



MANUFACTURING SUCCESS

A GUIDE TO CHOOSING YOUR MEDICAL MANUFACTURING PARTNER

WRITTEN AND COMPILED BY

 **PolarSeal**

+ TABLE OF CONTENTS

- 2 - Introduction
- 3 - Medical Manufacturing History
- 4 - The Benefits of Hiring a Robot
- 6 - How to Vet Your Manufacturer
- 7 - Local vs Global Manufacturing Partners
- 9 - The Elephant in the Room: Brexit
- 10 - Medical Manufacturing Services
- 11 - Medical Manufacturing Applications
- 13 - Medical Manufacturing Capabilities
- 15 - Manufacturing Timeline
- 16 - Onboarding CMO Checklist
- 18 - Conclusion
- 19 - Bibliography

+ INTRODUCTION

Welcome!

If you're reading this e-book, then you're probably looking for a place to start when it comes to getting a product made with a medical device and equipment manufacturer. Maybe you've come up with an incredible new concept that the public is yearning for. Maybe your old relationship with your previous contract manufacturing organisation (CMO) has fallen through. Maybe you're already working with a CMO and want to read up on whether you missed anything.

Don't worry – we've got you covered. While we aren't going to write a full book about best business practices and how manufacturing relationships should be properly conducted down to the very last detail, we did want to set out some of the more important things that you should know when you are looking to partner with a manufacturer. After all, there is a lot at stake when it comes to this relationship: it will be the foundation of your project's success or the reason for your project's failure.

We can't tell you who to choose or even prescribe which companies are best – that is going to be up to you to decide based on your needs. However, we can give you the questions to ask so that you have an easier time finding out who will be the best fit for those needs.

We hope that in the end, this book will give you a good starting point and help guide your research towards a profitable and long-lasting relationship with the CMO of your choice.

We're so glad to have you on this journey of learning. Let us show you the path towards manufacturing success.

+ MEDICAL MANUFACTURING HISTORY

Before you begin your journey to finding your perfect manufacturing partner, it can be helpful to know the collective history they all share. Medical manufacturing, as we know it today, was created in the early 1900s. While there was certainly manufacturing done for some of the more nightmarish devices of earlier eras (used for such old-timey procedures like 'bloodletting'), once the germ theory of medicine firmly took hold and the assembly line was invented by Henry Ford, the two were married, and medical innovations became quicker, easier, and cheaper to produce.

The 1930s became a landmark decade for medical manufacturing. Of all the lessons learned during the Great War, one of the most potent was that just as many, if not more, soldiers were killed by disease, malnutrition, and infection as were killed by the bullets, shells, and barbed wire. The aftermath of the war was even worse as the final stages of the conflict allowed for the perfect breeding ground for the era-defining pandemic: the Spanish Flu. As a result of the health failures a generation before, the ramp-up to the Second World War was done without taking chances: the Allied nations would not neglect their soldiers and would instead provide them with as much medical support as possible. Medical manufacturing was thus given national significance in both Britain and America.

After the war, an economic boom paved the way for a variety of off-shoots, novel innovations, and new opportunities springing out of the wartime scientific progress. In the middle of the 20th century, manufacturers were realising the vast potential that modern technology could have on the population. If such scientific progress could be harnessed for war, energy, and transportation, why couldn't it be used to help save lives?

The iconic example of personal medical devices in this era was the artificial cardiac pacemaker. Though it was theorised and designed as early as the



1880s, it was only in the relatively technologically sophisticated 1950s that the idea of a personal, implantable pacemaker became a reality. The first external pacemaker was developed in 1950 at the University of Toronto and the first successful internal pacemaker was implanted in a Swedish patient in 1958.

Medical devices were becoming not only novel, but a necessity around the globe – competition was breeding efficiency, and the rise of automation and nanotechnology further enhanced what technology was able to accomplish for the human body. The medical manufacturing community was constantly striving for new ideas, higher quality, and more volume – these people were not simply in the manufacturing game as capitalists out for the bottom line. They were men and women who truly believed in their products: medically-minded manufacturers constantly striving for the next discovery.

In short, a lot has developed since the early incarnations of medical manufacturing. We have precise technology to manufacture devices from the mundane to the spectacular. We have machines adept at anything from slitting to die-cutting to pouching. Medical manufacturing companies now focus on offering a vast array of products – from the simplest wound care equipment to advanced wearable medical technology. Not only that, the end-to-end management of their products – from sourcing materials right down to delivery logistics – has become a hallmark.

While the technology is more advanced, the devices more precise, and the process more refined, the heart of medical device manufacturing remains the same: there is still a true desire to do good, strive for a healthier world, and make products that can truly help the public. More than ever, health is more important to regular people. As it has been since the 1930s, medical and wound care technology is continuously developing and innovating to meet demand.



+ THE BENEFITS OF EMPLOYING A ROBOT



Now that you know about the past, where is medical manufacturing now? What does the future look like?

For that context, ask yourself what the perfect employee looks like – specifically from the perspective of an employer. They'd be punctual, have very few complaints, do their job speedily and efficiently, is reliable at their workplace, can take on new jobs with ease, and dedicates 100% of their energy to their job when they are in their workspace. Sounds pretty good, right?

And what if this employee also never took a sick day? What if they didn't need to have a salary? What if they never took lunch or bathroom breaks? What if they could process information hundreds of times faster than a regular human being? What if they didn't even need oxygen?

You've just stumbled into the realm of robotics.

[Back to top](#)

If there is anything that we have come to understand about medical devices and equipment, it is that precision may be the single most important aspect of their production. Yes, sometimes these devices are little more than a tongue depressor, but oftentimes, with these devices, you are holding a person's life in the balance.

This is where the precision of robotics or automation really comes to the forefront. Human beings are fantastic innovators, excellent workers, and inherently wonderful creatures. However, when you are dealing with devices that require superhuman levels of precision and are sometimes working on the microscopic level, an automated robotic system is sure to come in handy. Humans are always going to be needed to program the machines, ensure optimal functioning, and extrapolate the data derived from them, but when it comes to the actual manufacturing, there is no question that automation is the perfect solution.



In the 21st century, automation has come a long way from the assembly line. Robotic automation these days can incorporate a whole host of solutions, from the initial design through to manufacturing and even into the realm of distribution. Along with adaptability, automation processes ensure speed, accuracy, effectiveness, and programmability: products are created and manufactured at a high volume with exacting detail and reliable consistency in your product. For example, using automation, one can program the exact ratio of adhesive to coat the outside film of a product rather than relying on someone to 'eyeball' exactly how much goes on each device. Each device can be relied upon to have exactly the same specifications, every single time.

Robotic automation also functions at a high speed. While humans are excellent at processing and making quick decisions, asking them to perfectly process medical devices within milliseconds is literally impossible. Robots have no such qualms: program the process you want the machine to undertake, and it will quickly and efficiently get on with it, allowing a high volume of product to be produced much faster than a manual production line.

While some think that paying for an expensive automated machine will lock them into singular processes, it is actually quite the opposite. High-quality robotic machines designed for medical device manufacturing are known for their adaptability. Changing the processes and the output is as simple as giving an employee a new assignment.

The benefits of automation are obvious and the further we go in embracing this new robotic technology, strangely, the more human we can become. With less time spent on the minutiae of cutting and pouching and any other manual task on the production line, we find ourselves with more time to innovate solutions for medical problems that are affecting the population. And isn't that what a medical device producer is supposed to do?

+ HOW TO VET YOUR MANUFACTURER



So up to this point, you've got a basic understanding of the history of medical devices and you have some knowledge of the current industry trends – but if you're looking to manufacture a new device, do you know what to ask?

“Do you... uh... manufacture medical devices?”

We think you may need to be a little more specific than that. To get a more thorough understanding of the medical device manufacturing landscape and having a head-start when it comes to choosing who you'd like to work with to get your product created and distributed, you're going to need to ask some pointed questions.

If you're going into business with someone, you're going to want to know that you can get along with them. You're also going to want to know that they're competent, trustworthy, and qualified. While this general understanding is easy enough to have, what specifically should you look for in a manufacturing partner?



Qualification

These are medical devices that have direct contact and a major influence on the wearer's health and wellbeing. Like any provider of medical supplies from devices to services to medication, there are going to be some understandably detailed legal and ethical guidelines that a manufacturer must follow. Having an ISO 13485 qualification and being registered with the Food and Drug Administration is a must, as well as having registered production sites and staff with the proper education and qualifications. When vetting a potential partner, simply asking for proof of these qualifications should be enough, but they can also be acquired through a remote audit or a supplier questionnaire.



Production Environment

Products must be sterile and up to rigid specifications, and that means that the place where they are produced must also meet a high standard of cleanliness. Asking the following about the production facilities should give you some important information about your partner: do their sites focus entirely on medical manufacturing? What are their procedures in cleanroom operations? How do they handle raw materials? How often do they do inspections on the status of their facilities? What kind of protective gear do workers wear in the cleanrooms? Stringent protocols for a sanitary production environment are standard operating procedure for these places – so they should have lots of information for you.



Process

What exactly does your manufacturer do themselves? This question, as opposed to the other ones above, may be a little less common. While some producers only focus on the assembly of the device and prefer to outsource elements like sourcing (the irony...) or distribution, more trustworthy companies offer a complete process – following the product from conception all the way to delivery to the client. That way there is total control over the process from start to finish, eliminating the potential for costly errors down the line.



Risk

Assessing the risk of a potential partner isn't unique to the medical industry – it's just common sense. If you're about to rely on this company to make your product, you should know the potential pitfalls of doing business with them – do they have a plan B, C, or D should things go awry? How did their company handle the COVID-19 pandemic and the economic fallout? Are there additional production sites? Do they have a cohesive business plan? Drawing up a risk assessment questionnaire will be helpful in getting these answers.

The above questions may seem intrusive, but your future product shouldn't be manufactured in half-measures. Finding the right partner to help you on this journey is one of the most important steps you can take, and knowing what to ask is the best way to start.

+ LOCAL VS GLOBAL MANUFACTURING PARTNERS

Those four qualities listed above are rather obvious qualities that should be apparent about any potential CMO. Asking where your manufacturer is located could easily fit into the above section, but we thought that this topic was important enough to have its own section. The debate continues to rage in production and manufacturing circles over whether a local partner or a global partner is better for your business, with each side unsurprisingly championing whatever their designation happens to be. Really, what is best is usually apparent given the context of your desires and business plans.



Local Partners

Local partners are often tempting as they have some obvious benefits that will appeal to innate human nature – they're closer to you, and the people who work at these companies will often look like you, speak the same language, have the same opinions, and like the same sports teams. In short, these companies are familiar, and working with one of them can be very satisfying, particularly if you want a quick turn-around and communication in the same time-zone. Depending on where you live, there are also probably some government incentives to a same-country partnership.

However, a friendly relationship at the beginning will quickly turn sour if you overlooked productivity and efficiency in the name of patriotic job creation. While there is generally better communication, more effective logistics, and streamlined management with local partners, you must weigh these benefits with a comparatively smaller market. If you have modest local or national goals for your medical products, then local may well work for you. However, if you have any aspirations of taking your products internationally, then choosing a local partner might be limited by their connections to global networks.

Global Partners

Probably the most positive aspect of global partners is their efficiency. These companies cannot become successful in international manufacturing without creating and refining systems to make sure that they can be productive, efficient, and profitable. Partnering with a global manufacturer will often also mean that you are getting more of an 'all-in-one' package: many global companies have their own supply chains and will monitor the entire production of your product – from material sourcing to distribution logistics. This often turns out to be cost-effective and much less of a hassle than having to deal with a dozen companies, each one in charge of a different aspect of production. The global partner also opens up a wider market for your product and can better handle large-scale projects.

However, it must be noted that if you put your project in the hands of a global company with pre-established systems and entrenched networks, you are going to be ceding a whole lot of control over to them. Don't necessarily like the quality of adhesive going onto your product? Too bad – they've worked with this adhesive for years and that's what they will use.

There is also the potentially negative aspect of being lost in the 'bigness' of it all – can you count on a multi-national manufacturer to give your product the care and attention it deserves? A local producer might have a bit more of a 'boutique' feel to it – being able to focus on a dozen projects with great care rather than having to compete for attention with hundreds (if not thousands) of others when you're with a global partner.

So ask yourself: are you going to market locally or internationally? How big is your project? Do you want to be hands-on or leave it in the partner's hands? In short, your first decision is to figure out exactly what you want from your product before narrowing down what kind of manufacturing partner you would prefer to have.





+ THE ELEPHANT IN THE ROOM: BREXIT

Okay – so the difference between choosing a local or an international partnership may be a little more difficult now than it used to be due to the United Kingdom’s withdrawal from the European Union. With the older UK/ EU relationship, we might expect some more freedom to contract between companies based in the UK and on the Continent, but Brexit makes things a little more difficult. Costs of doing business with the UK are skyrocketing and contracting with a global partner may have you keeping your distance.

Well, all hope is not lost. There is one very helpful boon that can help you with your perceived manufacturing woes in the face of Brexit: a unified logistics and distribution network. Some global companies will network with dozens of different companies, each dedicated to their own goals outside of the manufacturer. While traditional thought is that manufacturers should simply stick to the production aspects and leave the logistical stuff to dedicated third-party companies, the more forward-thinking CMOs have embraced an all-in-one mentality: keeping a firm grasp on everything involved from early development to delivery of the final product.

Finding a global partner who has a hand in everything can consolidate all your costs in one place rather than having to spread yourself thin and racking up costs and tariffs from dozens of different companies, each involved in one aspect of production or another. Choosing a CMO with consolidated and reliable networks is the right move, and investing with the right people is one of the most important ways to actually deal with Brexit.

Communication is, again, an important consideration to your Brexit reaction. If you are already in a partnership or are considering a partnership with a CMO, ask them what their reaction to Brexit was on practical terms. What did they do? How did it change their business? Did they drop clients? Did they focus on different clients? Knowing what to expect or what has already happened with your partner is just as important as knowing how Brexit is impacting you.

Doing your homework and knowing what you can expect is another important preparation. There’s a reason that talks between the UK and the EU had been going on for years – there’s so much to discuss! Each import and export has now been given a new process that it must follow, and your product (as well as your partnership with your CMO) is no exception. Make sure you are up to date on any new processes, information, and financial expectations and make a plan for them. For instance, if you know that a product is going to get a more thorough inspection upon delivery to the UK, factor that into any logistical plans you already have and inform your clients of new timelines.

The UK can’t survive without contributions in terms of products, resources, and manpower from the EU – 50% of their imports will tell you how much they need a strong relationship with the EU despite their break-up. You shouldn’t avoid doing business in the UK, but you should rather be smart about how you do it – make sure you know what to expect and choose a partner whose supply lines won’t bog you down in delays, tariffs, and problems.

+ MEDICAL MANUFACTURING SERVICES

Now it's time to get down to the nitty gritty— what can your potential CMO actually do for you in a practical sense? You've heard their company aims, you know where they're based, and you know that they are at the very least capable of manufacturing medical devices. But what services can you expect your manufacturer to provide? While some manufacturers will only provide one or two of these, more successful and well-rounded companies will often provide all of them. Again, if you want to ask about these services when vetting companies to partner with, their answers will steer you away from less competent ones and towards a company you can truly trust.



Cleanroom Manufacturing

This may not need to have been stated – to expect cleanroom manufacturing from a medical manufacturing company is like expecting a baker to make bread. If it's not there, there's obviously something wrong. However, cleanroom manufacturing is no simple service. If you're creating and producing a medical device, a precisely maintained and operational cleanroom is going to be integral to not just producing the device, but ensuring a sterile and environmentally-controlled area in which it is made. We typically expect a good CMO to maintain a couple of cleanrooms per ISO 14644:2015.



R&D/Prototyping

You've got a concept, but you're unsure of how to build it precisely. That's where the R&D department

comes in. Companies will maintain entire divisions of their organisations dedicated solely to the groundwork of the product. Not only this, but these manufacturers are constantly using these wings to conceptualise, innovate, and test out new products and novel ideas. Manufacturing organizations would not go far without their own team dedicated to exploring new systems to reduce cost or wasted time. Does the company you're working with have a prototyping department?



Product Development

Your device will go nowhere fast if one hand is not communicating with the other – which is why many successful manufacturers maintain product development in-house. They make sure that your product is managed entirely through a singular guiding team of experts. Project management is a service designed to make sure there is optimal communication and cohesion. Ask your CMO if they manage your project from start to finish.



Material Selection

Especially with medical devices, material selection is the most important part of the process. Sub-optimal materials will ensure poor performance and failure, so companies will offer services and maintain teams dedicated to sourcing and selecting the best materials for the parameters of your project. Does your CMO have the necessary experience to identify the best materials for a specific project?

[Back to top](#)



Medical Adhesives

In a similar vein, medical adhesives must be selected with the utmost of care and experience – particularly with medical equipment and devices that are intended to stick to the skin. How much breathability must be present with the device? Will it need a powerful adhesive to compensate for a heavier frame?



Product Certifications

Another important quality to look for in your CMO is whether they actually have the capacity to certify your medical device when it is produced. As we all know, medical manufacturing is stringent and beholden to strict legal requirements. Does your CMO partner have the capability to legally CE mark your product?



Outsourced Operations

How often does your CMO outsource their own operations? Many successful companies know that they have highly skilled workers and quality production facilities – allowing them to be outsourced to other companies looking to make use of their expertise.



Quality

While this is one of the more nebulous of the above services – it should probably be at the forefront of your mind. Notwithstanding the other services that the CMO offers, how are their products? How reliable are they? What is their longevity? What is their reputation? These are the kinds of questions about the quality of their products and services that you should always keep in mind.

+ MEDICAL MANUFACTURER APPLICATIONS

The obvious next step once you understand your medical manufacturer's services is to figure out how to make the best use of those services. How can these services be applied? What capabilities do these services enable? How can you practically capitalise on your medical manufacturer's capabilities?

To give you a potent example of applications, let's take a look at what kind of applications a successful and capable medical manufacturer would offer.



Wound Care

Everything from the humblest bandage to surgical-grade anti-microbial wound dressings – this is pretty much a staple for any medical manufacturer. Wound care is a cornerstone

of the medical manufacturing industry as any product used in wound care needs to be both sterile and plentiful. However, as you know, simply creating a wound dressing takes more than gauze and tape – which is why applying services to designing, prototyping, and testing different materials is essential to producing an excellent product.



Fixation Devices

The human body can be notoriously difficult... which is why you're reading this book. Sometimes, it needs a little help with bringing things in and taking things out – everything from catheters to oxygen lines to endotracheal tubulation is a 'fixation device'. Making certain that fixation devices are perfectly created is critical as they represent the bridge between the inner body and the outer world.



Electro-Medical Devices

As technology evolves, electrical equipment and the human body are becoming more and more used to each other. These kinds of devices are often used in monitoring equipment like brain electrodes or skin patches with small electronic components to measure heart-rate, breathing, temperature, or pulse-oximetry. These kinds of devices benefit from R&D and prototyping and will potentially result in a longer 'engagement' period before it is produced in mass quantities.



Continence & Ostomy Components

Ostomy bags and components are going through a bit of a social revolution with more awareness being brought to what was traditionally seen as a shameful part of a person's health. This awareness is also in line with the growth in the ostomy industry, with a growing global market of around USD 2.8 billion. Like fixation devices, these devices are bridges between the inner and outer, with these devices in particular requiring long-term durability.



Surgical Films

Few components are more critical than those that are used when performing actual surgery, so surgical films, like incision films, fixation tapes, and bordering tapes are keys to minimising the chance of infections. Having a cleanroom up to standard will be massively important to make sure that everything is antibacterial and skin-friendly.



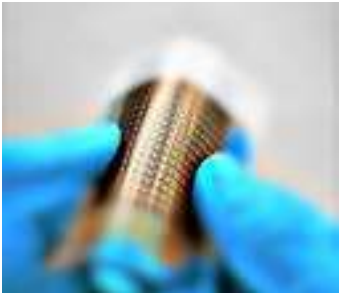
Diagnostic Products

These kinds of devices are membranous strips to be used in testing for various conditions, ailments, and infections. These are often produced in mass quantities as they are widely disseminated and used daily.



Consumer Healthcare

These kinds of medical devices are the drug store/chemist variety – things you can find on the rack of your local pharmacist. However, just because these blister plasters, cosmetic patches, or simple bandages are used for popular consumption, as opposed to being used in critical life-saving procedures, doesn't mean that your medical manufacturer will cut corners.



Wearable Technology

When most people think of 'medical devices', their minds will probably go to wearable technology. Things like pacemakers, diabetes monitors, and biosensors. These will usually have an emphasis on how to balance weight with breathable adhesives or fabrics that stick to the skin.



Personal Protective Equipment

In this era, even a specialising medical manufacturer has probably reserved some portion of their manpower and equipment to produce PPE. The demand from pretty much the entire global population for more plentiful and higher-quality PPE has informed the supply that most medical manufacturers are outputting right now.



Liquids

Finally, there is likely an entire chunk of your medical manufacturer that is dedicated to wet products – things like gels, pastes, creams, saline, and other liquid products to be used in medical procedures.

+ MEDICAL MANUFACTURER CAPABILITIES

The smaller jobs are as important as the big ones – just because your manufacturer can direct a project or lay out an impressive set of services and applications, doesn't mean it can properly complete the smaller details. Your manufacturing partner should be capable in equal measures to conceive and manage a project from start to finish, as well as complete any other smaller capacity jobs that are required.

This is where you might look for what your medical manufacturer is capable of – how far do their services stretch? What practical finishing touches can you expect? Can they fulfil the final 'end' of their so-called 'end-to-end project management'?



Material Slitting

Your project won't go very far if your manufacturer can't accomplish the simple act of slitting materials to measure. Especially with medical manufacturing, there is an understanding that the technology must be advanced enough to be able to handle both

adhesive and non-adhesive materials at varying degrees of thickness and toughness. If you're feeling very fancy when vetting your potential CMO, ask if they have 'lathe slitting equipment' – being specific to your project of course.



Cutting

That's right – slitting and cutting are different actions in the medical manufacturing community, despite what your thesaurus may tell you. 'Slitting' is the term we use for making an incision in a material and 'cutting' is the actual cutting out of a portion of the material (this is referred to as 'die cutting'). Your CMO should offer multiple forms (flat-bed, rotary, large format, etc.) of die-cutting as well as having the option of programming the automated cutting equipment to exact specifications for cutting through the low-resistance material to be used in your product.



Guillotining

Guillotining is a specific process in medical manufacturing that combines cutting and laminating large sheets of material at the same time and is used to combine adhesive materials with non-adhesive materials on a large-scale.



Tube Filling

Having wet medical products like gels, creams, or ointments is going to be no good if your manufacturer doesn't have automated tube-filling capacity. This kind of capacity should be quite open and have the capability of not simply filling tubes, but any kind of receptacle that the material can be stored in – jars, pouches, vials, bottles, etc.



Printing

Printing can't be that complex of a process, right? Well, with medical manufacturing, nothing is quite so simple. Effective printing explains to the client how to use your product, and most medical devices have stringent legal guidelines on what information/specifications must be printed on the product. Due to the nature of the product (being used on or around the human body) it is also important for the ink to be durable and resist rubbing off or fading.



Lamination

The lamination process is potentially the most integral part of medical manufacturing – it's the combining of adhesive materials to non-adhesives. This process must be precise due to the importance of adhesion, breathability, and water-resistance. It also helps if your CMO has multi-zone lamination, allowing for lamination of other materials to better enhance your product.



Packing

Your manufacturer can have all the impressive logistics and global distribution networks they want, but if they can't package your device properly, there's really no point. Since science hasn't figured out teleportation (yet), we're still having to send our products on gruelling journeys across physical space, so keeping the integrity of the product intact is important. You wouldn't drive your car without a seatbelt, so why would your manufacturer skimp on pouch packaging or proper water-resistant sealing?

+ MEDICAL MANUFACTURING TIMELINE



If you're reading this next section, then you've asked all of the pertinent questions, you've done a thorough examination of your business, and done an in-depth analysis of your potential vendor's services, applications, and capabilities.

You've chosen your CMO and you're ready to get the ball rolling on your product! Congratulations!

You've made the big decision – what does life look like now?

Well, it's safe to say that you won't see a prototype by next week. From the time you put pen to paper and do the literal (or virtual) handshaking with your new CMO partner, the initiation of manufacturing could be between 12 to 18 months. While this may seem like a long time, this shouldn't surprise any of the old hands when it comes to manufacturing medical equipment and devices. The fact of the matter is that we're in the healthcare industry, and taking shortcuts with manufacturing products that peoples' lives depend on is just not done. Cutting corners in this initial phase could lead to mistakes, a failure to meet industry standards, lawsuits, and (if a subpar product is manufactured) injury, ill-health, or death on the part of the people using your product. We are not using hyperbole here. This is the reality of this industry.

The first year of a CMO relationship is probably the most important in your partnership. While this time won't necessarily be typified by the mass output of products, it will be where you lay the groundwork for that future vast production you are envisioning.



You and your CMO partner are going to be in constant communication at this time, sharing ideas, specifications, and designs. This is where you will ultimately develop your product from a great concept to a fully-functioning physical device. You'll use this time to develop the product into the best possible incarnation – using both the physical and mental resources of your new partner to fine-tune and develop prototypes.

It may be helpful to think of this time like you are planning a wedding. You and your CMO have just become engaged, and are now looking through bridal catalogues and going to cake-tastings. Except instead of catalogues, you're looking through specifications and drafts. Instead of cake-tastings, you're sampling materials and adhesives. Your wedding day is, essentially, the first day your product gets manufactured. You want to make sure that every single thing is perfect and ready by the time that day rolls around. If you are reading this and have been through planning a wedding, you know the perfection comparison is apt.

And like a good marriage/relationship, communication is always the most important key to success. Neither you nor your CMO can achieve success without the other, so to keep the planning stages as painless as possible, the goal should be to communicate often, openly, and efficiently. Tell them what you want, what your requirements are, how you communicate, and how they must work with you to make sure you are both efficient. Efficient communication is estimated to boost productivity and profitability by up to 10%.

It's okay to be excited to get the ball rolling, but you don't want to rush your product out the door in the same way that you wouldn't want a shotgun wedding: neither is going to be good and both look suspicious. Take your time, develop your product, and make sure that you've got everything just right.

+ ONBOARDING CMO CHECKLIST

That was a lot of information. The above pages have given you a comprehensive guide on what to look for in your CMO: the skills, services, applications, and capabilities you now know to ask for. This checklist is here as a guide to make sure you use this new information to your full advantage. Here's how to take your project from just an idea to a tangible reality:

Research

Think about your concept for a product and what you want from a CMO. Will it be better to go local or do you want a global manufacturer? Do you want a CMO that specialises in a niche or do you want a provider with all-around capabilities? Once you've answered the basics, look up multiple potential vendors who will fit best with your project.

Relationship

Reach out to each of your potential vendors and let them know what you're looking for. In your opening discussions with them, keep an eye out for compatibility. How is the relationship? Are you getting along? Are you able to communicate effectively? Are you able to work together? Never be afraid to rely on your gut instincts here – if a company has a lot of plaudits but you aren't getting along with them, your project is going to suffer.

Assessment

Have your potential vendors explain their services, applications, and capabilities and assess which of them is best equipped to take on your project. Asking for this information to help you in your assessment is also important in seeing whether they can communicate effectively with you or not.

Project Deep-Dive

Give your potential vendors an overview of your project and ask what you can expect from them. How long do they estimate this will take? Do they lack the capabilities for any of the facets of the project? Do they expect any high or low-risk steps along the way?

Facilities Tour

device will be manufactured. What do the production lines look like? How effective is the workflow? This also opens the door to ask questions about their facilities.

Pricing

Probably the part of onboarding that everyone looks forward to least: how much is this going to cost you? Remember that this isn't just the cost of production, but also further possible costs if it is likely to be a long-term relationship like annual increases or inflation rates.

Supplier Collaboration

Find the suppliers? Are they adamant about using their own suppliers or are they open to using a suggestion?

Sampling

Every CMO worth their salt will have products that they have already made or are currently manufacturing. Ask for samples to see how these potential CMOs treat their products. Are they of high quality? Do they have obvious issues? Have they produced something along the same lines as your project before?

Contract Award

This is the step where all your question-asking will come to fruition: making the actual choice. The above steps should help you choose the best CMO for your project. Once you have awarded the contract, you can begin the process of making your project a reality.

Product Validation

Because it is important for medical devices to be certified by the proper regulating authorities, it is important that this is an early step after you have awarded your contract.

Product Manufacture

Now you can fully open the floodgates and manufacture your medical device. Make sure that you are still communicating often with your CMO to make sure you understand what is happening, when you can expect deliveries, and any updates along the way.

+ CONCLUSION

And there you have it – your very own guide for how to start your journey in selecting a partner within the medical device manufacturing industry. As mentioned, choosing the right partner is the most important thing, but it is always important to remember that there is no one-size-fits-all rule in this industry. Medical devices are technologies that stand between the wearer/ user and pain, illness, and potential death. More than any other kind of manufactured product, our industry deals in precise measurements, high stakes, and important work. Don't let laziness or disinterest get in the way of making a product that can truly help people – use the information in this e-book and base your research around it. You can't afford not to.

But we know that we are preaching to the proverbial choir – the fact that you're reading this final page means that you have taken the initiative and you want to do this right, so good on you for that!

You've read the book, but now comes the actual work and the tough decisions. We wish you the best of luck going forward and we cannot wait to see how the world reacts to your new product.



+ BIBLIOGRAPHY

Medical Manufacturing History

- Collections Canada. 2020. John Alexander Hopps - Library and Archives Canada. [online] Available at: <https://web.archive.org/web/20200728125042/https://collectionscanada.gc.ca/pam_archives/index.php?fuseaction=genitem.displayItem&lang=eng&rec_nbr=104318&rec_nbr_list=104318,3588818,815761,4385271,4385234,438526,4385302,4385311,4385420,4385246> [Accessed 25 February 2021].
- Editors of Encyclopedia Britannica. 2020. History of medicine - Verification of the germ theory. [online] Available at: <<https://www.britannica.com/science/history-of-medicine/Verification-of-the-germ-theory>> [Accessed 25 February 2021].
- Editors of History.com. 2009. Ford's assembly line starts rolling. [online] Available at: <<https://www.history.com/this-day-in-history/fords-assembly-line-starts-rolling>> [Accessed 25 February 2021].
- Kamps, B. and Preiser, W., 2009. Influenza Book | Overview. [online] Influenzareport.com. Available at: <<http://www.influenzareport.com/ir/overview.htm>> [Accessed 25 February 2021].
- Market, W., 2021. Wound Care Market - Forecast to 2024 | Growing at a CAGR of 4.6% | MarketsandMarkets. [online] Marketsandmarkets.com. Available at: <<https://www.marketsandmarkets.com/Market-Reports/wound-care-market-371.html?gclid=EAlaIqobCh>

Mly5n799vh7glVloFQBh1YaAjHEAAYAiAAEgL1VvD_BwE> [Accessed 25 February 2021].

- Plummer, D., 2006. Pacemakers: where is the block?. [online] GM Journal. Available at: <https://web.archive.org/web/20140716164021/http://www.gmjournals.co.uk/uploadedfiles/redbox/pavilion_content/our_content/social_care_and_health/gm_archive/2006/july/jul06p57.pdf> [Accessed 25 February 2021].
- PolarSeal. 2021. Our Medical Device Manufacture Capabilities | PolarSeal. [online] Available at: <<https://www.polarseal.net/capabilities/>> [Accessed 25 February 2021].
- Taliaferro, W., 1972. Medicine and the war. Freeport, N.Y: Bks. for Libs.

The Benefits of Hiring a Robot

- Crotti, N., 2019. How automation can boost medical device success | Medical Design and Outsourcing. [online] Medical Design and Outsourcing. Available at: <<https://www.medicaldesignandoutsourcing.com/how-automation-can-boost-medical-device-success/>> [Accessed 25 February 2021].
- Medical Device Online. 2021. Automated Manufacturing Services for Medical Devices. [online] Available at: <<https://www.meddeviceonline.com/doc/automated-manufacturing-services-for-medical-devices-0001>> [Accessed 25 February 2021].
- NuTec. 2021. Benefits of Automating Medical Device Manufacturing. [online] Available at: <<https://>

cdn2.hubspot.net/hubfs/3267768/DESIGN-BUILD/Medical/Medical_Device_Automation_Solutions-NuTec.pdf> [Accessed 25 February 2021].

- PolarSeal. 2021. Surgical Films | PolarSeal. [online] Available at: <<https://www.polarseal.net/applications/surgical-films/>> [Accessed 25 February 2021].
- Rockwell Automation. 2021. Medical Device Manufacturing. [online] Available at: <<https://www.rockwellautomation.com/en-za/industries/life-sciences/medical-device-manufacturing.html>> [Accessed 25 February 2021].

How to Vet Your Medical Manufacturer

- PolarSeal. 2021. Choosing a Wound Care Manufacturer | PolarSeal. [online] Available at: <<https://www.polarseal.net/choosing-a-wound-care-manufacturer/>> [Accessed 26 February 2021].

Local vs Global Manufacturers

- Chan, M., 2019. The Pros and Cons: International and Domestic Sourcing. [online] Unleashed Software. Available at: <<https://www.unleashedsoftware.com/blog/pros-cons-international-domestic-sourcing>> [Accessed 26 February 2021].
- Mets, R., 2019. Should I use an International or a Local Supplier? | MetaFuro. [online] MetaFuro. Available at: <<https://www.metafuro.com/resources/sourcing/international-or-local-supplier/>> [Accessed 26 February 2021].

● PolarSeal. 2021. Innovative Healthcare Services – Medical Solutions | PolarSeal. [online] Available at: < <https://www.polarseal.net/services/>> [Accessed 26 February 2021].

● Resnick, N., 2017. Domestic vs Foreign Manufacturing: How and Where to Manufacture a Product?. [online] X Cart. Available at: < <https://www.x-cart.com/blog/produced-locally-vs-produced-overseas.html>> [Accessed 26 February 2021].

● PolarSeal. 2021. The Simple Solution to Keep Shipping Costs Down. [online] PolarSeal. Available at: < <https://www.polarseal.net/the-simple-solution-to-keep-shipping-costs-down/>> [Accessed 26 February 2021].

● The UK in a Changing Europe. 2020. Manufacturing and Brexit. [online] Available at: < <https://ukandeu.ac.uk/wp-content/uploads/2020/06/Manufacturing-and-Brexit.pdf>> [Accessed 26 February 2021].

● Wattanajantra, A., 2020. What manufacturers need to do after the Brexit transition period. [online] Sage. Available at: < <https://www.sage.com/en-gb/blog/how-will-brexit-affect-manufacturing/>> [Accessed 26 February 2021].

Medical Manufacturing Services

● PolarSeal. 2021. Innovative Healthcare Services – Medical Solutions | PolarSeal. [online] Available at: < <https://www.polarseal.net/services/>> [Accessed 27 February 2021].

Medical Manufacturing Applications

● Market, W., 2021. Ostomy Care Market - Forecast to 2025 | Growing at a CAGR of 4.4% | MarketsandMarkets. [online] Marketsandmarkets.com. Available at: < <https://www.marketsandmarkets.com/Market-Reports/ostomy-care-accessories-market-267183143.html>> [Accessed 1 March 2021].

● PolarSeal. 2021. Medical Applications for the Medical Industry | PolarSeal. [online] Available at: < <https://www.polarseal.net/applications/>> [Accessed 1 March 2021].

Medical Manufacturing Capabilities

● Blue Label Packaging. 2021. Die Cut Process & Considerations. [online] Available at: < <https://www.bluelabelpackaging.com/blog/die-cut-mean/>> [Accessed 2 March 2021].

● PolarSeal. 2021. Our Medical Device Manufacture Capabilities| PolarSeal. [online] Available at: < <https://www.polarseal.net/capabilities/>> [Accessed 2 March 2021].

● Qimtek. 2021. Guillotine. [online] Available at: < <https://www.qimtek.co.uk/process/guillotine>> [Accessed 2 March 2021].

Medical Manufacturing Timeline

● Davis, C., 2019. Tips to Having a Successful Relationship with your Contract Manufacturer.

[online] Ordermatic. Available at: < <https://ordermatic.com/tips-to-having-a-successful-relationship-with-your-contract-manufacturer/>> [Accessed 26 February 2021].

● Mantec. 2019. The Importance of Communication in Manufacturing Companies. [online] Available at: < <https://mantec.org/communication-manufacturing/>> [Accessed 26 February 2021].

● Simpson, D., 2012. Exploring the Contract Manufacturing Timeline. [online] Natural Products Insider. Available at: < <https://www.naturalproductsinsider.com/manufacturing/exploring-contract-manufacturing-timeline>> [Accessed 26 February 2021].

● Valazza, M. and Wada, G., 2001. Creating a Successful Partnership with a Contract Manufacturer. [online] Outsourcing Resources. Available at: < http://alfresco-static-files.s3.amazonaws.com/alfresco_images/pharma/2014/08/22/4c57d7e5-7373-4288-b7ba-ffe66a4f2354/article-5151.pdf> [Accessed 26 February 2021].

Onboarding CMO Checklist

● PolarSeal. 2021. Product Certification – Medical Products | PolarSeal. [online] Available at: < <https://www.polarseal.net/product-certification/>> [Accessed 3 March 2021].

www.polarseal.net