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Quality by design through integrated quality processes

It's an age-old debate. Which is preferable? Siemens PLM Software asks: why not both?

In the medical device design and manufacturing industries, quantity (also known as revenue or wealth) is typically the winner, as sales figures and bottom-line increases drive decision making at the executive level.

And while making money is always the primary goal, shouldn't other factors be considered? In a field in which patient health and well-being is the ultimate result, shouldn't we be defining value in a different light?

What is value?

In the most strict, traditional sense, value is increased by maximizing shareholder wealth.

However, shouldn't we consider a more modern definition? Perhaps maximizing all elements of wealth and health?

In the quest for highest quality and best-in-class status, shouldn't value include both quality and quantity?

Value equals:
Quality + Quantity

Healthy, wealthy and wise.

Quality noun – qual·i·ty – \kwä-li-tē\

1. The result of ensuring that features and characteristics of a product that define its ability to consistently satisfy customer needs are realized, and the products:

a. Are safe, effective and provide usability
b. Achieve desired uniformity, reliability and performance
c. Satisfy customer and user requirements and expectations regarding design, production, delivery and service

(Source: AdvaMed, Case for Quality – Library of Successful Quality Practices for Medical Devices)

If early-stage manufacturing processes are driving success, then addressing organizational value in terms of overall quality and well-being is imperative. Identifying and correcting issues during the initial product lifecycle and via a designed-in approach becomes paramount.

Quality goes beyond compliance

(Source: United States Food and Drug Administration (FDA), 21 Code of Federal Regulations (CFR), Part 820)

"...the belief that quality should be designed – not tested – into the final product, including its manufacturing processes...this results in fewer compliance problems because a manufacturer addresses problems before they exist, and more systematically when they occur."

(Source: Alexander Gaffney, "EMA, FDA Publish New Guidance on Adhering to Quality by Design Principles" April 2013)

By adopting cross-industry best practices in quality assurance, the medical industry could improve patient outcomes, capture $5-to-6 billion in incremental earnings before interest, taxes and amortization (EBITA) and reduce risk.

Modern practices in quality assurance could lead to a 10-to-15 percent increase in the earnings of medical device companies, and even more in the years ahead.

(Source: McKinnsey & Company)

Real-world value – what cost quality?

The immediate costs:
The daily dollar and immediate cost of goods.

By implementing a manufacturing execution system (MES), in one day alone early-stage quality processes could save a medical device organization hundreds of thousands of dollars in scrapped materials.

The overall costs:
Product recalls can cost millions of dollars.

According to the FDA, product recalls have increased 2X over the last 10 years, with a 50 percent increase in the last four years.

The actual costs:
The cost of patient health and the general population's well-being.
Priceless.

Can you afford noncompliance? Can you afford to not recognize the real value of quality?

The cost of noncompliance can be millions.
Historically, the FDA has evaluated manufacturer compliance with regulatory mandates. Today, the FDA treats compliance as a baseline. Quality goes beyond compliance. (Source: FDA, 21 CFR, 820)

Fines, labor fees, recalls, lost revenues, out of stocks...there is no debate.

Noncompliance is costly.

Have you had your aha moment?

aha moment noun – a·ha mo·ment

A moment of sudden realization, inspiration, insight, recognition, or comprehension

(Soure: Merriam Webster Dictionary)

According to an Aberdeen Group research report, embedding quality and design-in processes can lead to a reduction in failure costs by more than **50%**, and the overall cost of quality by **8%**.

(Source: www.Aberdeen.com)

Integrated quality solutions can offer significant business benefits:

Increase operating margins **25%** and reduce failure costs by **29%**

(source: www.Aberdeen.com)

Increase bottom line by **10** to **15%**

(source: www.mckinsey.com)

So what does this mean?
Integrated quality through quality by design = Top-quality products + high-quantity dollars.

THIS is your aha moment! When you realize that you can have it all.

For additional information about the Siemens PLM Software Integrated Quality solution for the medical device industry, please visit:
www.plm.automation.siemens.com/en_us/medical-devices-pharmaceuticals/integrated-quality

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