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INFORMED DECISION MAKING

Product Qualification & Recall Consulting

The regulatory and litigation environments require that potential safety issues and problems with mass-produced products be investigated rigorously and that manufacturers develop and implement effective compliance and safety programs to minimize a product's risk.

Assessing the root cause of warranty claims and potential problems related to a particular product helps quantify the risk associated with that product, and the affected population, allowing the manufacturer to make informed decisions on continuing production, potential design changes, and any corrective action. Consumer-level recalls are intended to prevent potential injuries; however, in cases where the product does not represent an unreasonable risk of serious injury, recalling the product may not be necessary. Exponent's multidisciplinary teams can address every aspect of product design, manufacturing, and use issues to develop the technical information needed to make appropriate business decisions.

How We Help Clients

Exponent draws upon 50 years of failure analysis and safety evaluation experience to provide a unique perspective on qualifying new products for market and evaluating a firm's compliance, safety, and quality programs.

We provide testing services to address a wide variety of common failure modes that are known to have triggered recalls, as well as critical analysis of proposed products from a safety perspective. Exponent's database of more than 300 million accident and incident records enables us to quantify the performance of a particular product line. Our Human Factors consultants evaluate warning labels and instructions to ensure appropriate communication with the buyer and user of the product. We review manufacturing procedures to assess potential process risks. In fact, with more and more products being manufactured offshore, quality process is a significant concern among suppliers and manufacturers. Exponent's China office addresses specific quality and design issues for our clients with manufacturing facilities in Asia and the Pacific Rim. Part of our overseas work involves performing audits of manufacturers on behalf of our clients.

Product Qualification/Recall Work	Product Experience
<ul style="list-style-type: none">• Product failure/incident investigations• Formal risk assessments of products• Statistical analysis of warranty data• Design quality auditing• Manufacturing quality auditing• Design review/safety qualification testing• Regulatory support• Qualification planning (testing at manufacturer)• Warnings, labeling, and instruction assessment (human factors)• Exposure assessments/studies	<ul style="list-style-type: none">• Kitchen appliances• Exercise/sports equipment• Building control systems• Heaters and air conditioners• Portable electronic devices• Battery systems• Household and office furniture• Medical devices

Our global team of consultants works with clients to respond to regulatory agency investigations in North America, Asia, and Europe, and has presented findings in front of the major U.S. regulatory bodies, including the Consumer Product Safety Commission (CPSC), Food and Drug Administration (FDA), National Highway Traffic Safety Administration (NHTSA), and the Environmental Protection Agency (EPA). Our approach is focused on the robustness of the product related to particular safety concerns, so that if and when a failure occurs, it will occur safely.

Sample Projects

Coffee Maker Qualification

Coffee makers have exceptionally high power usage for their size, and if this power gets misdirected, it can lead to shock or fire risk. Exponent has worked extensively on multiple models of coffee makers with regard to potential product recalls. Because of our knowledge of the failure modes associated with these products and other kitchen appliances, we have designed and executed forced failure test plans to evaluate new designs. These test plans rely on a forced failure approach: assume that single-point failure can and will occur, and make sure that the new designs are robust to these failures. Exponent can perform this qualification work in our labs or work with clients to design test plans to be executed in their own facilities. Either way, our unique perspective allows us to apply our past knowledge to new designs.

Gas Valve Recall

As a result of customer complaints, a global automation, controls, and process solutions company identified a problem with certain models of gas valves used in a wide range of commercial and consumer appliances. The gas valves would sometimes stick in the open position and allow gas to flow even if the pilot went out. By reviewing the gas valve manufacturing and assembly processes and conducting a failure analysis investigation of failed gas valves, Exponent determined that the root cause of the valve failures stemmed from a subtle change to one of the manufacturing steps.

By analyzing the differences in gas valve construction for the different models and performing targeted laboratory testing, Exponent determined that the extent of the product recall could be limited to a small fraction of the total gas valve population.

Power Adapter Failure Investigation

A consumer product manufacturer approached Exponent with reports of heating and melting in the cables extending from their power adapters to computers. The adapter had

passed rigorous qualification tests designed to detect wear-out due to fatigue of the wiring without showing these problems. Upon our investigation, we found that fraying of the wires at a bending location was resulting in a short circuit on the low voltage side of the adapter. This led to melting, and eventual failure of the product. Exponent was able to demonstrate that the protection circuitry in the adapter worked as intended, and did not allow enough energy to be dissipated in a short circuit to cause a hazard. Exponent recommended that the manufacturer's qualification tests be changed to energize the adapter while fatiguing the cable as the fatigue alone was not enough to show a problem, but the resulting short circuit was sufficient to do so.

Product Safety/Compliance Program Development and Review

It's no longer enough to correct the specific problem that resulted in a recall. Civil penalty settlements approved by the CPSC have included stipulations that the firm implement and maintain a compliance program designed to ensure compliance with the regulations enforced by the CPSC.

Exponent has the diverse expertise necessary to assist our clients in identifying and correcting specific product deficiencies as well as any deficiencies in their programs, processes, and procedures that could result in noncompliance or a potentially unsafe product failure. Our work in this area includes all aspects of product design, testing, manufacturing, and post-production product awareness and responsibility, as well as evaluations of suppliers, supplied materials, and distribution channels to track products to the eventual user. This also includes the need for products and failure information to make their way back through the distribution channels.

For example, Exponent recently conducted a comprehensive safety/compliance program review for a client conducting a recall of a portable electrical appliance. The review consisted of a detailed review of the client's safety program, product design process, material receipt inspections, manufacturing, and post-production processes. In addition, Exponent also conducted an extensive program review for a client who imports and distributes a wide variety of consumer products from overseas. The review included detailed audits of the manufacturer as well as multiple component and raw material suppliers, product testing, and design and manufacturing process evaluations.

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