



MEDICAL DEVICE SEMINAR

“INTERACTING AND AVOIDING PROBLEMS WITH FDA”

COMMON DEVICE COMPANY PITFALLS – HOW TO AVOID THEM

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INTRODUCTION

- Most medical device firms intend to comply with FDA requirements.
- But best intentions are not always enough.
- Device companies can fall into practices and policies which undercut their FDA regulatory compliance efforts.
- They often miss or forego important compliance steps due to corporate culture, historical company approaches to addressing FDA regulatory issues, or simply lack of knowledge or training.



INTRODUCTION

- This presentation will identify common pitfalls in FDA regulatory compliance efforts which befall medical device firms.
- It also will address how and why they occur.
- It also will recommend steps to avoid the pitfalls.



PITFALL NO. 1 – “RA/QA MOONLIGHTING”

- Corporate culture and historical company practices often do not focus or place enough importance on FDA regulatory matters.
- This can occur relative to FDA’s Quality System Regulation (QSR) requirements, as well as other medical device “general controls” such as Medical Device Reporting (MDR) or premarket review (PMA or 510(k)) requirements.
- It often starts at the top with executive management.



PITFALL NO. 1 – “RA/QA MOONLIGHTING” (continued)

- This lack of attention or emphasis at the executive management level can lead to:
 - RA/QA understaffing – Not enough individuals devoted to FDA regulatory and quality functions.
 - Personnel with other primary job descriptions (engineer, sales rep., etc.) attempting to oversee and execute FDA regulatory and quality functions in their “spare” time.



PITFALL NO. 1 – “RA/QA MOONLIGHTING” (continued)

- Personnel from within the company being promoted to RA and/or QA managerial positions without the requisite knowledge and background.
- RA/QA managers without the requisite support and backing from executive management to assert appropriate power and control company-wide as necessary on FDA compliance matters.



PITFALL NO. 1 – “RA/QA MOONLIGHTING” (continued)

- The consequences can be significant:
 - Bad regulatory or quality compliance decisions due to inexperience, lack of authority, or lack of time to analyze issues properly.
- Which in turn can lead to:
 - Noncompliance risks and problems.
 - The possibility of FDA enforcement action, the need for recalls, bad publicity with your customer base and others, increased product liability exposure, etc.



PITFALL NO. 1 – “RA/QA MOONLIGHTING” (continued)

- Avoid this pitfall by:
 - Appropriate FDA education and training for executive management.
 - Hiring enough and appropriately experienced people to carry out FDA RA and QA functions, especially for managerial positions.
 - Provide personnel carrying out RA and/or QA functions with appropriate FDA education and training as well, specifically tailored to their functions.



PITFALL NO. 1 – “RA/QA MOONLIGHTING”

(continued)

- Empower RA/QA management within the company so they can succeed.
- Take “management review” responsibilities under the QSR seriously!



PITFALL NO. 2 – “THE PROCEDURAL PREDICAMENT”

- In many ways, standard operating procedures are the life-blood of an FDA-regulated device firm.
- They are the “how to” for implementing company practices which comply with FDA statutes and regulations.
- FDA requires written procedures in certain “general control” areas, including QSR and MDR.



PITFALL NO. 2 – “THE PROCEDURAL PREDICAMENT” (continued)

- Most device firms create and adopt written procedures in required and other areas with the intention of standardizing and controlling their FDA regulatory and quality systems.
- But having written procedures in place can lead to problems if they are not utilized properly.
- Firms may not refer and adhere to their procedures over time, developing informal and unwritten “day-to-day” practices for handling FDA regulatory and quality matters.



PITFALL NO. 2 – “THE PROCEDURAL PREDICAMENT” (continued)

- Firms also may not review and update their procedures to account for their changing and evolving practices or to address changes in the law.



PITFALL NO. 2 – “THE PROCEDURAL PREDICAMENT” (continued)

- These failings can lead to:
 - Inadequately controlled daily practices which vary from established procedures and may be inconsistent with the law; or
 - Outdated or non-compliant written procedures which do not reflect current company practice and possibly FDA law.
- FDA will often cite device firms for not following their own established procedures or for non-compliant procedures during establishment inspections.



PITFALL NO. 2 – “THE PROCEDURAL PREDICAMENT” (continued)

- To avoid this pitfall:
 - Do not treat your procedures as “pro forma” or static documents but instead as “living” documents which need to grow with the company, its FDA-related systems and the law.
 - Audit to your procedures to ensure consistency between written requirements and actual daily practice.



PITFALL NO. 2 – “THE PROCEDURAL PREDICAMENT” (continued)

- Periodically review and challenge your procedures for the need for refinement and improvement as your company and its practices/policies change and evolve.
- Keep abreast of changes in FDA law (and policy) so these developments can be accounted for⁵



PITFALL NO. 3 – “WAITING TOO LONG”

- For device firms, FDA regulatory and quality issues impact and affect many of their business activities and initiatives.
- As such, it makes good “business” sense to factor FDA issues into business planning and development at an early stage in the process so that the issues can be addressed efficiently without causing later problems or delays.
- Yet many device companies wait too long to factor FDA regulatory and quality considerations into their initiatives.



PITFALL NO. 3 –
“WAITING TOO LONG”
(continued)

- This “waiting” can lead to completely missing or foregoing a compliance step, taking too much risk, or delays in or derailment of business plans.



PITFALL NO. 3 – “WAITING TOO LONG” (continued)

- To avoid this timing issue, build FDA regulatory and quality issues or steps into initial business plans and projects and estimate times for completion.
- Have procedures which require business plans and projects to be assessed early as to the need for FDA compliance steps.
- Procedures should be developed for company initiatives with FDA regulatory or quality implications such as product launches, product design modifications, development or modification of labeling and promotional materials, site relocations, use of new suppliers or contract manufacturers, etc.



PITFALL NO. 3 – “WAITING TOO LONG” (continued)

- To avoid this timing issue in the M&A or product line purchase context:
 - Engage in FDA regulatory “due diligence” as early in the process as possible.
 - Do not rely on the target’s “say so;” independently review and challenge through questions, interviews, document requests and audits as early as possible.
 - Involve appropriately skilled and experienced personnel to do the “due diligence” assessment from the start.



PITFALL NO. 4 – “WHAT’S THE PROBLEM?”

- Most medical device firms have procedures in place for complaint handling, MDR, and corrective and preventive action (CAPA) to comply with FDA requirements in these areas.
- However, too many firms simply go through the motions and the “paperwork” of complaint handling, MDR, and CAPA without actually identifying the root cause of problems leading to complaints, MDRs and CAPAs.
- They do not identify the root cause to the objective level necessary to take effective CAPA to eliminate or minimize the chance of recurrence.



PITFALL NO. 4 – “WHAT’S THE PROBLEM?” (continued)

- Lack of appropriate root cause analysis can lead to:
 - Non-identification and continuance of design, manufacturing and/or other QSR deficiencies.
 - Which in turn can lead to:
 - FDA enforcement action or recalls.
 - Loss of customer confidence in the product.
 - Increased product liability exposure.



PITFALL NO. 4 – “WHAT’S THE PROBLEM?” (continued)

- To avoid these problems:
 - Give failure/root cause analysis of product problems the proper emphasis within the company.
 - Too many device firms do not devote sufficient time and resources to it, instead overly favoring other interests such as product development or new production and sales.
 - Too many device firms emphasize product replacement/repair without further problem analysis or stop short in their analysis.



PITFALL NO. 4 – “WHAT’S THE PROBLEM?”

(continued)

- Establish appropriate failure investigation procedures which delineate the proper steps to be followed to achieve the most specific and objective root cause analysis possible.



PITFALL NO. 5 – “LISTENING TOO LITTLE (OR TOO MUCH)”

- Too many device firms forge ahead with FDA-related projects or steps without all the relevant facts, i.e., without doing their “homework” on the applicable FDA laws or policies.
- This can lead to uninformed decisionmaking, suboptimal strategies or simply wrong conclusions.
- Device firms need to research the relevant laws and policies, and even discuss issues with FDA officials (e.g., CDRH Office of Compliance or Office of Device Evaluation) so that they can make the best informed decisions.



PITFALL NO. 5 – “LISTENING TOO LITTLE (OR TOO MUCH)” (continued)

- On the flip side though, some firms can at times too blindly follow FDA pronouncements, policies or interpretative dictates without challenging them where they are questionable and do not have the force and effect of law.
- Other legitimate legal positions may exist.
- Firms need to challenge where appropriate so that again they can make the most informed and educated decisions.



PITFALL NO. 5 – “LISTENING TOO LITTLE (OR TOO MUCH)” (continued)

- Finally, challenging does not necessarily mean not following FDA’s recommendation, but it allows a firm to better assess how aggressive or conservative it wants to be on a particular matter based on the follow-up dialogue with the Agency.



CONCLUSION

QUESTIONS?



HOW TO HANDLE
THE FDA

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Preparation Prior To Communication

- Understand issue(s)
- Outline key facts
- Identify goal(s)
- Prepare to present in less time
- Anticipate FDA responses
- Draft outline for FDA



Subjects To Be Discussed

- ODE
 - IDE
 - 510(k)
 - PMA
 - Combination Product
- CDRH Compliance
 - FDA 483
 - QSR
 - MDR
 - 806/recall



Subjects To Be Discussed (Cont.)

- Warning Letter/Untitled
 - QSR
 - MDR
 - 806/recall
 - Seizure
 - Labeling/advertising/promotion
 - Injunction
 - Civil penalties
 - Mandatory recall
- Trade Complaint



Subjects To Be Discussed (Cont.)

- Field
 - FD 483
 - Warning Letter
 - Legal actions
 - Trade complaint



Types Of FDA Personnel To Communicate With

- Types of FDA personnel to communicate with CDRH
 - Field
 - Headquarters



Modes Of Communication

- E-mail
- Letter
- Phone
- Conference Call
- Meeting



Common Questions/Issues

- Who should contact FDA?
- What role should company personnel play?
- Do lawyers help or hurt?
- What works best – honey, vinegar, or sweet and sour?
- What about political pressure?



Human Factors

- Different approaches for different people