GLOBAL MARKET CHAOS IS COMPROMISING YOUR CLEANROOM GLOVE INTEGRITY

The market for cleanroom gloves has faced unprecedented challenges from the COVID pandemic fallout. Numerous factors creating the perfect storm drastically altered availability and quality of controlled environment products. This disruption has thrust the balanced process into chaos and forces calculated consideration in structuring a requisite response. The primary causes of chaos are identified as follows:

1. **Labor Issues** – Labor shortages ensued as foreign governments issued Movement Control restrictions, constraining workers' travel to manufacturing sites. This spurred increases in child labor trafficking abroad, causing some prominent manufacturers to face legal action, and making it unlawful to purchase their products in the US.

2. **COVID Numbers and Vaccine Rates** – Top suppliers from Malaysia have been forced to cease or reduce production until designated levels of vaccine rates and COVID cases are met. Four large sites in the most serious lockdown areas are not operating, including the radiation sterilization facility for sterile gloves.

3. **Logistics** – Inability to book or ship containers shattered transportation methods. Empty containers forbidden to return from Malaysia and China sit in foreign ports. Vessel booking fees are 2-1/2 times greater and shipping costs quadrupled since pre-COVID levels.

4. **Raw Materials** – The use of raw materials for nitrile gloves has increased over three times the normal rate. The cost of nitrile gloves has doubled, exacerbated by challenges in getting materials to the manufacturer.

5. **Quality** – Lower quality material has permeated the market. China is known to produce high volume, low quality exam gloves, with unsafe filler levels. Subpar content causes gloves to fail, especially in tensile and elongation tests.

6. **Consumer Practices** – Consumers initially hoarded gloves. Now inventories are depleted causing excess demand. Many manufacturers replaced cleanroom glove production with less costly lower grade exam gloves. Users are not being advised of the new formulations and new countries of origin, or any other changes in their gloves' content.

7. **Pricing Trends** – As recently as July, costs were up 200% for exam gloves and 193% for cleanroom gloves (down from 300% and 200% respectively in January-March.) However, any cost decreases are offset by increased vessel bookings cost, increased transit times, and lengthy manufacturing lead times.

In light of unprecedented circumstances, steps must be taken to establish **Chaos Risk Management** practices in your organization. Disruptions in supply chains, and deviations from manufacturing standards, could be resulting in compromised material in your cleanroom gloves and consequent failures in controlled environments. Recommendations for specifying a primary and secondary glove manufacturer, and implementing a **Manufacturer Qualification Program**, are further outlined here.

CE Glove Market Chaos

The current state of the worldwide glove supply has shown several disturbing issues regarding supply, logistics, raw material availability, quality, and consumer practices. Worldwide COVID-19 infections have shown that the market and product availability have limitations and constraints. Just in In Time (JIT) logistics and purchasing is no longer a viable option regarding gloves and other Personal Protection Equipment (PPE).

1. Labor issues with some of the top primary glove manufacturers:
   a. Due to COVID-19, there is a shortage of laborers who can travel to manufacturing sites. Movement Control Orders and plant shutdowns in regions that are under these strict movement limitations have presented a global shortage of low-level workers to man the remaining open manufacturing plants.
   b. Because of the unavailability of workers, there has been an uptick in exploitation of child labor laws. This has affected not only glove production, but also in production of some disposable garment products.
   c. Top Glove, the world largest glove manufacturer, is facing multiple legal actions.
      Malaysia violations include breaching Minimum Standards of Housing and Accommodation for its employees.
      USA violations: Top Glove is on the Watch List for violation of human rights. US Customs and Border Protection prohibits the import of Top Glove products due to evidence of forced labor. Containers have been seized.
   d. Risk - manufacturers currently on watch list (Hartalega, Brightways and Supermax gloves)
      Watch list of US Customs and Border Protection for similar offenses:
      https://www.reuters.com/world/asia-pacific/us-seizes-shipment-malaysias-top-glove-over-forced-labour-concerns-2021-05-13/

      https://www.freemalaysiatoday.com/category/nation/2021/05/29/us-probes-2-glove-makers-over-forced-labour-claims-says-report/

2. COVID-19 related factors - Vaccine rates are low
   a. Labor constrained by Malaysian government's Movement Control Order
      - Phase 1: Lockdown with only essential businesses allowed to operate. These services can only operate at 40% labor in production.
      - Phase 2: If COVID cases drop below 4000 cases per day. Phase 2 will see several more economic sectors allowed to operate. We estimate this to be the end of July.
      - Phase 3: If cases drop below 2000 cases per day with 40% Malaysians already inoculated with their second vaccine dose. This is planned by the end of August. This will see ALL economic sectors opening except for high risk such as night clubs, pubs etc.
      - Phase 4: If cases drop below the 500 mark and with 60% of Malaysians vaccinated. This is planned by the end of October.
   b. Recently, **four large glove manufacturing sites** are in the most serious lockdown areas and are not operating. This also includes the radiation sterilization facility for sterile gloves.

Labor issues are constraining glove availability, particularly in the USA Market.

3. Logistics
   The availability of shipping containers in Malaysia & China remains constrained. This has been caused by:
   a. Global increase demand on Personal Protective Equipment (PPE). Containers departing origin such as China (mainly) and Malaysia have yet to be returned to origin, thus causing "orphaned" empty containers in foreign ports.
   b. The recent Suez Canal shutdown caused vessel re-scheduling and delayed delivery dates.
   c. Shenzhen (China) port container release is now limited due to covid outbreak.
   d. Average vessel booking fees are up 2.5x versus pre-Covid levels
   e. Overall, there has been a 4X cost increase in costs for shipping.

   https://www.maritime-executive.com/article/delays-and-capacity-constraints-are-new-normal-in-container-shipping

   https://www.theguardian.com/world/2021/jun/16/covid-outbreaks-in-chinese-ports-could-cause-global-goods-shortages

   Logistics flow will continue to be limited due to constraints in container availability. Even with products available, vessels are delayed.

4. Raw Material
   a. Raw materials used for nitrile gloves has increased over 3X, including getting materials to the manufacturer, the cost of the actual glove is up 2X.

5. Quality
   China is known for producing high volume, low quality, exam gloves. Chinese gloves contain inconsistent raw materials and a higher-than-average filler content. Typically, fillers for exam grade gloves are about 5%. China is known to add up to 20% filler to reduce cost and increase profit. More fillers will cause the gloves to fail, especially in tensile and elongation tests. Malaysia is also known for innovation in the glove industry, being well ahead of China.
   https://insights.omnia-health.com/patient-safety/how-malaysias-booming-rubber-glove-industry-innovating-stay-ahead

   https://www.thestar.com.my/business/business-news/2020/06/25/ramp-up-in-china-nitrile-glove-output-not-a-threat

   Lower Quality material has entered the Controlled Environment market, triggered by suppliers "hoarding" non-compliant product.

6. Consumer Practices
   a. Customers began early in "hoarding" of gloves. Now that these inventories have been depleted, there is an increased demand for gloves.
   b. Manufacturers moved to production of exam glove grade due to lower manufacturing costs to increase revenues, causing higher raw material costs and fewer lines to support Cleanroom Glove manufacturing.
   c. Limited supply chain for "cleanroom" gloves with manufacturing expertise.
      i. Nationally recognized glove manufacturers have discontinued production on specific product lines, and white color is in limited supply. Products previously manufactured in Thailand are now manufactured in Malaysia using a new formulation. No change notification has been distributed to customers of the new formulation and country of origin.

7. Pricing and Trends:
   2021 price trend analysis (percentage versus pre-COVID levels)

	Exam	Cleanroom
Jan-Mar	300%	200%
April	275%	200%
May	250%	198%
June	225%	198%
July	200%	193%

Any glove manufacturing cost decreases are offset by increased vessel bookings cost, increased transit times, and manufacturing lead times.

Chaos-Risk Management

Specifying a Primary and Secondary Manufacturer

The same glove from two different distributors does not constitute a contingency plan. Recent events have shown that restricted supply affects all modes of distribution of the same glove manufacturer.

1. The primary and secondary glove need to be from different manufacturers; that will allow for redundancy.
2. While the primary glove product may have a majority of the usage (60%), the secondary glove product needs to be actively in use at the facility to guard against allocation restrictions in times of need.
3. All allocations from the manufacturer for products with tight supply are based on prior usage. Without prior usage there will be no allocation available.

The following questions should be answered to ensure a smooth transition to any new glove manufacturer.

1. What are the internal requirements or specifications of the gloves that are currently being used for your controlled environments?
   a. If the gloves for the ISO 5/6 are sterile. What are the sterility requirements for bioburden? i.e., SAL (Sterility Assurance Level) of 10^{-6} or 10^{-3} reduction of bioburden?
   b. What are the total particulate count requirements for the gloves being use in the ISO qualified space?
   c. Do the current supplied gloves consistently meet the requirements set forth in the product specification?
   d. What is the trend data collected, if any, that will be a significant attribute of the glove?
2. What are the steps in the Manufacturer Qualification Program to bring in a new manufacturer for critical (low total particulate) or sterile materials used in all ISO specified cleanroom or controlled areas?
3. Is it possible to use a low particulate (used in ISO 3/4 areas), non-sterile glove for some applications, in lieu of a sterile glove and used in conjunction with a sterile sleeve?
4. Any testing performed by the user outside the manufacturer's quality testing is at risk for failure, since it cannot be assured that the testing is performed consistently unless qualified.
5. What other attribute of the gloves do end users like or want?

How to Qualify Valutek as an Alternate Glove Manufacturer

Manufacturer Qualification program:

1. Do you have a written Manufacturer Qualification Program/SOP(s)?
2. If so, does the SOP have an emergency provision(s) for qualifying a new manufacturer if currently qualified manufacturers cannot fulfill product need?
3. If not, can the SOP be amended to include concurrent qualification of a new manufacturer on an emergency basis?
4. If the new manufacturer can be qualified on a concurrent basis, then after qualification, will the manufacturer then be added to the qualified manufacturer list?
5. Is a Change Notification process set up with each manufacturer to be notified as soon as possible of any changes to manufacturing process, raw materials, or manufacturing site?
6. **Valutek offers production samples, training, and documentation to meet all these qualification needs.**

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