



**Survey Results on  
The Structure of Medical Device Firms'  
Quality/Regulatory/Compliance Functions**

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## Introduction

Throughout my career (as a prosecutor, educator, lawyer in private practice, and trade association advocate), I have met many professionals in the health care industry. They have told me that they would like a mechanism to benchmark best practices for building a quality organization.

My company, Compliance-Alliance, collaborates with knowledgeable experts to create surveys on how companies are setting up their procedures for regulatory compliance. We ask professionals in device and drug firms to complete the surveys, and then we disseminate the results.

My goal is that people will use the data to convince their management to provide them with the necessary support to construct quality organizations that produce safe and effective health care products.

The purpose of this survey on the "The Structure of Medical Device Firms' Quality/Regulatory/Compliance Functions" was to find out about the internal organization of medical device firms. The results indicate that although many professionals have the resources and authority to do their jobs, some do not.

I believe that an ideal organization should have the following structure:

- 1) If the firm has many divisions and a corporate headquarters, the corporate staff should have oversight of the regulatory compliance activities of the divisions. FDA will hold all of the divisions accountable for fixing discrepancies found at any location. Corporate staff needs the authority to institute corrective and preventive actions throughout the company.
- 2) The top officials for quality, regulatory and compliance should be at the vice president level, equal in seniority to other officials in staff positions.
- 3) The top quality and compliance officials should report to the president and periodically address the board of directors.
- 4) All firms need to measure the cost of poor quality and invest sufficient resources in preventive action.
- 5) Firms need to embrace risk management and utilize its concepts throughout their quality, regulatory, and decision-making processes.

The next seven pages contain the survey results. I have summarized the data and asked the following people to provide comments:

- Denise Dion, Regulatory Consultant, EduQuest, (formerly with FDA),
- Ken Imler, Senior Vice President for RA/QA, Arrow International,
- Steve Ojala, Vice President RA/QA Zimmer, and
- Tim Wells, President of The QualityHub, Inc. (formerly with CDRH).

## Demographics

Two hundred and fifty eight (258) professionals in medical device firms completed the survey. Respondents represented firms of various sizes that manufacture medical devices in class I, II and III. With the exception of the number of personnel employed in specific functions, there were no significant differences among the answers based on the size of the firm. For a breakdown of the number of personnel employed in various functions, see Appendix 1.

### 1. Organization of Quality/Regulatory/Compliance Function

Approximately half of the firms organized their quality/regulatory/compliance function locally by manufacturing site, while the other half had corporate oversight for these functions.

#### Comments:

- Corporate must have oversight responsibilities and direct responsibility for QA and RA. Corporate is the umbrella over all other systems and facilities. - *Ken Imler, Arrow International*
- In large firms, any given manufacturing site quality system should have a definite mechanism for assuring the site complies with corporate quality policies. FDA will hold headquarters management accountable/responsible for site failures. Corporate management reviews should include assessments of site quality functions. - *Denise Dion, EduQuest*

### 2. Responsibilities

There was variation among the responses about who was the responsible party for each function. The most common responses indicate that

- **Quality has responsibility for** CAPA management, document control, equipment calibration, external audits, final inspection, incoming inspection of raw material, in process inspection, internal quality audits, management representative, product and GMP audits, product complaint management, product releases, process validation, risk management, sterilization, supplier program management, and supplier qualification.
- **Regulatory has responsibility for** adverse event reporting, annual product releases, facility registration and licenses, production registration and certification, product regulatory submissions, and recalls.
- **Compliance/other groups have responsibility for** business code of conduct, environmental program management, health and safety program management, preventive maintenance, and training.

#### Comments:

- In addition to the items others have listed, my experience has been that the most effective QA and RA groups have a major role in establishing, maintaining and continuously improving metrics,

monitoring and reporting of quality data. The key areas are NCMR, CAPA, complaints/MDR/field actions, change management, risk management, and management responsibility. This does not exclude other areas; these are the primary areas. - *Ken Imber, Arrow International*

- Having separate functions for quality, regulatory and compliance is normal. The management representative should have a mechanism to be informed of all quality issues, no matter what department he/she is part of. It is also important to assure quality remains independent of production (or R&D in design only) facilities. - *Denise Dion, EduQuest*

### 3. Reporting Structures

The respondents described various reporting structures with

- 41% of quality/regulatory/compliance groups reporting to a **single point of control** and
- 28% of quality, regulatory and compliance groups having **independent** reporting structures.

#### Comments:

- There are as many ways to do this as there are companies. The goal is to have a structure that allows effective, efficient and timely oversight and control. The most effective companies I have seen have independent facility RA, QA and Compliance groups with a common corporate oversight group that establishes and maintains consistency. - *Ken Imler, Arrow International*
- I am surprised that so few organizations have a single point of control. I would prefer to see more central control. - *Tim Wells, The QualityHub*

### 4. Top Official

There was a wide variation as to the title of the top of official for the quality, regulatory, quality/regulatory and compliance functions. The most common title was vice president or senior vice president.

#### Comments:

- The major issue here is that the top QA, RA and compliance person is at the same level as the top finance, marketing, R&D, etc. executives. - *Ken Imber, Arrow International*
- It is important that the quality organization have similar titles as that used in the production or manufacturing organization. These organizations should be viewed as peers. - *Denise Dion, EduQuest*
- I concur that this needs to be VP level. In fact Senior VP is appropriate for the larger companies. - *Tim Wells, The QualityHub*

### 5. Reporting Relationships

Most of the respondents reported that their quality, regulatory, and compliance officials report directly to the president.

#### Comments:

- Quality, regulatory and compliance are senior management responsibilities and should be recognized as such. - *Steve Ojala, Zimmer Corporation*
- In my opinion, companies where quality and compliance functions do not report to the president are often the same companies facing compliance actions by FDA. It is essential that quality report to the CEO/President. This assures independence as well as access to resources. - *Tim Wells, QualityHub*

### **6. Reporting to the Board of Directors**

A majority of firms (59%) had their senior quality/regulatory/compliance functions periodically report to the Board of Directors.

#### Comments:

- Focused quality companies provide regular updates to the Board of Directors. - *Steve Ojala, Zimmer Corporation*
- Since the Board of Directors can also be held responsible for quality system deficiencies, they should be aware through management reviews of quality problems. - *Denise Dion, EduQuest*

### **7. Ability to Stop Production and Order a Product Recall**

Most respondents (91%) reported that their firms allow their top quality/regulatory personnel to stop production or order a recall.

#### Comments:

- All world-class quality companies empower the quality and regulatory functions to stop production or initiate a recall. - *Steve Ojala, Zimmer Corporation*
- This is a positive trend that should be reinforced. - *Denise Dion, EduQuest*

### **8. Scope of the Regulatory Function**

A majority of firms (67%) reported that the regulatory function was responsible for product submissions, compliance to QSR, **and** ISO13485; while 37% reported that the regulatory function was **only** responsible for product registrations and licenses.

#### Comments:

- Depending on the size and structure of the organization, this can be combined or separated. In either case, the functions must communicate and coordinate their activities. - *Ken Imber, Arrow International*
- Regulatory and quality are almost inseparable functions that need to be tightly coordinated to be effective. - *Steve Ojala, Zimmer Corporation*

- I am seeing more and more separation of the quality and regulatory functions. Unless the company is quite small, I would not recommend combining responsibilities. It spreads the manager too thin. - *Tim Wells, The QualityHub*

## 9. Commitment to Quality/Regulatory Compliance

When asked about commitment to quality/regulatory compliance,

- 27% reported that their firms strive to be the best in industry,
- 62% reported that their firms wanted to assure product safety and efficacy, and essential quality system compliance, and
- 7% reported wanting to minimally meet the requirements.

### Comments:

- This is also an “it depends” situation. All companies should strive to be “state of the art.” Best in class and world class efforts may be beyond many companies’ ability to achieve. The investment is too great in terms of people, resources and capital. - *Ken Imler, Arrow International*
- “Best in the business and an attractive place to work” is an attractive vision for me. - *Steve Ojala, Zimmer Corporation*
- The goal for products, processes, and systems should be perfection. A company that strives to be the best in quality shows a true understanding of the reason for having a quality system. Perfection will never be reached, but moving in that direction is why we control design, manufacturing and changes, and utilize a feedback loop (CAPA). - *Denise Dion, EduQuest*
- I am disappointed that any company would be in this business and strive for only meeting minimal requirements. - *Tim Wells, The QualityHub*

## 10. Performance of Quality/Regulatory/Compliance Function

When asked about how they would characterize the performance of their quality/regulatory/compliance function,

- 17% reported that they were among the best in the industry,
- 59% of respondents reported that they had strong performance (few to no major nonconformities),
- 21% reported mediocre performance (some major nonconformities in some areas), and
- 3% reported weak performance (major nonconformities).

### Comments:

- The brutal facts are that only a small percentage is truly among the best. Most are in the average/competent range and a few are not effective. The problem is that many of the average/competent companies fail to recognize and accept their true status and therefore fail to make the investments (people, infrastructure, systems) required to reach and

maintain “state of the art” let alone continuous improvements. - *Ken Imler, Arrow International*

- If you believe your quality system needs an overhaul, take the time to look at your policies, procedures and actual practices as part of a failure investigation. Flowchart your systems and your processes. Use technical writers to write your procedures to assure they are concise and well written and not ambiguous. Make sure your flow charts for each process or subsystem flow together to form a complete quality system. The time spent in developing systems and processes that are complete, easy to follow/implement and comply with is time well spent. - *Denise Dion, EduQuest*

### **11. Measuring the Cost of Poor Quality**

The majority of firms (53%) are not measuring the cost of poor quality (the cost of internal and external failures, appraisal, and preventive action).

#### Comments:

- The “Cost of Quality” is a metric that all good companies should utilize. How can you measure effectiveness and efficiency without it? It must include the price of conformance as well as the price of nonconformance. It can be just as important to lower the price of conformance as the price of nonconformance. - *Ken Imler, Arrow International*
- The “Price of Non-Conformance” was one of the four absolutes that Phil Crosby promoted in his fundamental overview of Quality, which is still relevant today. *Steve Ojala, Zimmer Corporation*
- When nothing bad is happening, how do we convince management that it is because of our good quality system? We need to show how good quality has increased our market share, decreased our inspection times, reduced our nonconformities, increased our yields, reduced costs of purchased products, etc. - *Denise Dion, EduQuest*

### **12. Use of Risk Management Principles in the Quality System**

The majority of firms are using risk management principles throughout their quality system.

- 94% design control,
- 72% CAPA,
- 89% complaint management,
- 50% management review, and
- 54% process control.

#### Comments:

- Risk management principles need to be utilized throughout the life cycle of the product, as it is a dynamic process, not simply a design control tool. - *Steve Ojala, Zimmer Corporation*

- Using risk to help us make better decisions will assure that we spend our resources wisely. But only if quality is part of our risk decisions, not just cost/benefit issues. *Denise Dion, EduQuest*
- These numbers are good, but I think they should be higher. Risk management is huge. Clearly it is not just needed for design control. The FDA stated in the QSR preamble that risk management should also be used in CAPA. It also is essential in production and process control. It is worth noting that the FDA used the word "risk" close to 50 times in the QSR preamble. - *Tim Wells, The QualityHub*

Appendix 1

**Mean Number of Personnel Employed by Various Functions**

Number of Employees	Quality (FTE)	Regulatory (FTE)	Compliance (FTE)
1 - 100	1 - 5	1 - 5	1 - 5
101 - 500	6 - 10	1 - 5	1 - 5
501 - 1,000	6 - 50	1 - 5	1 - 5
1,001 - 5,000	Over 50	1 - 5	1 - 5
5,001 - 10,000	Over 50	16 - 25	16 - 25
Over 10,001	Over 50	Over 50	Over 50

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