

5 Tips to Improve Quality of Medical Devices

Author : Dev Raheja



1. Validating Usage Requirements

The best method for validating usage requirements is to use formal statistical tools to translate customer requirements into accurate technical specifications or use panels of medical device experts, academics and leading physicians to achieve the same.

2. Software Development

Update all software's and develop new software's for devices. Do away with outdated software's, adding patches and workarounds to these systems often increases the chances of failure. For example, a robotic surgery device was affected by unintentional performance issues due to software fixes that were implemented to address a different problem altogether.

3. Post Production Monitoring

One critical factor in improving quality of medical device is post-production monitoring and feedback of field learning to improve design and manufacturing processes. In order to overcome this crisis, use predictive analytics to build field performance predictor models before production and marketing, which are subsequently refined based on actual performance.

4. Supplier Management

Risks are basically around uncontrolled material or process changes, especially when suppliers have an imperfect understanding of how their components influence end-product quality. In order to overcome this, carefully select the suppliers with the help of an internal quality organization, and identify vendors who deal with the most serious aspects of their product and invest greatly in training and monitoring them.

5. Limitations in Quality Metrics

There are a lot of benefits if you define quality metrics early in the design stage. Quality metrics at the design stage permits focused resources on the gravest elements downstream in the value chain, especially while managing supplier quality. Tracking metrics are also a key success factor in driving an effective mindset around quality.

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