

Profiles of Success: 20 Years of Service

Artificial Hearts, Heart Assist, and Heart Valves

Paladin Medical, Inc. has served clients in this field by defining durability testing, animal testing requirements, clinical research, and regulatory support of IDE's and PMAs to the US FDA. Specifically, Elaine Duncan of Paladin Medical has provided years of service to artificial heart, heart assist, and heart valve development. Projects have included testing of axial-flow heart pumps, congestive heart therapies and alternative perfusion technologies. Ms. Duncan's notable experience includes the Jarvik-7 Artificial Heart, the Pierce-Donachy heart project, the Milwaukee Heart, an Ohio axial-flow heart pump project, and numerous other consultations to start-up programs. Heart valve experience includes testing of the Shiley valve failure modes, development of an improved pericardial heart valve, and flow simulation testing of heart valve design.

Biomaterials, Surface Modifications, and Combination Products

Paladin Medical has helped define qualification and validation strategies for new and replacement biomaterials for medical devices, such as silicones and polyurethanes. We've streamlined testing and helped to reduce costs for ISO-10993 by leveraging existing knowledge. We've also helped companies enhance device performance with custom surface modifications and combination drug/device technology. Paladin Medical has extensive experience with surgical mesh used in a wide variety of applications and manufactured from an array of materials, with or without surface modification. We've developed regulatory strategies, defined testing, and shepherded successful clearance of many such products through 510(k) submission.

Bone Graft Substitutes, Restorative Materials and Devices, Implants

Paladin Medical has expertise in orthopedic and dental biomaterial applications, including coatings and bone graft substitutes (like hydroxyapatite and calcium sulfate.) We have provided development and regulatory services to various spinal implant technologies ranging from rods and screws to implantable disc and spinal nucleus devices. Paladin Medical has coordinated a multi-center dental implant clinical trial, as well as clinical studies for bone substitutes leading to successful FDA submissions. Projects in orthopedics have included unique wedge osteotomy devices, intramedullary rod alternatives, and bone growth stimulation, in addition to more conventional orthopedic products.

Electrophysiology – Cardiovascular and Neurological

Paladin Medical experience includes product submissions [PMAs and 510(k)s] for implantable defibrillators and AEDs, pacemakers, leads and electrodes, wearable external pacemakers and electrophysiology stimulators. We are also experienced in the use of pacing systems for congestive heart therapy, bone and muscle electrical stimulation. Paladin Medical led a key project to convert to an alternative biomaterial supplier for a critical component in pacers and defibrillators, including qualification of new manufacturing processes.

Minimally invasive technology

Paladin has served a variety of clients in laparoscopic, arthroscopic, and other minimally invasive technologies, including instruments for spinal disc surgery. Our contributions have included the selection of unique materials and designs, testing requirements, clinical evaluations, reusability protocols, and 510(k) notifications.

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Ophthalmology and Otolaryngology

Paladin Medical has provided services to hearing aid manufacturers for materials, device qualification, and clinical trials. We have also provided expertise in the selection of biomaterials for ophthalmic and otolaryngology products. Elaine Duncan was one of the first in the intraocular lens industry to conduct comparative testing of lenses for optical quality and to recognize this as a critical requirement for clinical outcomes. Ms. Duncan worked on two of the earliest cochlear implant devices and submitted investigational applications to FDA on these early systems.

Powered Mobility, Proshetics and Physical Medicine

Paladin Medical serves this device area with experience in powered stand-up wheel-chairs, physical medicine devices for the home, and new materials for prosthetic interface. We've served the developers of new technologies, and recognize that there are no "dis"abilities, only a lack of sufficient "abilities" to address the needs of the physically impaired.

Safety Syringe

Paladin Medical has successfully cleared several safety syringe products for the US market. These initiatives required coordination between the US importer and the Chinese OUS manufacturers, as well as conducting clinical evaluations in the US.

Software, Electronics, Internet Medicine

Paladin Medical is experienced with cochlear implants, hearing aids, powered wheelchairs, patient monitors, defibrillators, pacemakers and variety of implantable electronic devices – to name a few of the many electronic and software based systems we've championed through the regulatory process. Our experience also includes internet-based medical services and software that supports medical professionals. We have been an effective communicator between the FDA and the software and electrical engineers, ensuring that clients' design, validation, and documentation conforms with FDA and international requirements.

Sterility and Shelf-life Testing

Paladin Medical has experience and expertise in assisting firms with tailoring qualification protocols to product needs. An often overlooked aspect of product qualification is confirmation of product performance after sterilization. Regulatory agencies are placing increasing emphasis on shelf-life testing and expiration-date labeling. We have defined requirements for sterilization validation, determined the potential effects of sterilization processes on products, and designed shelf-life aging and testing protocols. Paladin Medical has also helped clients to qualify new sterilization methods by conduct testing materials and device qualification for pre-market applications.

Urological and Dialysis Catheters

For numerous products in urology and dialysis, Paladin Medical has managed clinical trials, helped refine device specifications, conducted design reviews, submitted filings, and coordinated FDA interactions. Our expertise also includes biomaterials qualification, anti-infective coatings and other surface modifications, and standards conformance testing.

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Vascular Grafts and Stents

Paladin Medical has extensive experience with peripheral vascular graft, coronary artery bypass graft, and stent technology. We have consulted on cell-seeding technology and tissue derived vascular prostheses. Additional related experience in this field includes clinical study start-up training, product readiness planning, device retrieval, and auditing clinical centers for Good Clinical Practices compliance prior to FDA-Bioresearch monitoring.

Other Experience

Other important areas of Paladin Medical experience include:

- Consulting on re-use instructions, sterile tray and sterile package testing, and durability studies.
- Developing cleanroom requirements.
- In-vitro fertilization products and in-vitro diagnostic submissions.
- Early and earnest compliance with Quality System Requirements, including Design Control, and Review implementation and training.

For more details about our many services and customized training, please call us at 715-549-6035 (US), or visit our website at www.paladinmedical.com.

Note: Confidentiality requires that we omit client names from the projects profiled. References are available upon request.