Test Method Development Project

Background

A large multinational medical device company was challenged with developing a second generation endoscopy device and bringing the device to the market with an accelerated timeline. While the employees of the group were still in the development phase of the project, a resource shortage was identified to begin work on the test methods that would be needed to complete design verification testing.

Objective

Test method development to verify the device design met the product specification requirements needed to begin for a challenging medical device that utilized a hand-held scope with an imbedded camera and a separate controller system to visualize the images captured by the device. The employees of the company had limited knowledge of test method development, specifically test methods for a visual control system.

Enhanced Compliance Engagement

Numerous test method experts were deployed to augment the teams over a 7-month engagement. The project team supported the test method development of the two-part device with the following tasks and activities:

- Identification of 78 controller specifications requiring test methods.
- Identification of 48 hand-held device specifications requiring test methods.
- Creation of tracking sheets to organize the entire test method development project.
- Update of Product Specifications as required.
- Creation of rationales where test methods were able to be leveraged from existing devices.
- Creation of Product /Manufacturing Fixture /Testing Fixtures.
- Release of fixtures for TM use into the company's asset system.
- Validation of equipment (with software) utilized in specific test methods.

Result

All test method development was completed for the company's new device. The project was completed on time and within budget. The consulting team was then engaged on another 6-month project to complete test method validation for the new test methods, ensuring that the timeline to move into design verification testing would be achievable.