



# 15 Crucial Questions to Ask When Looking to Partner with a Coatings Company

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# Medical Devices and Chromium Coatings: A Proven Strategy for Optimal Performance

From clinical studies to real-world experience, the results are clear: Chromium coatings on medical devices help them function more effectively, last longer, and look better over the course of countless uses, cleanings, and sterilization cycles.

When medical device designers and manufacturers learn about the benefits of chromium coatings, the inevitable next question is, “Who are the providers that can apply this type of coating for us?” Or more to the point, “Who’s the best coatings provider?”

These are great questions, with one modification: The term “provider” should be changed to “partner.”

Whether a designer or manufacturer is looking to apply advanced, biocompatible, ISO-tested and certified coatings to all of its products going forward or to a single item needed by a customer ASAP, organizations want

to work with a coatings company that is as eager to see them succeed as they are—one that puts the customer’s interests first and will do whatever it can to help them and their device users get more from their products.

But how can a medical device design firm or manufacturing company find the ideal coatings partner? The key is to ask the right questions. Simply reading the description of a coatings company’s services on their website or in a brochure is not enough. It is vital that the person or people making the decision to start (or not start) a relationship with a coatings company dig deeper and truly get to know the organization that may become their partner and a critical contributor to their success.

**Ask the following 15 questions to your potential partners as you’re comparing different companies and use the space below each question to note what they have to say.**



# Qualifications and Expertise

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## 1. What processes do you use?

It's important to know not just what a coatings company does, but how they do it. A company's sales and/or technical team should be able and willing to explain in as much detail as necessary exactly how a device they are given goes from uncoated to coated.

## 2. How many different coatings do you have?

While it's the quality and not the total number of coatings that's most important, it is best to work with a coatings company that offers different options, particularly if you're looking for a long-term relationship in which you may have different needs for medical coatings.



### 3. Do you have biocompatible coatings?

Biocompatibility is crucial for medical equipment. Items that provide the needed functionality but cause negative reactions or outcomes in the human body—both in the short and long term—are essentially worthless. In fact, they can be dangerous. And statements of biocompatibility must be backed up by proof like ISO certifications.

### 4. What is your average rejection rate?

Every company that creates large quantities of finished products produces some that fall below the agreed-upon standard. Therefore, it's important to take a coatings company's rejection rate into account when evaluating them. What's a "reasonable" rejection rate to them? There is no simple answer to that question. The better way to look at that statistic is to compare one company's true and accurate rate with another's.

### 5. What is your on-time delivery rate?

Like rejection rate, a coating provider's on-time delivery rate is very important. Perfectly coated medical devices are not helpful to an organization if they arrive after they're needed. While 100% would certainly be ideal, there will certainly be exceptions and mishaps that happen along the way—especially if you're in a long-term partnership. Be sure to ask the on-time delivery rate of every coatings company you're talking to and compare those numbers to determine what's acceptable to you.



## Compliance

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### 6. Do you perform regular testing on your coatings and processes?

Achieving compliance of any kind—with customer requirements, government regulations, etc.—is notable, but maintaining that compliance through regular testing is key. Make sure you're asking not only what compliances the company has, but how long they've upheld them.

### 7. How environmentally conscious and sustainable is your company?

All medical device coatings companies deal with substances that can be harmful to the environment if not handled properly. Working with a company that has a track record of environmental excellence is a good idea for a few reasons. First, it means that a business is doing its part to encourage sustainability. And second, if the business decides to share information about its environmentally conscious coatings partner, that choice can have a positive impact on its ability to acquire new customers.

## 8. Can you share any results from OCEA inspections?

As the FDA notes on its website: "The Office of Clinical Evidence and Analysis within CDRH's Office of Product Evaluation and Quality (OPEQ) provides policy and program support regarding clinical trials, biostatistics, real-world evidence, epidemiological analysis and outreach, and collaboration with hospitals and other external stakeholders." Knowing how a potential business partner performs in this type of inspection is helpful.

## Location

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### 9. Where are you located?

When looking for a true partner, it's important that you trust you can get a hold of them in a timely manner. It's simply harder to create an established relationship when the time difference between your office and their plant is significant.

### 10. What is your lead time?

It is best to work with a coatings company that has the capacity to "flex" to accommodate varying workloads. One that cannot accommodate a manufacturer for many days or weeks (or longer) for the current project will likely have similar issues with future projects.

## 11. Do you perform all processes in-house or are some outsourced?

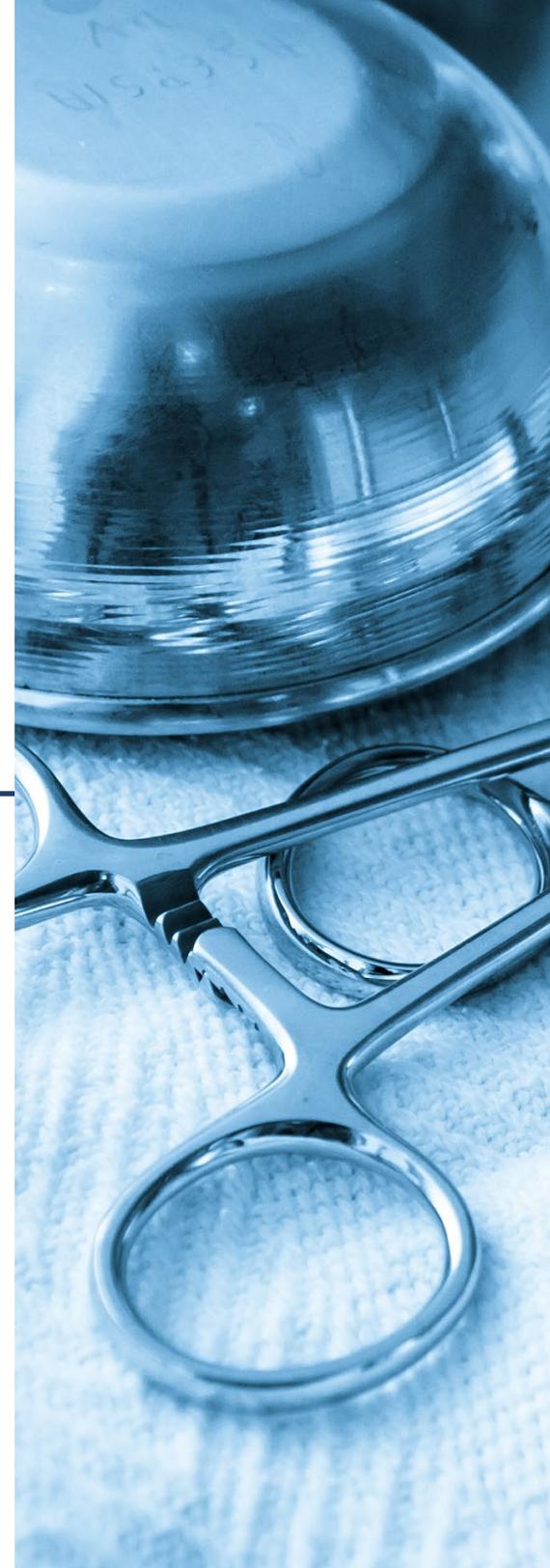
If a coatings company outsources some (or all) of its work, it is more difficult for them to ensure that finished products meet their quality standards or those of the customer, as well as ensuring accurate lead times. Additionally, if a company completes all work in-house, you're ensured that the devices and instruments you're sending to them will not leave their establishment until they're fully coated and on their way back to you. Additional shipments to an outsourced coating service simply adds more potential for something to go wrong.

## Partnership

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## 12. How did the COVID-19 pandemic affect your supply chain?

A coatings company's ability to operate and meet deadlines is directly affected by its ability to obtain the materials it needs. The pandemic strained that ability for many companies of all kinds. Ideally, a coatings partner should have made it through the pandemic without too many or especially lengthy disruptions.



### 13. How do you onboard new customers?

The proper application of chromium coatings is an exact science, so a company must have a process for introducing new customers to its team and its coating methodology so that everything about the engagement is clear and well-defined.

### 14. What types of companies/products do you prefer to work with?

If a coatings company replies to this question with something like, "Any and all!" that may be an indicator of broad experience or of a desire to develop broad experience. Getting them to elaborate on that reply is essential. The company doesn't necessarily have to be an expert in your specific area, but they should at least have significant experience in a comparable industry or with similar products.

### 15. Do you have experience developing device-specific solutions?

The key to a successful partnership with a coatings company is finding one that can develop the right approach for your specific needs rather than simply making a few minor changes to its standard process.



# Finding the Ideal Medical Device Coatings Company

Ultimately, there is no “calculus” for finding the right chromium coatings partner. There is only the right chromium coatings partner for you. But answers to the questions above can help you get a good feel for each candidate’s experience, capabilities, and business philosophy. And those characteristics should provide everything needed to make a sound decision.

ME-92 Operations is a division of the [Armoloy Corporation](#) that focuses exclusively on chromium coatings for the medical industry. The company has been a leader in the industry for nearly 30 years and is a pioneer in the area of biocompatible chromium coatings.

ME-92® coating can be integrated into design specifications and applied to medical tools, instruments, and devices as part of the manufacturing process or it can be applied to items already in use. It is highly customizable, with thicknesses ranging from 0.00004” to 0.001” per side (1.0-25.0 microns), and can be applied with precision masking where necessary to ensure the coating material only comes in contact with specified areas of a device.

In addition, ME-92 is continually recognized as an industry leader as a result of ongoing R&D efforts. Not only do results from these initiatives improve existing processes, but the research also enables the company to adapt quickly to ever-changing medical technology requirements.

ME-92 invests heavily in safe operations and earth-friendly practices. That investment has resulted in eleven consecutive years of perfect compliance with the wastewater discharge regulations of The Narragansett Bay Commission. ME-92 takes pride in that accomplishment, particularly since fewer than 5% of the organization’s industrial accounts achieve even two consecutive years of perfect compliance.

To learn more about ME-92, visit [me-92operations.com](http://me-92operations.com).

