

## Doing It Once!

Based on its Doing It Once! philosophy, QNET's FDA regulatory experts develop a project plan for its clients that includes the use of existing information such as CE technical file documentation to get your devices on the US market.

QNET's FDA experts have established a track record assisting clients achieve FDA clearance on schedule and keeping the amount of technical documentation to a minimum.

## Doing It Once!

### CONTACT QNET TODAY:

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#### In the USA

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## QNET LLC US FDA Consulting Services



# QNET LLC



QNET LLC offers an affordable and practical approach for small and medium size medical device manufacturers desiring to enter the US market through its:

## Comprehensive FDA Consulting Services In Four Modules

### MODULE A:

#### DEVICE CLASSIFICATION

Assist client in finding the regulation number for their device among the 1,700 established FDA generic types of devices. The correct regulation number is used to determine device classification and whether exemptions from pre-market notification or parts of the Quality System Regulation (QSR) apply.



Medical devices in the US are assigned to one of three regulatory classes based on the level of control needed to assure safety and effectiveness of the device.

### MODULE B: MARKETING CLEARANCE—510(k) PREPARATION AND SUBMISSION

Identify devices already on

The US market that may be used as predicate devices based on equivalent intended use and technological characteristics. Determine the type of 510(k) that needs to be filed:

1. Special 510(k)
2. Abbreviated 510(k) or
3. Traditional 510(k).

Work with client to properly document the 510(k) application and submit for acceptance.

Assist client in responding to any application deficiencies

cited by the FDA

### MODULE C: QUALITY SYSTEM REGULATION (QSR)

Assist ISO 13485 certified manufacturers to identify and fill the gaps between ISO 13485 and QSR Quality Management systems.

### MODULE D: US AGENT SERVICES

Act on behalf of NON-US medical device manufacturers in accordance with US FDA regulation 21 CFR 807.40.

## QNET LLC Objectives and Deliverables

- Determination of correct regulation and device code.
- Planning the content, documentation required for a 510(k) submission.
- Properly written 510(k) and submission for FDA review.
- Responses to any deficiencies cited by the FDA.
- QSR gap analysis and compliance.
- Compliance with FDA Regulation 21 CFR 807.40 by acting as your FDA US Agent, on behalf of NON-US manufacturers.

