise value is destroyed. While leaders and experts from each affected corporate function play a vital role in an investigation, it is a smart business strategy to bring in specialists to support the effort with their expertise and experience.

In addition to minimizing damage to the company's value and brand, the quick building up of expertise also speeds up the forensic process itself. One of our clients asked both the FDA and the notified body for its European markets to participate in an investigation. As a result, the company tripled its lab capacity and bolstered its credibility with shareholders and the marketplace at large.

Independent consultants can add muscle to an investigation, while buttressing investor confidence. As an added benefit, they can often give employees the freedom to speak without repercussion because they're beyond the “politics” of the enterprise. Also, outside resources with the right knowledge and “know how” will be well-versed in Corrective and Preventive Action (CAPA) processes and can use this expertise to streamline and speed up the investigation.

### **Roadmap: Imagine a practical path forward, including a “stop” point**

Each team needs a directed course of action based on scenario planning. Given a set of variables that would vary by product and case – including (but not limited to) the severity of the crisis, geography, financial liability, and the possibility of substitute products – what steps should each team take to contribute to the problem identification, resolution, and ongoing prevention?

The steps required of each team can be captured in “punch lists” to minimize redundancy and duplication of effort. Then, it is relatively easy to assign responsibility for each item on the list. If the product is used in more than one country or region, the work of the corporate teams needs to be mirrored by local teams. And everyone's findings need to roll up to the top.

Perhaps one of the most critical points in the investigation roadmap – and the one that is most often missing – is a “stop” point. The longer an investigation goes on, the more enterprise value it can destroy. In the beginning, it's important to decide: when is the problem solved? Is it when the contaminant is found? When the process in the factory or the supply chain is fixed? Or when the product is reintroduced to the market? Among these inquiries is another with implications for continuous improvement: why didn't the QA processes in place (for design, manufacturing, and other functions) detect the potential failure?

Scope control is a fundamental component of good project management. In most cases, there is no need to parse the problem beyond a practical solution. The crisis playbook should include prototype action plans, checklists, work streams, decision processes, schedules, milestones, resource requirements, budgets, and documentation (see the sidebar, “Steps for Post-Crisis Resolution”).

#### **Steps for Post-Crisis Resolution**

- Assure that all commitments made have been honored
- Update all prevention measures, including procedures and policies, as appropriate
- Debrief the crisis management teams to mind “lessons learned”
- Ensure appropriate closure communication with key stakeholders, including regulatory agencies, media, customers, investment community, and employees

## Communication: Make it strategic, proactive, and real-time

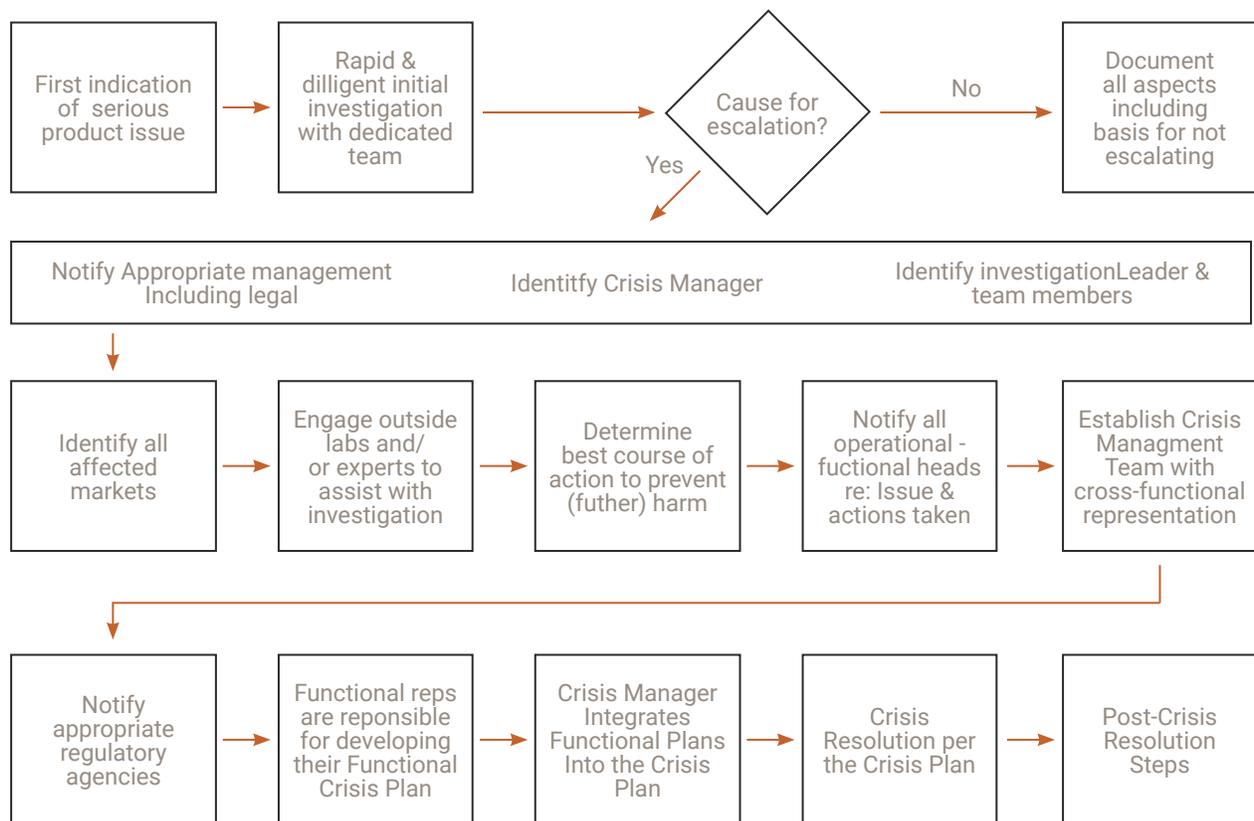
From day one, the crisis manager needs to share information about commitments, expectations, and progress. Communication – internally with employees and externally with investors, supply chain partners, regulatory agencies, the public, and sometimes competitors – is critically important.

The overall process needs a “point person” for communication, as does each team, whether at the corporate or facility level. The role of each communication channel – including press releases, internal newsletters or briefs, media contacts, video, and letters to shareholders and the investment community – can be planned well in advance: a crisis playbook can take

chaos out of the process and enable the company to put its best foot forward. In communication, the current best practice is a dedicated portal, a single source for real-time updates on the investigation, typically accessible through the company’s website.

The old proverb “a stitch in time saves nine” captures the value of a crisis playbook: being prepared will save time and money down the road; most importantly it could literally save lives. By being mindful of the components of effective and efficient crisis management – building up and deploying expert resources; coordinating and integrating parallel work streams; following and documenting rationalized processes – a company’s leadership can be confident in its preparedness to handle a product failure to the satisfaction of everyone’s best interests.

### Key Steps In Crisis Management



**REGULATORY COMPLIANCE ASSOCIATES®**

A Nelson Labs company

rcainc.com | info@rcainc.com | 262.288.6300