



You Revolutionise, We Productionise.


*Manufacturing for Life*



## OUR ETHOS

*“Honest, Open, Measure and Improve”*

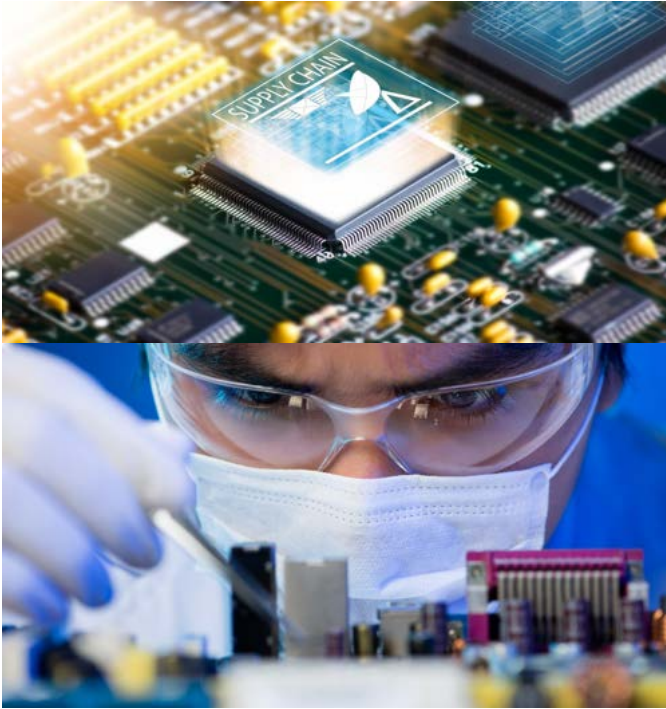
ISO 9001, ISO 14001, ISO 13845 & FDA Registered

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# 1 Introduction

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## ESTABLISHED EXPERTISE YOUR MANUFACTURING ORGANISATION



### Cogent Builds Technology to Enhance Lives

This is what motivates the team at Cogent in the knowledge that the products we manufacture for you improves peoples lives in some way, its what drives the team to deliver you a first class service you can rely on over and over again.

Cogent Technology has, since it's infancy, been servicing the a wide range of 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....

“We needed a partner that could provide a complete 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**

## 2 Proactive innovation, supporting the road to production

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# YOU REVOLUTIONISE, WE PRODUCTIONISE

Our goal is to take your product from concept to high yield series production.

Cogent has a comprehensive multistage approach to ensure this is effective;

**DFMA** – we'll assess your designs for manufacturability, determining how well they lend themselves to the processes with the aims of minimum assembly time, maximum repeatability and yield.

**Prototype** – after the conceptual work is done, you need to prove your assumptions before proceeding. Our prototype service is focused on fast turn and is our hands-on opportunity to identify further opportunities for improvement.

**PFMEA** – as your ultimate design approaches conclusion a detailed assessment of risks in the assembly that may lead to failure is conducted and addressed.



**Supply Chain Management** – prior planning and assessment of the supply chain, pre-empting issues with lead time, availability and quality of third party electronic and mechanical parts is essential to avoid uncontrollable impacts on delivery.

**Process Protocol** – having established the risks associated with the assembly process a protocol for validation is established which will be deployed to confirm the outputs meet expectations.

**NPI Pre-Production** – Generating a first batch to prove the product, processes and documentation are fit for purpose

**Validation** – absolute confirmation that the product meets specification and that the processes are appropriate

**Series Production** – to your schedule; we offer a variety of models based upon your pattern of demand to ensure optimum batch sizes and minimum inventory and lead time.

### 3 Cogent's Manufacturing Standards

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Cogent Technology is certified to ISO 9001, ISO 14001, ISO 13485: 2016 and also FDA registered. In respect to the latter, 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 certified to the ISO9001:2015 standard and are regularly audited to ensure quality standards are maintained.



**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 our processes tailored to ensure RoHS compliance. 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 our in-house training. All products are 100% inspected, both at PCB level and complete unit assembly, to meet the IPC standards, IPC A 610, IPC7711/7721 and IPC A 620, and where possible are functionally tested to meet specification.



# 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 35 years investing and building a skilled team to ensure they can support the complex and dynamic nature of 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 Project Management

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# SUPPORTING YOUR ROAD TO MARKET

Successful manufacturing projects begin with a plan. Cogent are happy to dovetail our plan with yours or offer a complete planning and project management solution bringing together our teams and third-parties within the supply chain to deliver on time.

An effective plan acknowledges the need for concurrent activity to compress timescales, so we'll be working on the supply chain before you've finalised design, securing fixed long lead time parts, proving third party capability.

An essential stage of the project plan is a review of costs, it's too easy for projects to drift whilst meeting engineering needs, away from the price point that makes them feasible

With the right commercial and engineering oversight Cogent works in partnership with our clients to deliver quality, on time.



## 6 Manufacturing Services

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Our Team offer three levels of service to meet your needs:

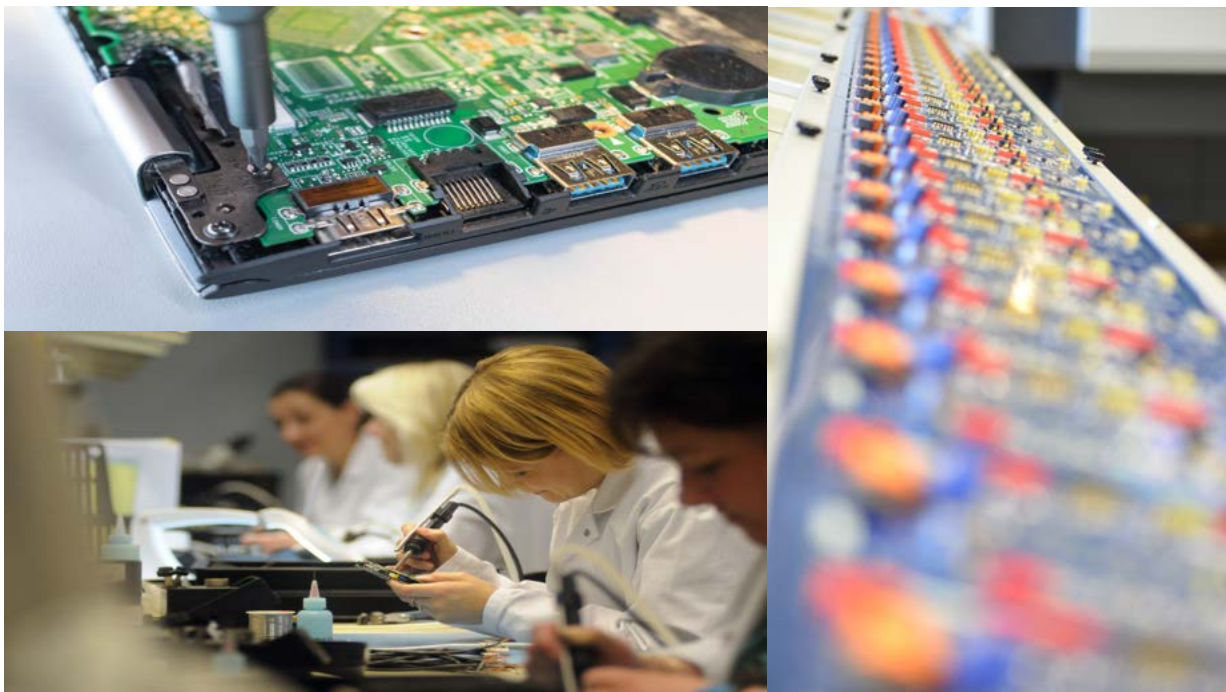
**Fast Track**, when you need development prototypes with rapid turnaround times.

**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.

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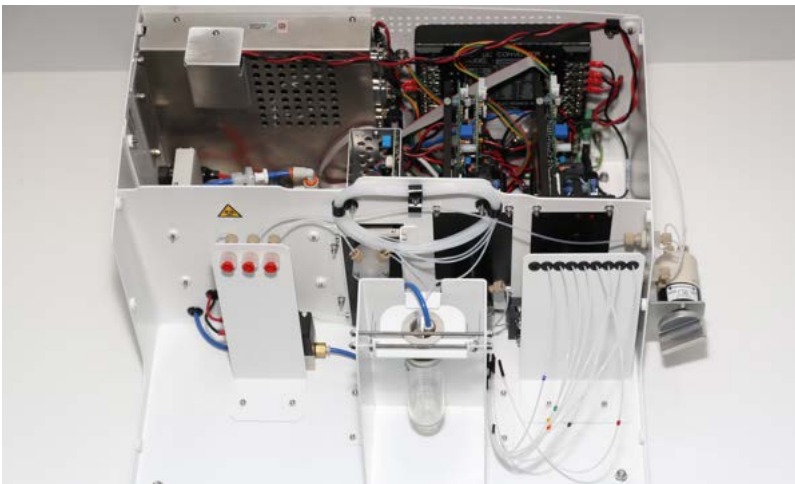
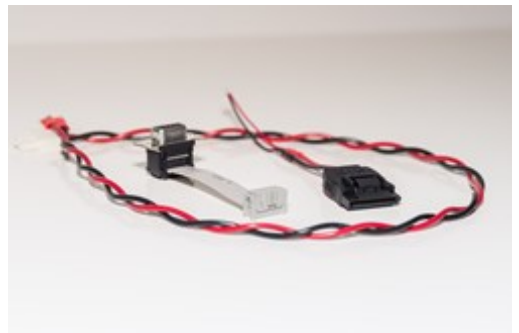


**Why just subcontract your PCB assembly when you can outsource the production of your complete box build or electro mechanical assembly?**

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.

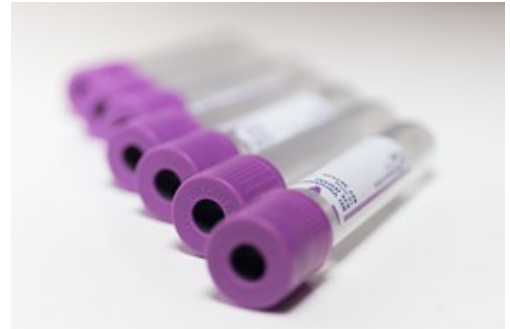
There is no better way of establishing the overall integrity of a system than bringing both the electronics and mechanical components together in one place, tested, validated and recorded by one manufacturing partner you can trust.



# COGENT TECHNOLOGY MANUFACTURING GROUND BREAKING DEVICES

The images shown are from 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.



# 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?

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1

**OUR 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

2

**EXPERIENCED COMPANY**— Established for over 35 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 2500 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 A 610 ensures every joint is to standard.

4

### **OUR STANDARDS**

ISO 9001 is your guarantee that we are governed and comply to legislation  
ISO 13485 is imperative if your product is a medical device and assurance if it is not  
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 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—You have to see it to believe it !

**VISIT US ON LINKEDIN, TWITTER OR OUR WEBSITE!**

or



**COMMUNICATION EATS MILES**  
**SERVING CLIENTS, WORLDWIDE**

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