

Contract Design and Prototype Services

BRIVANT MEDICAL ENGINEERING

You have an idea and you want to see it turned into reality. The Brivant Medical Engineering 'Contract Design and Prototype Services' has the expertise to facilitate. Brivant's innovative spirit offers 'change that creates a new dimension of performance'. Our expertise in medical device design and development has been enhanced with each device that has come to reality at our 'Contract Design and Prototype Services'.

YOUR IDEA

- You have an idea
- You want to see it become reality
- You want the experts to maximise your devices capabilities
- Talk to Brivant's Contract Design and Prototype Services in confidence to understand the possibilities that lay ahead

Where ideas and
innovation meet

OUR INNOVATION

- Brivant engineers can offer input at the concept phase
- Our project engineers will develop your engineering drawings
- Join a brainstorming session with our project engineers to overcome problems
- Brivant engineers will use their expertise to choose the ideal materials for your devices application

At Brivant we understand that Innovation encompasses the entire process, from idea to implementation, for the development of new devices. Therefore at the Brivant Contract Design and Prototype Services we provide a total solution for our customers medical device needs. With our involvement from design through validation to manufacturing we can deliver sterile, customer labeled product to you ready for clinical use.

BRIVANT
MEDICAL ENGINEERING

Contract Design and Prototype Services

At Brivant's purpose built 'Contract Design and Prototype Services' at Parkmore our experienced Project Engineers offer a wealth of knowledge in device prototype building using novel engineering techniques and materials to make your idea a reality.

YOUR PROTOTYPE

- Hypotube
- Solid wire construction
- Fibre optic integration
- Movable cores
- Hydrophilic or Hydrophobic coatings

Where ideas and innovation meet

OUR PROJECT

- Prototype design will involve foresight to mass production.
- Design History File compilation with every device.
- Product characterisation including:
 - Cantilever stiffness
 - Tip deflection
 - Tensile testing
 - Torque testing
 - Flexure and friction testing
 - Push ability
 - Memory testing

Our experienced engineers have extensive materials and engineering expertise. Our equipment and tooling design & build capabilities enable our project teams to turn around devices quickly. Our 'Contract Design and Prototype Services' is fully equipped to manage your prototype build from concept through manufacture.

Brivant has a wealth of experience designing and developing new technologies. Whether new iterations or next generation devices we can manage your device from concept through to regulatory approval.

Project Services

- Project planning
- Device Classification
- Project timeline estimation
- Project Costing
- Design Control Services
- Product Validation
- Process Validation
- Regulatory Submissions

Design Control Services

Design Input

- Functional Requirements
- Performance Requirements
- Interface Requirements

Design Output

- Product Specifications
- Assembly drawings
- Component Specifications
- Design FMEA
- Design History File

Design Verification

- Approved Design Verification Report
- Labelling Verification
- Hazard Analysis

Design Freeze

- Essential Requirements
- Manufacturing Engineering Documentation
- Process FMEA

Design Validation

- Clinical Literature Review
- Clinical Risk / Benefit Analysis
- Summary of Technical Documentation

Design Transfer

- Device Master Record
- Validated Processes
- Validated Product



Contract Design Services

Contact Brivant today and discuss your device requirements with one of our experienced Engineers. We are happy to offer consultation in relation to the direction your project will take and outcomes expected from your unique project.

Regulatory Submissions

- CE Registrations
- Substantial change submissions
- FDA Registrations
- Traditional and Special 510(k) submissions
- MDD & AIMDD
- Health Canada approved

Product Validation

Biocompatibility Testing

- Toxicology testing
- Cytotoxicity Testing
- Sensitization
- Irritation
- Haemocompatibility

- EtO Sterilization Validation

- Animal Studies

- Clinical Reviews

Product Performance Testing

- Tensile Strength
- Torque Strength
- Torque Response
- Coating Adherence
- Coating Performance
- Radiopacity

Transportation Testing

- Drop / Impact Test
- Compression Test
- Vibration Test

Age Acceleration Testing

- Bubble Leak Test
- Dye Penetration Test
- Peel Strength

