THE COMPLETE GUIDE TO MEDICAL DEVICE STAMPED COMPONENTS

Clamason Industries

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Welcome to Clamason Industries' complete guide to medical device stamped components.

Demand for complex devices aimed at treatment and harm reduction has soared over the course of the last twenty years.

During this period Clamason have emerged as a market leader in the manufacture of high volume and high precision parts alike.

Vast experience, combined with unrivalled capability and reliability, have placed the company at the forefront of a sector that is positively booming.

Our full-service solution is one widely revered and undertaken in accordance with ISO 13485 accreditation. It has enabled countess pharmaceutical companies to bring products to market quickly, without ever compromising on quality.

In this document, we'll break down the process that has served them (and us) so well. We'll explore the key considerations and common challenges in developing products where there is simply no margin for error.

We'll walk you through all notable milestones, starting from an initial concept through to industrialisation.

You'll also discover the benefits of partnering with suppliers that can offer speed and accuracy in equal measure.

Throughout the course of this document, we'll answer the following questions:

- What is medical validation and how many steps does this entail?
- What is technical cleaning and why do international clean room standards matter?
- What is the difference between automated and manual packing of medical products?

The stamping of medical device components is as involved as it is invaluable. Truly understanding the process is essential if you are to fulfil ambitions and steer clear of product recalls, along with the reputational damage that accompanies them.

IT ALL STARTS WITH AN IDEA...

We'll walk you through all notable milestones, starting from an initial concept through to industrialisation.

You'll also discover the benefits of partnering with suppliers that can offer speed and accuracy in equal measure.

CONCEPT

Those looking to partner with medical device tooling experts such as Clamason Industries tend to approach potential suppliers with an initial concept.

This has often been formalised following a series of internal ideation sessions, wherein product ideas have been bounded about and duly consolidated.

The best concepts are those which identify a gap in the market. Those aimed at the medical sector nearly always set out to solve a pain point for patients and/or clinicians.

This is harder than you might think and explains why a growing number of stamping projects set out to improve on an existing idea, as opposed to developing a new one.

Indeed, countless devices now seek to do things better, faster and with greater accuracy than those that have come before them.

Whether yours is an original or re-imagined concept, it serves to define its USP.

Likewise, it makes sense to gauge whether there is enough differentiation to facilitate demand. This is ordinarily established in the wake of market analysis and competitor research. Risk analysis is similarly insightful...

While leading pharmaceutical companies will doubtlessly canvass the opinion of in-house professionals it's equally important to survey the target audience, be they care givers or patients. Theirs are the opinions that matter.

Before researching possible manufacturers, it is also advisable to familiarise yourself with any regulatory guidelines that will have to be adhered to. These are restrictive for good reason and can very quickly render a concept meaningless. Be sure to factor in clinical trials in any planning also.

Once all of the above is locked down it's a case of researching possible manufacturing partners, ideally those with a proven track record in medical device tooling given its complexities.

Once that relationship is established, you will invite them to review your concept.

This is the exact process followed for some of our most successful medical devices, including auto injectors and dry power inhalers.

Lead times vary and can extend into a second year. This first exploratory phase however is well worth the time and effort, laying the foundation for the entire project.

DESIGN PROPOSAL

Once a proof of concept is established the next phase is arguably the most important.

That's because the design of any medical component must satisfy governing bodies like the FDA and European Commission in the US and European Union respectively, as well as adhering to strict regulations laid out by ISO 13485 here in the UK.

Often an iterative process, it's important to document any changes in the design phase. This is to demonstrate a commitment to fulfil user needs, meet intended uses and deliver on specified requirements.

Failure at this juncture is often the reason for product recalls longer-term.

The best method is to emplot a design manufacture process, taking the likes of components, assembly and mass production into consideration. This should, theoretically, simplify the production itself.

Establishing a User Requirements Specifications (URS) document will also keep the intended recipients needs front of mind throughout.

In short, the key is ensuring the design you put forward (output) meets the requirements promised at the outset (input). You reach this stage courtesy of several reviews, wherein you draw opinions from all key stakeholders. These should be documented in a process referred to as Design Controls in the United States.

Detailing the journey proves you have taken the requisite steps to limit failure and harm to the end user.

Those looking to bring a medical device to market will often partner with medical device developers in this initial design phase.

On receipt of a design proposal Clamason are ideally positioned to make recommendations ourselves. We boast our own specialist team of engineers who double as designers at our UK Design Centre in Kingswinford.

Between them they boast more than 50 years' experience in creating new designs or re-interpreting existing ones to maximise component performance. They do so using industry leading software which could result in them proposing alternative materials, finish or component design before moving onto tooling and industrialisation.

Our in-house pressing simulation technology also comes into its own here. This clearly displays the effect the pressing process will have on the design and raw materials, again prompting changes ahead of production – minimising costs as a result.

INITIAL PRICING

Once designs for a medical device component are finalised, the next step is to talk costs.

Given the nature of tooling projects, it's not uncommon for requirements to change between the concept and prototype stages. For that reason, the Clamason team only ever discuss initial pricing at this early juncture. Indeed, things become a whole lot clearer after a prototype is built and physical parts can be reviewed.

There is no set price for the stamping of medical parts. Quotations instead rely on complexity, volume and the likely timeline, which can span several months.

Those new to the industry can sometimes overlook key milestones, all of which have costs associated with them. These may include the purchase of parts and testing. Biocompatibility testing for instance can run into the tens of thousands.

While designs dictate processes, most medical projects involve the following checkpoints:

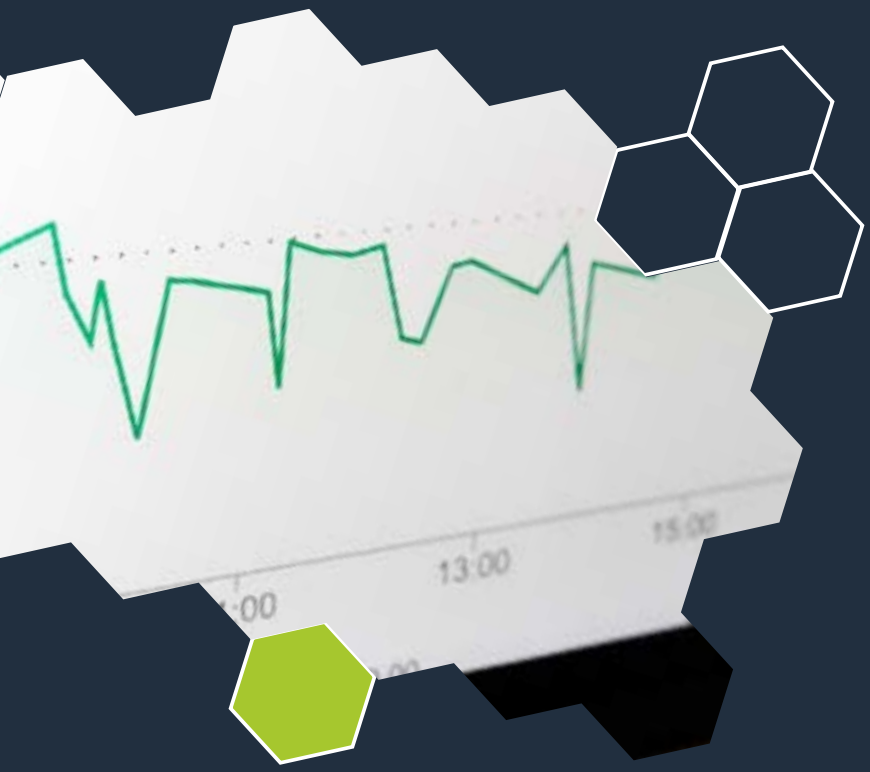
- set up of manufacturing area
- validation
- purchase of parts
- storage of parts
- retrieval of parts
- assembly
- testing (biocompatibility testing can costs tens of thousands)
- regulatory compliance
- clinical trials
- packing
- invoicing

And all of the above is factored into the finalisation of commercials.

Well established pharmaceuticals can recoup this spend in a relatively short period, providing their market research is solid. This may inspire them to flood a market without prior contracts in place, thus yielding a big return.

Newer companies may rely on initial capital and a team of partners if they are to bring their idea to market. Either way a business plan is recommended.

An initial quote, if accepted, formalises an agreement between OEM and supplier, paving the way for that all-important prototype.



PROTOTYPING

Prototypes are vitally important in the development of medical device components. While digital designs are insightful, there is no substitute for handling and testing a physical part.

Prototyping is, in many ways, a first quality check.

What's produced here can be tested and used to lock down costs, timescales and resource requirements. Indeed, a good prototype will combat spec creep further down the line.

This key step should be seen as a last chance to accommodate design changes before progressing into full scale production. And while tooling can seem tantalisingly close, prototypes should never be rushed. Thorough analysis is the only way to combat unforeseen failings or defective parts.

The best manufacturers allow for flexibility and innovation at the prototype stage. A growing number now offer 3D printing as an alternative to using actual product materials, if preferred.

It's not uncommon for suppliers to utilise the likes of plastic injection moulding, nor silicone or urethane moulds – depending on the application.

Neither is it unusual to create various prototypes for different scenarios. You could, for instance, request a laboratory device, a pre-clinical prototype, followed by a clinical device and then several variations aimed at specific patient needs.

This leaves no stone unturned when evaluating the likes of precision tolerances and the ability to withstand different chemicals.

Here at Clamason we base our prototypes on detailed drawings created during the design phase itself. We partner with international manufacturers to realise quick turnaround times and detailed testing before any production is pencilled in.

We encourage OEMs to seek initial customer feedback to ensure the product delivers on its promise. Clinical trials are a safe and regulated way to do so.

Prototyping is about transitioning from a flat visual to a physical product, one that can be scaled up for high volume production.

They open a window for improvements and refinements, all of which should be documented.

FINALISATION OF COMMERCIALS

Evidently, the prototyping of any medical device component is a key staging post. Not only will this reveal the product's viability but its affordability also.

Once clinical trials are concluded, OEMs and their suppliers will have a better idea on end design, materials and time to market.

This enables manufacturers like Clamason to confirm costs and deliver final quotes.

Most pharmaceutical companies will have budgeted accordingly and set out a business plan that includes costing for the likes of promotion and international registration.

Even smaller companies will, in all likelihood, have secured capital to ensure there are no major delays at this final checkpoint.

Once a quotation is accepted and the relevant paperwork signed, production can begin in earnest.

PRODUCTION STAMPING/TOOLING

When patients' health and indeed lives are at stake there really is no margin for error. This places great importance on the manufacture of medical device components and partnering with an experienced supplier.

The production phase itself involves the pressing of medical grade metals such as stainless steel or titanium, all with a view to inserting them into surgical instruments, casing components, implants and more.

For many decades this was achieved courtesy of machining exclusively but Clamason have adopted innovative methods to allow OEMs to realise a far quicker return on investment.

Both our progression tooling and high-speed metal stamping services are provided in line with ISO 13485 and IATF 16949 standards, the benchmark for medical pressings.

Let's take a look at both in more detail...

PROGRESSION TOOLING

Progression tooling is an automated process which cuts and bends single sheets of metal. It could be described as 'rapid manufacturing'.

Put simply, it sees the material fed into a press and 'progressed' through various stages of cutting and shaping. Remarkably, the entire procedure is achieved using a single tool.

By investing in machinery such as the Bruderer press, Clamason facilitate accelerated production. Parts are suddenly realised in less time with a lower cycle per finished piece. Crucially, this does not come at the expense of either precision or quality.

Further benefits include a sudden reduction in waste. The upfront work at the design hase to optimise the component design and also strip layout now starts to show itself through the material utilisation, saving both waste and cost.

That sheer repeatability all but eliminates failed parts. High volume and high quality is realised given the degradation of die is so slow.

What on the surface may appear an expensive investment is soon offset by the speed and efficiency gained.

Progression tooling is a great way to achieve stringent tolerances and with them durability and longevity. It's no exaggeration to say it's revolutionised the medical stamping sector.

HIGH SPEED STAMPING

High speed metal stamping has proven equally as transformative.

As the name suggests high speed stamping is capable of producing more than 1,000 components per minute utilising stamping machines from the likes of Bruderer,

In fact, attention to detail is heightened in lieu of in-die sensors and camera vision systems which allow for 100% inspection of parts as they are fed through presses. This makes it easier than ever to identify defects, even with products created at breakneck speed.

As a result, incredible levels of precision are guaranteed, ideal for medical pressings where high tolerances are so often required. Bespoke and intricate components are suddenly pressed relatively easily. This has allayed fears over the cost of what was previously rare work.

TECHNICAL CLEANING

It goes without saying that any device used to administer treatment must be free of contaminants. Oversights in this department could prove fatal.

That's why great emphasis is rightly placed on the cleaning of medical device components. So important is this process it's written into law by industry regulations, including Clean Room Standards (8).

In 2021, there are two prominent methods used to rid devices of particulates, oils and general contamination – namely passivation and technical cleaning.

The second of those has emerged as the more effective and calls on state-of-the-art machinery, with varying levels of cleanliness.

Both automatic and fully enclosed systems are used by trained operatives able to clean what may previously have been hard to reach areas. Just as importantly, the machinery can adopt a lighter touch when tackling 'delicate' instruments.

Clamason have embraced technical cleaning since 2008 and specialise in both vapour degreasing and ultrasonic technology.

VAPOUR DEGREASING

The former is extremely effective and sees two chambers filled with non-flammable solvent. One of those has its solvent heated to a boil, which duly creates a vapour cloud which rises and meets nearby cooling coils. These conspire to cause the vapours to condense before returning to their liquid state.

This returning fluid is then channelled back to the second chamber, better known as the rinse chamber.

Our medical pressings are fed through the vapours and into the boil sump for initial cleaning. In time they progress to the rinse sump, now filled with clean solvent distilled from the solvent vapours.

High density and low surface tension make for effective cleaning, more advanced than any system reliant on water alone. Vapour degreasing even includes the drying of components by way of a vacuum, dramatically reducing staining.

ULTRASONIC TECHNOLOGY

Solvent cleaning itself is equally as effective in that it's guaranteed to wash away the smallest particles and allows penetrative cleaning of obscure crevices.

The process relies primarily on the physical effect of waves being passed through a liquid. That pressure causes it to collide against an object in a process more commonly known as Agitating.

Millions of bubbles then appear which disintegrate, spawning jets of plasma energy in the process. It's these bursts which connect with the surface of a component, which finds itself immersed in liquid. Grime and the like is very quickly removed as Cavitation takes place.

Solvent cleaning enables thousands of components to be cleaned at one time, hence its popularity.

MEDICAL PACKING

Clamason's is the definition of a full-service solution, which moves from tooling and cleaning to packing.

Again this is a sensitive area, with great vigilance required when boxing components used in medical devices.

It serves to partner with a manufacturing company that offer in-house packing and validation services, this to combat product recalls and the reputational damager that comes with them. 10% of all recalls are a result of these exact failures.

Once pressed, medical components should be packaged using known traceable materials, according to ISO standards. These must be non-toxic, non-leaching and odourless.

The packing itself should take place in verified cleanrooms. These are permanent or semi-permanent installations that offer floor to ceiling protection and with it a superior level of cleanliness.

Configuration is permitted but each has a maximum particle count of 100,000 per cubic foot of interior air.

The definition of a controlled environment, air flow rates must also be kept between 4 and 8 CDM per square foot, with a minimum of 20 air exchanges taking place every hour.

Filtration, lighting and temperature controls can be found in the Class 8 Cleanrooms erected by Clamason which may even encompass pass-through chambers and air showers.

That attention to detail extends to the handling of components themselves. Adhering to strict ISO 13485 protocols, our expert team pack stamped components into medical grade bags or trays, depending on the specification.

Both automated and manual packaging services are available and can be arranged on a sub-contract basis.

Design and production matter little if packaging is found wanting.

MEDICAL VALIDATION

What sets Clamason Industries apart from so many of our competitors is an ability to offer medical validation in-house.

An essential and inescapable aspect of bringing a new medical device to market, it acts as the ultimate quality check.

A pre-requisite of both the US FDA and ISO 13485 protocols, validation is the process by which manufacturers can prove, with supporting and objective evidence, that their product produces the result promised in its original specification.

That proof comes by way of case analysis, inspection and testing. The aforementioned will focus on the likes of accuracy, tolerances, clarity and more to ensure the end user needs are not only satisfied but satisfied without risk.

In those instances where results cannot be verified by inspection and test alone, validation should come with a high degree of assurance and be approved according to established procedures. Any results recorded this way must come with the date and signature of the individual approving validation.

In the modern era the means of testing have evolved somewhat to include automated testing and more advanced data collection and diagnostic tools alike.

However it's achieved, validation is required at each and every stage of the manufacture of the product – hence the various protocols:

However it's achieved, validation is required at each and every stage of the manufacture of the product – hence the various protocols:

- Design (DQ)
- Installation (IQ)
- Operational (OQ)
- Production (PQ)

The results are recorded at every one of those points to guard against discrepancies which could have potentially fatal consequences in this field.

Medical validation results in fewer errors which in turn leads to less revisions and a faster time to market - when done right.

Validation is nothing if not thorough. All elements of an inhaler for instance would be validated individually to guard against malfunction. Everything pressed or stamped must be compliant with those all-important medical device regulations. The final product cannot be launched without that seal of approval.

The reason in-house validation is so desirable, is due to how complicated it can be to arrange this independently. Indeed, various processes need to be put in place, with the likes of accessible connectors and data retravel capabilities difficult to come by.

Moreover, a validation team, once assembled, will be tasked with forming and documenting an exhaustive and air tight process that encompasses the likes of creating a VMP, specifying parameters and outputs and establishing protocols, before you even begin to consider DQ, IQ, OQ and PQ protocols.

All of the above and more will then need to be summarised in a final report that has to meet regulatory standards.

As of May 26th 2021 meanwhile, any medical device manufacturer must have a Quality Management System in place, as per the EU's Medical Device Regulation.

Clamason remove that stress for OEMs and have done so for more than 20 years. All components manufactured at our plants are full process validated by staff well versed in the use of corrective and preventative actions also.

INDUSTRIALISATION

The final stage of a medical device component project is typically industrialisation.

Once the newly created component has passed clinical trials OEMs ordinarily look to scale up production. They do this by investing in their own factories or partnering with another manufacturer(s).

The goal is to ramp up output to meet what they anticipate will be growing demand. It's at this point that the client takes ownership of the component design and tooling themselves, thus concluding the relationship with Clamason.

Effective industrialisation does depend largely on detailed preparation. How quickly a pharmaceutical company scales production will nearly always be informed by market research and sale estimates forecast during ideation.

It's also important to plan with a degree of caution. Announcing release dates in marketing promotions that are eventually missed will negatively impact the brand and lead to customer dissatisfaction right from the outset.

This is why establishing the aforementioned Design for Manufacturers guide is so important. The latter can ease the transition over to a new manufacturer, reducing manual costs whilst increasing productivity.

Of course, any new partnership of this kind should also be documented in the form of a written agreement, protecting all parties and guarding against regulatory violations.

Clamason's own full-service package extends to post-production and our expert team are on-hand to advise on scaling up should our clients have any questions or concerns.

CONCLUSION

So, that concludes our overview of a typical medical device component project.

Evidently, this is a process that is governed by strict regulations aimed at protecting end users above all else.

Understanding those protocols is vital if your product is to reach the market and deliver that sought-after return on investment. Even those with the best intentions can find themselves struggling to navigate regulatory waters. That's why partnering with an experienced manufacturer can prove so beneficial.

Clamason have been at the forefront of medical pressings for more than 70 years and held ISO 13485 accreditation since 2008.

We produce more than 300 million components intended for this sector every year, manufactured at speeds of up to 1,000 per minute.

That productivity, paired with unrivalled precision, has led to us producing pressed parts fundamental to the likes of drug delivery devices, auto injectors, dry power inhalers and more. These come not just in the form of stainless stell but increasing titanium, given its resistance to bacterial growth and corrosion.

Moreover, ours is a full-service solution that can begin as early as the design phase and encompass not just expert tooling but cleaning, packaging and validation services to boot.

Our experienced team and cutting edge machinery have positioned us as market leaders in this rapidly expanding sector. There is no better partner to assist you in this long but rewarding journey.