



**BUSINESS INTELLIGENCE SOLUTIONS**

Quality Management Systems  
for FDA Regulated Industries

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## What Can You Control Under the New 510(k) Process



## Leveraging What You Can Control Under the New 510(k) Process

For medical device companies the looming changes to the 510(k) program requires compliance with all FDA regulations to continue selling their products in the USA.

The 510(k) process and regulations apply to most Class II medical devices sold in the US and a small number of Class I and Class III devices as well. The FDA can visit your facility at any time to conduct an inspection to ensure you are in compliance with Quality Systems Regulation (QSR).

Since the only certainty about the 510(k) review process for the foreseeable future is uncertainty, now is the perfect time for companies to gain competitive advantage by leveraging what they can control.

The 510(k) review process presents an opportunity for companies to streamline and automate critical internal processes to ensure that compliance is maintained with minimal impact on R&D and other facets of the business.

Companies are pressed to taking a hard look inside their own houses to determine where new improvements can be made to their quality and compliance operations because of staffing, training and outdated standard operating procedures.

How can companies in the industry make additional investments in quality systems, ensuring that critical processes are automated and running with the utmost efficiency and effectiveness when staff has been cut and other resources are scarce?

When a deviation occurs in the manufacturing process, are you prepared to track, collect and report the necessary data to the FDA?

Do you have closed-loop processes in place to effectively resolve and report customer complaints? Are you effectively set up to comply with the electronic reporting (eMDR) mandate?

What improvements can you be making in these and other processes that will enable you to divert resources to innovation that would otherwise be spent scrambling to comply with the FDA after the fact?

Regulatory compliance under 510(k) will be a challenge and device companies should look for new opportunities to take stock of their current quality systems and pinpoint where investments can be made to ensure greater compliance with changing regulations.

In doing so, companies can streamline and automate critical processes, giving them the ability to continue innovating in the face of increased regulation.

**Business Intelligence Solutions** offers very practical steps on how to implement some of the sweeping changes in the mindset that smart drug and medical device manufacturing require, in bite-sized steps.

**Medical Devices/IVDs:** Our staff of FDA consultants can prepare and implement the entire system or advice on a specific subsystem to meet the FDA QSR compliance (21 CFR 820: Quality System Regulation).

Our quality system program for medical device and IVD manufacturers focus on the proper implementation and sustainability of the following seven major subsystems:

- 1) Management Controls
  - 2) Design Control
  - 3) Corrective and Preventive Action (CAPA)
  - 4) Production and Process Controls
  - 5) Document Controls
  - 6) Purchasing and Material Controls
  - 7) Facility and Equipment Controls
- \*Medical Device Reporting- 21CFR Part 803

If you have specific project needs and would like to speak with a member of our staff, please use the **Contact Us** form so we can assign the right expertise for further discussion. If you wish to speak to us immediately **call 1 800 782 0580**.

Information on additional key resources and professional services can be found at **Business Intelligence Solutions**

