

The Cincinnati Advantage

COVID-19: GENERAL MEDICAL PRODUCTS MANUFACTURING

Loss Control Services - Technical Bulletin



Manufacturers across the country are identifying ways to use their capabilities and systems to help solve current overwhelming demand for medical products – items such as face shields, gowns, masks, disposable items and gloves.

Give these questions some thought if you are considering manufacturing medical products that are outside your normal scope:

- Was a formal design analysis – by an engineer with medical manufacturing experience – performed to evaluate all potential hazards before production commences?
- Has a thorough review of your raw material and component part suppliers – including internet research, reference evaluation and written contract review – been conducted?
- Are you using raw materials or component parts designed to be used with the product? Defective raw materials and components can cause product failure or defect.
- Have you obtained contractual indemnification from your raw material and component parts suppliers?
- What type of formal manufacturing quality controls or systems are in place? In short, how good is the quality management system?
- What warnings or instructions are provided with the product?
- What kind of product traceability controls are in place? Serial numbers, or another tracking mechanism?
- Who are your customers? Are they sellers or medical facility end users?
- Have you provided contact information – a toll-free number or email address – so your customers can reach out with questions, needs or product-related concerns?
- Is a tracking, safety or procedural mechanism in place for tracking product safety?
- Have you reviewed if any intellectual property exposures are associated with manufacturing and distributing of the product?
- Do the changes required to manufacture this new product present additional fire-related exposures to your facility and its occupants? For example, are you now storing more or different flammable liquids, plastics, textiles and lumber?
- Was the current fire protection system designed with capabilities sufficient for the potential risks presented by the new storage occupancy?



Everything Insurance Should Be®

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