Helmsman Management Services LLC

Repurposing operations to help with COVID-19 supplies
Risk Control insights

Manufacturers are a crucial part of enabling our healthcare workers to do their jobs safely. While answering the call to produce masks, ventilators, and other COVID-19-related items may be the right business decision for your company, it's no small feat to overhaul your operation.

Highlights:

- Transitioning your operations raises complex questions
- The Public Readiness and Emergency Preparedness Act (PREP Act) can help protect your business, but consult your legal advisors to make sure your operation qualifies
- Other manufacturers might be able to give you peer-to-peer guidance

We're here to help you think through the potential impacts of repurposing your business operations. The situation is changing by the minute, and we can help answer your questions and give guidance to help reduce the risks of transition.

What to consider when transitioning your operation

As you change operations, new or unexpected exposures can be created. Before beginning to manufacture products to help combat the COVID-19 pandemic, consider the following elements:

- If the product you are making is a medical device, submit an authorization registration to have the device listed on the FDA database.
- Determine whether the product you are making is backed by tort immunity under the PREP Act. It is covered if it falls within the definition of a "covered countermeasure" as spelled out by the Secretary of Health & Human Services (HHS) in a declaration published in the Federal Register, and referenced documents.
  - If you're planning to make medical use masks, the U.S. Food and Drug Administration (FDA) explains which masks are acceptable here and here.
  - If your legal counsel does not believe PREP Act immunity applies, you can also try to limit your risk by ensuring your contracts have a visible disclaimer you are selling the products without warranty in an "as is" condition. Do not overstate any COVID-19 protection. Ask for defense and indemnity protection from the ultimate purchaser.
- Perform a literature search for related standards using this FDA standards database.
- Consult with current manufacturers of related products you wish to replicate or modify to be sure you are within your expertise and capabilities.
  - For example, Ford and General Motors consulted with GE Healthcare and Ventec engineers to learn the appropriate ways to fabricate ventilators on a wider scope.
- Clarify the regulatory standards your operations are following by referring to ASTM Standards and COVID-19.
- Review specific warnings/labels and post-sale communications that should be included with the product(s). For example, if not for resale, identify that on the product label.
- Apply your current recall/traceability programs for newly manufactured products. Consult with legal counsel to determine the best approach based on the type of product being manufactured.

Our dedicated Consulting Center (1-866-757-7324) is available 9 a.m. – 7 p.m. ET Monday through Friday to help with your risk control needs.

Additional resources

Best Product Safety Practices for Manufacturers

Best Practices for Motor Vehicle Operations

ASTM Standards and Covid-19

FDA Recognized Consensus Standards (Database Search Tool)

Looking for more comprehensive safety information? As our customer, you have exclusive access to risk control tools and resources through SafetyNet — visit lmi.co/safetynet

For more information, contact your local service director or the Risk Control Consulting Center. Email anytime — **RCConsultingCenter@LibertyMutual.com** — or call 1-866-757-7324, Monday – Friday, 9 a.m. to 7 p.m. eastern.

Helmsman Management Services LLC®

https://www.helmsmantpa.com/solutions/risk-control

04/20 RC 2041 HMS