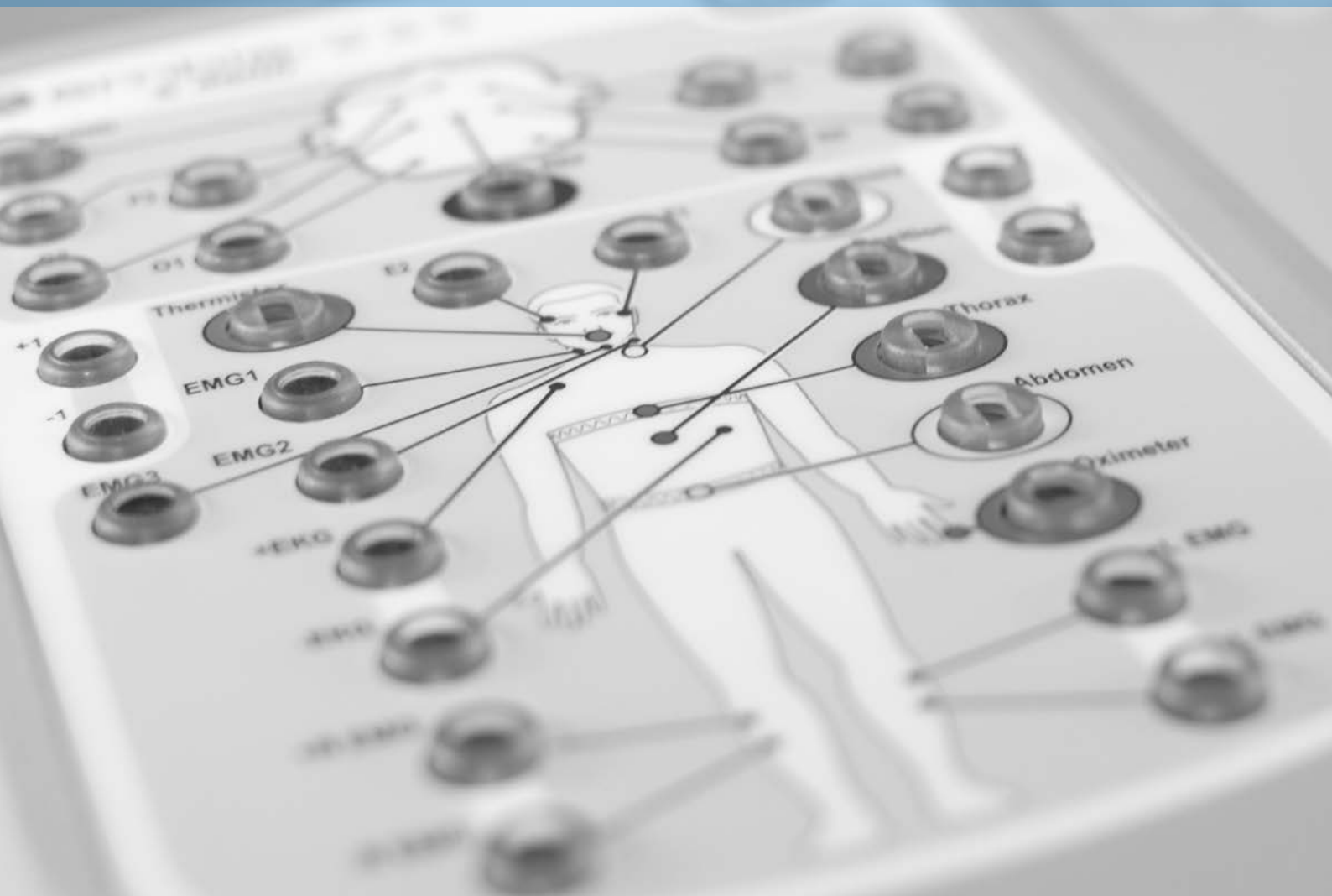




You Revolutionise, We Productionise.

Bringing Medical Devices to Life




Cogent Builds Technology to Enhance Lives



OUR ETHOS

“Honest, Open, Measure and Improve”

Medical Device Manufacturing: FDA Registered, ISO13485 Certified

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1 Introduction

ESTABLISHED EXPERTISE YOUR MEDICAL DEVICE MANUFACTURING ORGANISATION



“We needed a partner that could provide a complete ISO13485 manufacturing service and support solution for a new-to-market product where that infrastructure did not pre-exist. Our experience with Cogent is that the team take pride and ownership in the product and work hard to optimise and control the manufacturing processes to mirror the significance of the device they are producing.

The thing you can't measure at supplier selection stage is the passion and expertise of the people, the evidence I can see is that we can depend on the team at Cogent” .

Martin Cooke,

Head of Manufacturing and Regulatory at ANGLE

Cogent Builds Technology to Enhance Lives

Health is the foundation of life itself, everything else is secondary, so manufacturing products to diagnose, prevent and treat the human condition is a pretty compelling reason to come to work each day. This is what motivates the team at Cogent and the knowledge that the products we manufacture, determine outcomes for patients, is what drives us to be the best.

Cogent Technology has, since it's infancy, been servicing the medical device sector providing manufacturing and supporting services.

At the heart of Cogent's business ethos is an Open Book Policy, a core principle that has benefited Cogent and its clients, creating a foundation for long term commercial partnerships.

From concept through to new product introduction, Cogent Technology provide a plan to deliver with flexible scheduling options and an uncompromising commitment to excellence, supported by dedicated staff trained and operating to stringent, recognised standards.

Read on to learn more about how Cogent can make a difference to your New Product Introduction or Product Transfer ambitions, delivering your devices and much more besides....

2 Meeting Your Demands

ONTIME, JUST THE WAY WE PLANNED IT

YOUR JOURNEY BEGINS WITH A PLAN

Once your product design phase is beyond concept, engaging with Cogent Technology will bring your device to life.

You can engage with our team for the full portfolio of below services or just the key elements you require, to bring your designs to fruition:

Project Planning

Cogent will produce a project plan from Concept into Series Manufacture. Prince 2 qualified planners, with experience and a full understanding of all the intricacies of the journey from design, through prototype approval and series manufacture, will provide the blueprint, giving our teams the ability to respond to real time issues moderating the impact on the project plan.

Beta Design Consultancy

Cogent manufacturing engineers will perform DFMA and PFMEA to your design files, the beginning of Productionisation and validation for manufacture; casting our expertise over your bills of materials from PCB and electronics to hydraulics, pneumatics, mechatronics, and plastics. This review at an early stage will save time and money.

During this stage Cogent are able to add detail to the cost model to give you a better understanding of what it will cost to manufacture your medical device. We can also generate technical files for regulatory submission.

Material Planning

Ensuring materials are on hand to meet the plan, whether that be for prototype, clinical trial batches or first off the line, is key. Your procurement lead will absorb themselves in the BOM, gather intelligence of lead times, component life cycle (even before design fix) and contain exposure to MOQs whilst ensuring parts are to hand; right time, right price.

Manufacturing

Planning to manufacture is not just about parts and people, it's about optimising the facility, training the team and ensuring the process controls are in place. With skills in 6 Sigma and LEAN manufacture our aim is 100% yield, on time. We have 2 dedicated controlled environments for the assembly of Medical Devices.



3 Medical Device Manufacturing Standards

Cogent Technology is certified to ISO 13485:2016 and FDA registered. In respect to the later, Cogent has been surveillance audited under 21CFR820 and separately for product specific PMA.

Our Quality Manager sits on the BSI Technical Committee for Medical Devices in the UK, which allows us to keep abreast of the latest requirements and industry direction.

For clients who's businesses have been spurred by innovation ahead of implementation of their own Management Systems we have a deployable solution to implement ISO13585 QMS for you, with support through to your first certification audit.



To Our Clients ISO 9001—Cogent are approved to ISO9001:2008 standard and are regularly audited to ensure quality standards are met.



To Legislation & Regulation ISO 13485—Cogent Technology are proud of their reputation for going beyond just building in compliance with regulatory requirements, but supporting early stage development and NPI with innovation and delivering results specifically for the medical device industry.



To Our Environment ISO 14001—Cogent Technology strive to minimise waste and any adverse effects of our operations upon the environment with all of their processes adhering to be RoHS compliant. Energy usage is also constantly monitored and investment in new technologies introduced where appropriate to reduce consumption and environmental impact.



To Our Staff IPC A 610—standards achieved by their in-house training. All products are 100% inspected to meet the IPC standards and where possible are functionally tested to meet specification.



To Safety Standards—standards that demonstrate a tried and tested way to work more efficiently and effectively, helping organisations like theirs to improve performance, reduce risk and help to become more sustainable.

WORKING WITH YOU TO SUPPORT COMPLIANCE

Open

Honest

Measure

Improve

Systems are key to compliance but only the right culture and the commitment of the team will ensure they serve their purpose and stand up to scrutiny.

Cogent Technology have spent more than 30 years investing and building a skilled team to ensure they can support the complex and dynamic nature of the medical device contract manufacturing market. They are constantly investing back into their business through technology and training to ensure they continually improve their working practices and quality standards; providing assurance to their clients that they can deliver products that are commercially lucrative, produced to a high quality and delivered on time.

Continuous improvement is a way of life, our disciplined process ensures that performance indicators are monitored frequently and opportunities for improvement are actively pursued, monitored and effectiveness checked.

Whilst certification provides evidence of compliance, effectiveness is a result of how that compliance is achieved. Our systems are designed to be intuitive, propagated throughout the business and to serve the needs of Cogent and it's clients.

Cogent will serve you from the moment you engage, working in synchronous with your design team to provide process Validation and Verification of all stages of manufacturer and provide support with a pre submission audit of your technical file.



4 Showing our commitment with MaPS...

your route to quality and on-time delivery



Cogent Technology is a progressive company, always seeking the most effective solution. In order to manage the demands of manufacturing within a tightly controlled environment, Cogent have created a bespoke system called MaPS (Monitoring and Planning System).

This is a system so advanced it enables Cogent to have complete control of everything, from its business strategy to capacity planning and all the supporting processes in between. The system always prompts accolades from those who get to see it in action whether as part of supplier assessment or certifying body Audits. Working in tandem with our MRP it has been described by third parties as “Epic” and “The best system I’ve seen, period”. When you see it, you’ll believe it.



Quality Assured

Our quality policy begins with our ethos, **“Honest, Open, Measure & Improve”** which is managed through our QMS within MaPS, making it quick to navigate, for the Cogent team to verify policies and procedures as well as for auditing purposes or clients conducting their due diligence when selecting a manufacturing partner.



On-time Delivery

We have defined quality gates and daily sunset meetings in place which flag early warning of potential issues triggering communication with our customers where necessary, ensuring we meet our deadlines and client expectations.



Drives Contract Review Actions

On receipt of your order a PO Entry Gate is held to determine the level of contract review meeting required. Actions are assigned as a result of the meeting, are linked to the clients order then monitored and recorded in accordance with the deadlines defined by the High Level Plan. This ensures tooling and assembly documentation is in place prior to production.



Facilitates Strategic Planning

The system helps us identify untapped production capacity which enables us to respond positively to existing client needs and new sales opportunities ensuring we have the necessary skills available for your requirements.



Improved Efficiency

MaPS provides greater control of resources by using the high level plan to drive team plans and individuals work stacks ensuring less waste and reducing costs for clients.



Flexibility

Changes to your schedule can be easily reviewed and processed to give timely responses to your requests ensuring peaks in demand are met and we can prioritise your requirements.



KPI Performance

MaPS enables us to measure and monitor Key Performance Indicators, including live yield data to drive continuous improvement in accordance with our regulatory requirements. Providing you with the confidence and peace of mind that as your chosen subcontractor your products are being produced to a high standard on a repeatable basis.



Improved Customer Response

Live order status tracking in MaPS enables us to quickly and efficiently redeem information needed to go back to our client and update on order status.

5 Proactive innovation, supporting the road to production

YOU REVOLUTIONISE WE PRODUCTIONISE

You stand ready to meet a clinical need, you have a concept but need to satisfy stakeholders fast. The road to market is steep and must navigate the many necessary stages to achieve compliance.

In order to speed that passage you'll be endeavouring to perform as much concurrent engineering as possible. Engaging Cogent at the earliest opportunity can assist in a number of ways;

- Performing PFMEA and DFMA, heading issues off at the pass, minimising design iterations, slashing time and cost. Our experienced team can engage as soon as you have first pass design.
- Sourcing; early sight of a provisional BOM will enable Cogent to explore the market, avoid late redesign due to obsolescence and prepare our extended supply chain for plastics, metal work and key components. Long lead items are secured ensuring readiness to build your first article.
- Manufacturing processes can be subjected to validation protocols to support your technical file and subsequent verification.
- Training is disseminated ensuring production ramp up is accelerated.

Cogent's contribution to your product development is distinct from design but forms a key element, Productionisation.



6 Manufacturing Services

We offer three levels of service to meet your needs:

Fast Track, when you need development prototypes with rapid turnaround times.

New Product Introduction – bringing control and added expertise, such as PFMEA and DFM feedback, to ensure your product is proven, documented and ready for full-scale production.

Series Production offers flexibility for you through scheduled orders and our KANBAN service.

All of this is controlled via our MRP system which offers;

- Total batch traceability, to component level
- Visibility through SFDC for live progress
- Leap-frogging of process steps is prevented, electronically
- Use of non-calibrated equipment prohibited, electronically
- Operator activity, recorded and traceable to product serial numbers
- Integrated skills matrix restricts operators; only those certified to build specific devices can handle them
- Rework and subsequent re-validation logged - in detail
- Complete electronic device history record (DHR)



7 Electronics, Fluidics, Optics; Your Device, Complete.

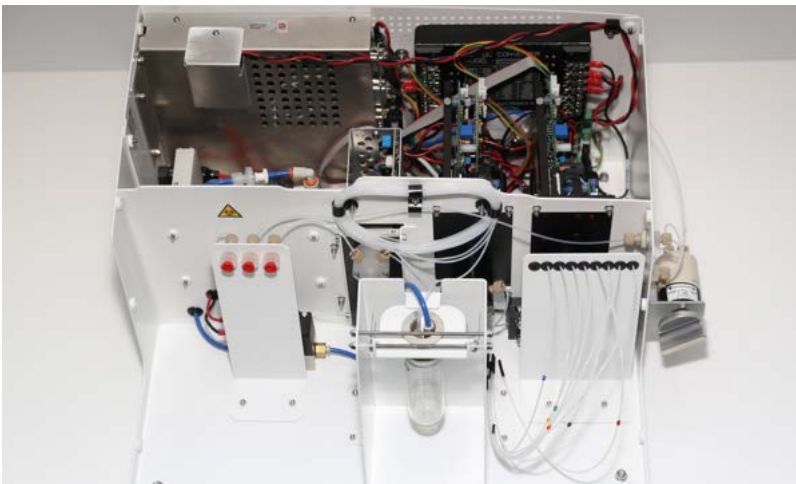
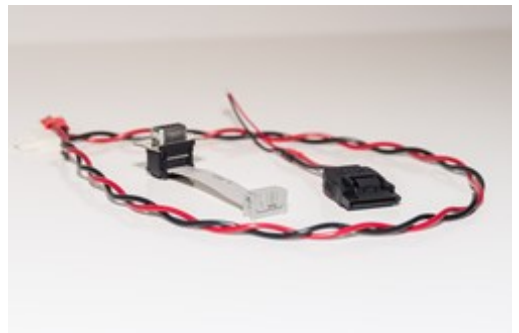


Why just subcontract your PCB assembly when you can outsource the production of your complete box build or electro mechanical assembly?

Whilst Cogent Technology is undeniably a PCB Assembly specialist, many of the devices we produce include significant elements of mechanics, fluidics or optics.

This may include sensors, valves, solenoids or a myriad of electromechanical devices all assembled within an enclosure, rack or mechanical system.

There is no better way of establishing the overall integrity of a system than bringing both the electronics and mechanical components together in one place, tested, validated and recorded by one manufacturing partner you can trust.

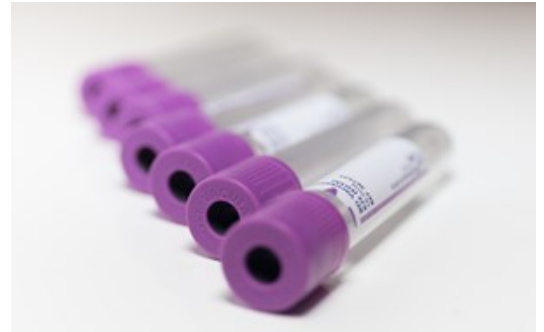


Cogent Builds Technology to Enhance Lives

COGENT TECHNOLOGY, MANUFACTURING GROUND BREAKING MEDICAL DEVICES

The images shown form a break-through medical device from ANGLE which uses a patented micro-fluidic technology to capture and harvest rare cells from blood.

ANGLE's proprietary cassette captures rare cells based on their less deformable nature and size compared to other blood components.



As a precision in-vitro diagnostic device and research instrument the rigorous approach applied to its electronics manufacture is equally applied to the electromechanical assembly.

A combination of electromechanical, fluidic and PCB assemblies each have a serial number linked and documented as part of the permanent Device History Record (DHR.).

Many of the electromechanical assemblies we produce, as medical devices, demand high levels of traceability. Every serial numbered sub-assembly is traceable and linked from source of the component to the people who assembled and tested it.



Bringing Medical Devices to Life

FULFILMENT SERVICE, FOR COMPLETE SATISFACTION.



Cogent Technology continues to service our clients after the box is sealed. We offer a complete fulfilment service, delivering your device and any ancillary parts direct to your customer. As with manufacturing, it can be cost effective to sub contract a function which may not demand full time resource in a location where overhead is lower than the bio or technology hub that you occupy to attract scientists and engineers.

Electronics are robust and rarely need attention but Batteries, Pumps, Drives and Optics all have a finite service life and it is likely that your devices will need a competent experienced centre to support them and your customers. Cogent can offer a complete returns service, supported with the same controls and expertise that manufactured your device.

The lifecycle of a successful medical device is long, but during that time the components within it may become subject to scarcity, inflation or at worst, obsolescence. Working with Cogent Technology, we can provide early warning strategies around these eventualities, finding alternatives, securing stock and managing change. Cogent Technology looks to secure long term client relationships, to that end we aim to deliver, consistently, always.

9 Why Cogent Technology?

1

OPEN BOOK POLICY— Openly sharing raw material and labour costs, as a valued client you can see where the value is in your products and when working together we can ensure you can compete in the market. Your dedicated account manager will openly show, in detail, raw material and labour costs so that you can see where the value is in your product. Working together we can concentrate on the highest cost and engineer you into a more competitive position in the market place.

2

EXPERIENCED COMPANY— Established for over 30 years, Cogent Technology have an experienced team of specialists on hand that you can rely on. This enables us to exceed your expectations for the quality of your products, the Design for Manufacture know how and competitive materials sourcing ensures total dependability as your preferred supplier.

3

TRAINED TEAM— As any successful sportsman will tell you, performance comes with training. That is why we have spent more than 4000 hours per year training staff throughout the company to ensure we can deliver you “Excellence in Manufacture”. The ultimate realisation of good training is build quality and our ability to certify operators in-house to IPC 610 ensures every joint is to standard.

4

STANDARDS

ISO 13485 is imperative if your product is a medical device and assurance if it is not
ISO 9001 is your guarantee that we are governed and comply to legislation
ISO 14001 so we sustain an environmental policy which means we operate with integrity

5

A PROGRESSIVE COMPANY— The premise that what is excellent today can be better tomorrow is integral to the culture of the Cogent Technology team; their history and success is the testament to this genuine ethos of continuous improvement of the services they deliver. A great example of this is ‘**MaPS**’ our Manufacturing and Planning System, a unique system which provides end-to-end control in every step of your product realisation.

or

VISIT US ON LINKEDIN , TWITTER OR OUR WEBSITE!



COMMUNICATION EATS MILES

SERVING CLIENTS, WORLDWIDE

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