

# Medical Device Pathology

We know you need efficient and effective development and manufacturing support for your medical devices from the proof-of-concept stage to pivotal safety and efficacy evaluations. Charles River offers an integrated approach to medical device studies with a commitment to scientific excellence, an appreciation of client-specific issues, and an understanding of regulatory considerations. In addition, our board-certified veterinary pathologists' knowledge of animal models is unparalleled in this industry.

Our technicians and pathologists have experience with the preparation and evaluation of all categories of devices in any anatomical configuration from in-life programs conducted at your facility or at one of our preclinical facilities around the world. Standard operating procedures (SOPs) have been designed and are tailored as needed to ensure the implanted devices are handled and processed appropriately. Every procedure is conducted under the close supervision of trained pathologists acting as principal investigators.

Prior to tissue preparation, the engineering, therapeutic, and pharmacological specifications of your device are carefully reviewed and taken into consideration for optimal collection of study end points. Medical device evaluation at Charles River is enhanced by our expertise in anatomical and clinical pathology as well as our network of state-of-the-art laboratories.

## Options for Sample Preparation

- Paraffin processing
- Plastic processing
  - Methyl methacrylate (MMA)
  - Glycol methacrylate (GMA)
  - Epon
- Ground sectioning for biomaterials using MMA or EXAKT™ resin
- Carbide tungsten blade microtome sectioning for undecalcified bone and devices such as stents
- Electron microscopy
  - Scanning (SEM)
  - Transmission (TEM)
- Histochemical stains for highlighting tissue components
  - Collagen
  - Elastin
  - Fibrin
  - Muscle
  - Extracellular matrix
  - Cartilage
- Immunohistochemistry
  - Biomarkers of cell proliferation
  - Apoptosis
  - Angiogenesis

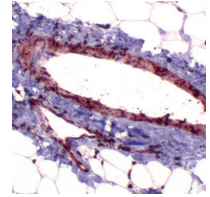
## Services

- Protocol preparation and review
- Necropsy support
- Sample preparation
- Plastic embedding
- Sectioning of hard materials
  - Intact stents
  - Bone devices
  - Biomaterials
- Histopathology
- Peer review
- Photographic documentation
- Morphometric evaluation
- Imaging techniques
  - Macrophotography
  - Faxitron® X-rays
  - Bone densitometry (DEXA, pQCT)
  - Micro-CT
- Comprehensive GLP-compliant reports



## Regulatory and Scientific Infrastructure

Charles River has a more extensive range of expertise in a Good Laboratory Practice (GLP) environment than any other contract pathology group in the world. Our facilities are regularly inspected by the Food and Drug Administration (FDA), and we have an impressive record of compliance gained over decades. In all our locations, Charles River has dedicated quality assurance (QA) support staff. Our medical device pathology services offer the broadest possible range of GLP-compliant specialty histology techniques and the highest throughput plastic capability.



With a unique commitment to biomedical technology, including medical devices and combination products, Charles River offers specific in-life expertise in the areas of interventional medicine, cardiothoracic and general surgery, cardiovascular pharmacology, orthopedics, bone research, and ophthalmology. Our study directors, interventionalists, surgeons, and pathologists work together to ensure a seamless transition from in-life to the reporting phase, eliminating delays and improving the quality of the finished product.

