



Providence Enterprise

Full-Service Global Contract Manufacturing

When We Ran Out Of Everything:

Material Shortages and Options for Medical Device Manufacturers



When there's no supply in supply chains

Finished products only emerge from supply chains because other things go in. A single discontinued component causes bottlenecks and a ripple of delays. What we are seeing now is the unprecedented unavailability of multiple materials required in the production of medical devices.

Take plastics. Events we thought would only happen in the U.S. when Texas froze over happened as Texas froze over. Extreme weather, including storms, hurricanes, floods and even a lightning strike severely disrupted petrochemical plants. Natural disasters, coupled with consumer spending rebounding from pandemic lockdowns contributed to a dramatic shortage of plastics used in medical devices, parts and packaging. Factors great and small drove up the price of ethylene, PVC and epoxy resins by 43%, 70%, and 170% respectively.



Common metals become precious

Medical devices and their components depend heavily on metal and its alloys. Manufacturers suffer from irregular access to palladium, titanium, chromium, cobalt and nickel or magnesium alloys. In addition, they themselves in the long breadline for semiconductors and lithium batteries, often far behind ravenous mega industries such as automotive, electronics and defense.



The Magic 8 Ball

Experts who make predictions about material price and availability will probably tell you something else next month. There is no historical data for first time events, including global shutdowns and destructive patterns caused by global warming. Some tariffs imposed during the last U.S. presidency have been changed or revoked during the current one, with ongoing pressure to continue or change many more.

Access to some metals has been curbed by the war between Ukraine and Russia. It so happens that these two nations provided one third of the world's neon gas, essential to the production of, among other things, semiconductors. What was meant to be a three-day war has dragged on for months (at the time of writing, it's approaching its first year anniversary). Neon gas prices increased by 5000%.

In case of emergency, break open lines of communication

Times are tough, and your Contract Manufacturer (CM) should already be pulling out all stops to ease the risks of uncertain supply. **If your CM is less than proactive, here is a list of questions:**

1 What changes have you made to BOM parts selection criteria?

By asking this question, you get an immediate picture of whether your CM is stuck in the old normal. New normal preparedness means new approaches to the BOM, including redundancy in supply lines and opting for parts mass produced for larger industries.

3 Do you see anything in our design that could be adversely impacted by current or future supply shortages?

We've said it before: getting things right at the design phase is the closest to a guarantee for a smooth journey along the product lifecycle. More than ever, this includes making judgements about parts and materials that may be hard to come by or increase in price.

5 How much are you leaning into your 'big customer' purchasing power?

Your CM has aggregate purchasing power because they source for many customers. In the past, this primarily meant they could secure your parts and materials at a competitive price. In current times, it boosts their chances of obtaining your share of scarce resources.

2 How prepared are you for known future disruptions?

A CM who is interested in working with you long-term, prepares for the long-term. The climate crisis promises that we will continue to see "once in a lifetime" natural disasters. It also continues to influence customer and company priorities, so you will want a CM well versed in sustainable materials and processes.

4 Have you leveraged your entire network to obtain the materials and parts we need?

Established CMs have built a large and diverse network of suppliers and operate in various countries. More trusted suppliers mean more avenues for procurement.

6 Am I getting equal treatment?

A CM partner should be increasing – rather than decreasing – your chances of success. If your CM serves industry giants, which customers will they favor when supplies are limited? Even if your partner is a right-fit CM it doesn't hurt to get reassurance that they have your back.

7

What are my options?

Don't discount that sometimes your best bet may be to switch to a different part or material. Even if you have your own materials scientists and engineers, have them sit down with your CM's team. Are there, for example, biocompatible alternatives that won't impact quality, functionality, or safety? With skyrocketing prices on 'cheap' materials, the traditionally pricier options may be more viable.

8

What do you look for in alternative materials?

CMs with long experience in medical device manufacturing prioritize safety and functionality. Neither will be compromised in an updated BOM. Your right-fit CM will only recommend alternatives are safe and compatible with other parts. They will provide assurance that none of the materials are or may become toxic, that metals won't corrode or react with cleaning or bodily fluids, and that plastics won't wear down.

9

Will regulatory compliance be affected by material changes?

All new medical devices require approval from regulatory bodies such as the FDA or CE. In addition, any change to a previously approved device requires more paperwork. When your right-fit CM partner advises you on alternate materials, they will also share plans on how to get through approval processes as efficiently as possible.

10

Aside from cost will these options affect my bottom line?

Critical to that multidisciplinary team are manufacturing experts. Material replacements may result in different machining decisions or sterilization requirements. Your CM's team provide the information you need to make the best decisions.

Navigating the New Normal

Contract manufacturers can't accurately predict the long-term future of each of the many materials used in medical device manufacturing. Even though leaders are struggling to get it right. However, your CM partner can reduce risks and increase your chances of success. They will make sure they understand your company, your goals, and your product better than anyone. When supply shortages mean there is no ideal solution, they will be honest and tell you. They will manage your expectations while working tirelessly with your teams to find alternatives.

There's no question that we're living in a *new new normal*.

Your CM will have strategies to

Help you make through.

About Providence Enterprise

Providence Enterprise is a Hong Kong contract manufacturer with manufacturing in China, Vietnam, and Mexico. We specialize in electronics, electro-mechanical assemblies, and high-volume disposables. We are FDA registered and ISO 13485, ISO 14971, ISO 14001, ISO 27001, IATF 16949, and ISO 45001 certified. Our capabilities include fabricating tooling for silicone rubber and injection molded plastics, clean room injection molding, electronics, clean room assembly, and sterilization.



Providence Enterprise
Full-Service Global Contract Manufacturing

 www.providencehk.com

 [LinkedIn](#)

US Office
1500 Quail Street, Suite 420,
Newport Beach, California,
92660, USA
Phone: +1-949-851-8888

Europe Office
Pastelblauw 75
5245CD's-Hertogenbosch,
The Netherlands
Phone: +31-6247-869-20

China Office
Shan Xia Community, Pinghu
Street, Longgang District, Postal
Code 518111, Shenzhen, China
Phone: +86-755-8465-4611

Hong Kong Office (HQ)
Unit 13-15, 6/F., Grand City
Plaza, No.1, Sai Lau Kok Road,
Tsuen Wan, N.T., Hong Kong
Phone: +852-2415-2293