cogent technology

Excellence in Medical Device Manufacture

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OUR MISSION

"To document, measure, record and continuously improve everything we deliver within
Our open book pricing policy is the catalyst for fluid communication throughout our bu
with our customers."

n an open and honest environment.
usiness, our supply chain and

Medical Device Manufacturing produced to ISO 13485 Standards

ESTABLISHED AND EXPERIENCED MEDICAL DEVICE AND CONTRACT ELECTRONICS MANUFACTURERS

"We needed a Partner that could provide a complete ISO13485 manufacturing service and support solution since as a new-to-market product that infrastructure did not pre-exist. Our experience with Cogent is that 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 Parsortix

Cogent Technology... a team truly serious about SERVICE and QUALITY

What is more fulfilling than manufacturing products that support human health and in some cases save lives? That is what motivates the Cogent Team to deliver in all areas, knowing that the products they assemble make a difference to mankind.

Cogent Technology provides electronic manufacturing solutions for the assembly of PCBs and Instrumentation for Medical Devices.

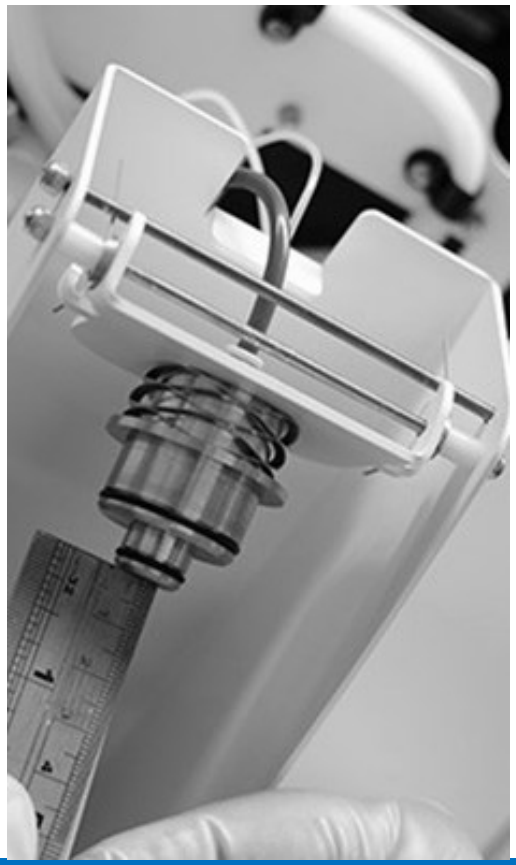
At the heart of Cogent's business ethos is an open book policy, one of a number of LEAN inspired principles that have benefited Cogent and its customers, creating a foundation for long term trading partnerships in excess of 15 years in some cases.

From concept through to new product introduction, Cogent provide flexible scheduling options with an uncompromising commitment to excellence supported by 100 dedicated staff trained and operating to stringent recognised standards.

Talk to Cogent to feel the pride that the Cogent team will apply to the manufacture of your product.

ENSURING YOUR MEDICAL DEVICES MEET QUALITY STANDANDS AND LEGISLATION

FOCUSING ON REGULATION - WHAT DOES THIS MEAN FOR YOUR BUSINESS?



Cogent's ethos is - **"To document, measure, record and continuously improve everything we deliver within an open and honest environment"**

The people at Cogent have a natural embedded commitment to their ISO 13485 certification, ensuring that strict requirements are met while achieving innovation in assembly - and their robust quality system is central to everything they manufacture.

Cogent Technology have spent nearly 30 years investing in 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.

Having clients geographically spread around the globe, Cogent continue to keep a close eye on medical device manufacturing and standards worldwide. This is to ensure their clients have complete peace of mind, that they understand customer needs and are able to deliver the most innovative products whilst continuing to meet compliance in accordance to the regulatory requirements of ISO 13485.

After all, apart from legislation, the most important standards for the team at Cogent to exceed are the expectations of its clients.

2 Medical Device Manufacturing Standards

Cogent Technology operate and comply with internationally recognised quality systems, manufacturing products in a transparent and auditable environment. All medical devices manufactured by Cogent have complete traceability and have been designed, developed and manufactured using standards specified by ISO 13485:2003.

With this in mind, Cogent Technology's commitments for you to build on are...

To our clients ISO 9001—Cogent are approved to ISO9001:2008 standard and are regularly audited to ensure quality standards are met

To Legislation and 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 demonstrates a tried and tested way to work more efficiently and effectively, helping organisations like theirs to improve performance, reduce risk and help be more sustainable.

QUALITY, SPEED, RESPONSIVENESS, CONSISTENCY, LOYALTY AND COMMITMENT - A TRUSTED SOURCE FOR MEDICAL DEVICE MANUFACTURE

Transitioning a medical device idea from concept to an effective, commercially viable product involves rigor and expertise - breaking new ground is never easy. Cogent Technology support their clients year after year successfully delivering a wide range of new and innovative devices to the medical market.

Cogent's passion for manufacture starts with them engaging with your team at product design stage and as soon as key components crystallise, supply chain development commences in parallel, ensuring long lead materials are secured for prototype and pre-production so no time to market is lost. Likewise, future obsolescence can be headed off at the pass. The NPI stage is the opportunity to prove not just the design but the most effective manufacturing and test regimes for future serial production. NPI concludes with product plus full DFM reports, sustaining and supporting your product through to end-of-life. Each of these elements is underpinned by a series of quality gates documented and recorded within state of the art software tools that regulate the whole process.

Overseeing and monitoring project objectives and deadlines, your dedicated Account Manager at Cogent will keep you updated on progress throughout your product build, assuring complete confidence throughout the manufacturing period.

- **TOTAL BATCH TRACEABILITY, TO COMPONENT LEVEL**
- **VISIBILITY THROUGH SFDC FOR LIVE PROGRESS**
- **LEAPFROGGING 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**

To validate the manufacturing home for your next medical device you are welcome to visit Cogent's facility, assess the range of skills and processes and witness how they strive to go beyond compliance. The team would be only too pleased to demonstrate how they would be proud to be custodian of your next NPI to market.

4 Innovative controls regulate the Delivery of your Product

MEDICAL DEVICE NEW PRODUCT INTRODUCTION IS WHAT WE ARE PASSIONATE ABOUT

Millions of pounds go into building medical device prototypes every year, with a very short time frame in which to prepare for the unveiling of a new product.

At Cogent, we understand that our clients are faced with extreme pressure to achieve development goals, so to prevent setbacks, Cogent Technology pioneered a 'New Product Introduction' process which concentrates solely on the essential steps to rapidly grow your product from development stage; ensuring you meet the commercial objectives to launch your product.

As part of this process and for continuous improvement, we introduced a paper-free approach, which means we have been able to integrate the compliance processes necessary for producing prototypes into our business systems alongside refinement in our shop floor data collection process, to provide the highest standards of traceability and device history to ensure tight process control.

The implementation of the ISO 13485 standard allowed Cogent to build into their workflow a number of attributes, some of which go beyond just being compliant - all of which means your new medical devices will be built to the highest possible quality standards, regulated by legislation and within your project parameters!

5 Case Study - what our clients say about us!

CHOOSING THE RIGHT PARTNER - TWO COMPANIES WORKING AS ONE

"Despite the distance between Cogent Technology and our operations team in Denver, the service we receive is better than the on-site manufacturing facility we had. Their engineers work with ours from the outset of the design process to ensure that the product is optimised for manufacture and that specified components will not quickly become obsolete."

Embla Systems designs, markets, sells and supports sleep diagnostic equipment used worldwide by doctors, research facilities and hospitals to study sleep and to diagnose sleep disorders.

The company used to manufacture its sleep diagnostic equipment in house before making a strategic decision to focus on its commercial competencies, like product design. Manufacturing was not core to the business and could be outsourced to a trusted partner.

Cogent Technology has since handled all of the manufacturing and is effectively Embla Systems' production department.

Outsourcing its manufacturing process had an immediate commercial effect for Embla Systems. Quality improved, manufacturing costs reduced and production was more responsive and flexible.

"When it comes to recommending an outsource supplier, Cogent Technology are my first choice." – David Baker.

"Cogent Technology's attention to communication and professional account management makes them feel like an extension of our operation. Few manufacturers embrace the spirit of partnership in the way Cogent Technology does. Dealing with them, you feel that they really do recognise that their fortunes depend on meeting the expectations of our customers."

-David Baker
CEO of Embla Systems

6 Why Cogent Technology?

1

OPEN BOOK POLICY

Openly sharing raw material and labour costs, as a loyal client you can see where the value is in your products and when working together we can ensure you can compete in the market

2

EXPERIENCED COMPANY

Established almost 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 and provide dependability as a

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”

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 4001 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; and our history and success is the testament to this genuine ethos of continuous improvement of the services we deliver

or

CLICK TO VISIT US ON YOUTUBE , LINKEDIN OR OUR WEBSITE

COGENT TECHNOLOGY WILL BE AT THE FOLLOWING TRADESHOWS...

Medica Trade Fair

12-15 November , 2014 Düsseldorf, Germany (Stand F10-5, Hall 16, Block E)

Cogent Technology's success at delivering Medical Devices manufacture is underpinned by ISO13485; our escalating growth in medical prototypes allows us to service a growing number of significant medical device suppliers internationally. If you are looking for a new supplier for your existing products or looking at a New Product Introduction we would like to invite you to meet the team at Medica!

Southern Manufacturing & Electronics Show

10-12 February 2015 Farnborough, UK (Stand F73)

Cogent Technology will once again be exhibiting at the Southern Manufacturing show which is the UK's largest regional manufacturing technology, electronics and subcontracting exhibition. So make a plan to come and see us , along with all the all the other exhibitors that boast the very latest in technology, components, materials and products...we look forward to seeing you there.

Subcon

2-4 June 2015 NEC Birmingham, UK (Stand S455)

Subcon is the UK's national subcontracting, advance manufacturing and technology exhibition providing a platform for engineers and manufacturers to compare suppliers and develop new partnerships. It will give you the opportunity to review manufacturing processes and costs, benchmark solutions and optimise your business...so book this into your diary today, we would love to see you there.

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