## Test Method Validation (TMV)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 Method Validation that would be needed to complete design verification testing.

### Objective

The test methods used to perform the design verification testing are required to be validated. The test methods required to be validated were needed for a challenging medical device that utilized a hand-held scope with an imbedded camera, a separate controller system, and a sterile single use disposable device. The employees of the company had limited knowledge of complex test method's validation.

### Enhanced Compliance Engagement

Numerous test method validation experts were deployed to augment the teams over a 10-months engagement. The project team supported the test method validation with the following tasks and activities:

- Identification of 51 test methods (TMs) requiring Test Method Validation.
- Identified Variable and Attribute TMs and grouped them separately.
- Further identified variable destructive and non-destructive TMs.
- Creation of tracking sheets to organize the entire test method validation project.
- Considered following TMV approaches based on the type of TMs:
    - Report only approach for Standard based TMs
    - Gage Repeatability and Reproducibility (Gage R&R) study approach.
    - Process Capability study approach.
    - Correlation study approach.
    - Self-evident approach.
    - Attribute TMV approach
- Designed and qualified testing fixtures.
- Performed feasibility studies.
- Updated TMs.
- Drafted and release TMV protocols
- TMV protocol execution.
- Failure Investigations when applicable.
- Drafted and release TMV reports
- Update and release TMs.

### Result

All test method validation was completed for the company's new device. The project was completed on time and within budget ensuring that the timeline to move into design verification testing would be achievable.