

Developing a Quality System on a Managed Budget

Client

PediaVision

Industry

Medical Device

Business Challenge

Developing a regulatory and quality pathway for a new device.

Project Timeline

Continuous work for 5 years

Background

PediaVision, the inventor of an objective pediatric vision screener, was in need of a quality system surrounding their medical device. The early-stage company had a business plan in place, a solid IP platform and a distribution plan, but they needed a regulatory and quality pathway.

Solution

Regulatory Compliance Associates® Inc. (RCA) provided PediaVision with an overview of the RA and QA requirements and helped PediaVision develop a compliant quality management system. As the company transitioned to manufacturing stage, RCA helped PediaVision implement a CAPA program, a management review process and an internal audit plan.

Results

RCA worked alongside the organization, providing quality management oversight and backfilling their gaps while working within a fixed monthly fee. This enabled PediaVision to scale the company on a managed budget while meeting quality and regulatory standards.

“We would absolutely recommend RCA to set up and manage a quality system. We couldn’t afford to hire personnel with RCA’s expertise and our engagement allows us to tap into their experts as needed while we focus on growing the company.”

