



# HOW TO WRITE TO REGULATORY AGENCIES WHEN THINGS GO WRONG

## YOUR ESSENTIAL GUIDANCE

by Martin Lush

### THE STORY SO FAR

It's Friday, it's late and you are just leaving for the weekend. The inspection you hosted two weeks ago remains a painful memory. The exit meeting didn't go well. There were five major observations all relating to your quality system. When your boss enters your office, you know it's not to wish you a good weekend. She looks stressed, anxious and keen to offload a big problem.

"We've received the regulator's audit report. We now have one critical and seven majors, and we have 15 days to respond in writing. Our license to operate is at risk. Please cancel your weekend. I need the draft response by Tuesday."

### SO WHAT DO YOU DO?

Firstly, acknowledge receipt of the report immediately. Always be respectful and polite, never defensive or officious. Keep this immediate communication short and to the point. Commit to providing a full and comprehensive response within the permitted time frame. Emphasize your total commitment to fix the underlying causes and to address any immediate risks... and then leave for the weekend! This is not a frivolous point. So many responses are written by people who are tired, stressed and just not thinking straight.

#### **When putting anything in writing, imagine you are the regulator.**

In writing the audit report, the regulator is (subconsciously) expressing two emotions. Fear over patient safety and/or lack of trust and confidence in your company. Your primary objective is to reduce both fears and engage in a dialogue that seeks to rebuild credibility.



**Fear:** The auditor's primary objective is to safeguard public health. A damaging audit report means they have concerns about your company's ability to manufacture products that are safe, efficacious and of the right quality. This may be due to specific observations or just a feeling that systems, procedures or practices are not in a state of control.

**Lack of trust and confidence:** Poor inspections quickly erode trust and confidence between the regulator and your company. The relationship between company and agency has been badly damaged. Remember, auditors are human! Although good auditors base conclusions on facts, emotions (gut feel) will play an important part in how they perceive your company, your leadership and your quality culture. This is not a precise process and cultural differences can often sabotage good intent. These cultural differences can easily lead to miscommunication and misunderstanding that then create the gut feeling of distrust.



## Doing any of the following during an inspection will erode trust:

- > Not answering questions clearly
- > Not providing documents quickly or using delaying tactics in general
- > Attempting to justify bad practices using risk assessment
- > Appearing to hide bad data
- > Not being transparent
- > Putting barriers in front of the inspector (making their life tough!)
- > Management answering all of the questions

## So, when responding to regulatory criticism, remember:

- > Your primary objective is to rebuild trust and remove fear. Don't just focus on providing data and information
- > Accept that rebuilding trust and removing fear takes time, often years. Be consistent and genuine in your messaging. Don't attempt to fake it
- > Even if you feel that you have been ill-treated or misunderstood, or the inspector was just having a bad day, remember the perception of the inspector is their reality, particularly when it's in writing! Companies who feel victimized or unfairly treated often respond emotionally, making the situation worse

## Before writing to the regulators, remember the essentials:

- > Speed is of the essence. Make it clear which actions you will take immediately to protect patient safety. Be thorough in justifying why some products and markets are at risk and others are not
- > Don't just rely on words; phone calls and face-to-face meetings are always better
- > Choose your words carefully. If you were misunderstood once, it can happen again!

- > Less is more. Make sure your response is easy to understand and easy to navigate. Regulators are busy people. Your response may be the center of your universe but it is not the same for them! A response that is simple to read and understand, and which conveys your desire to rebuild trust and respect by delivering what is needed, will be well received
- > Make sure your response is credible and that the resources and financial investment required will be made available. Fixing big problems without investment is not credible. Attempting to fix problems with the same thinking that created them will not be well received
- > Convey the support and active engagement of your senior leadership. Their involvement must be front and center stage. After all, they are ultimately responsible



## Never ever:

- > Openly disagree with the auditor's findings
- > State that you've been audited by other regulatory agencies who gave you a clean bill of health
- > Respond only to single observations and ignore the big picture
- > Treat the symptoms, not the cause. If you find yourself including statements such as 'SOP rewritten,' or 'policy document updated' or 'retraining completed,' rip it up and start again
- > Justify bad practice by using risk assessment, validation or spurious statistical methods
- > Over promise and under deliver
- > Be anything other than truthful and sincere



# DRAFTING YOUR RESPONSE: DOWN TO THE SPECIFICS

## Step 1: Mindset

- > Get rid of the victim mentality and mindset quickly
- > Focus on meeting the emotional needs of the regulator; rebuild trust and remove fear in actions, not just words

## Step 2: Ask Yourself if the Observation is Factually Correct

Or has there been some misunderstanding or any miscommunication between you and the regulator? Always view this from the auditor's perspective. Acknowledge any potential misunderstanding by providing the real facts and data. Accept responsibility for not conveying these clearly during the inspection. Remember, the effectiveness of communication is measured by the response you get. If there has been any misunderstanding, it's your fault, not the inspector's.

## Step 3: Acknowledge Each Observation

Accept the validity of all observations that you feel are justified. However, if you don't agree with the observation or criticism, you must say so. You must defend your position based on good science, good regulatory practice and common sense.

For example, one of our clients was cited for insufficient detail in an SOP covering gowning procedures. The auditor felt that the three-page SOP with eight photos and very few words was not detailed enough to ensure consistency of practice. The company rejected the validity of the observation by providing:

- > A copy of the comprehensive education program that supported the SOP
- > Gowning validation data demonstrating excellent consistency in practice
- > Exit monitoring data showing excellent levels of aseptic practice in the manufacturing area
- > The latest research on cognitive overload, emphasizing that pictures are better than words and that less is more for instructional details

They also provided the regulators with links to NSF webinars and resources:

- > The Art and Science of Simplification – How to Win Your War on Complexity
- > Human Error Prevention – Solutions and Answers

Visit [www.nsf.org/info/pblibrary](http://www.nsf.org/info/pblibrary)

## Step 4: Complete a Far-Reaching Risk Assessment

This must address:

- > Potential severity of harm
- > Probability of occurrence
- > Likelihood of detection/non-detection

The scope of the risk assessment is vital. When did this issue first happen? How many batches are involved? Remember, these deficiencies probably extend to other plants in your network. Do not limit your risk assessment and CAPA plan to the plant in question or just to the specific observation.

## Step 5: Identify Your Immediate Risk Mitigation (Correction)

What steps will you take immediately to mitigate risk? Who will do what, by when? What are your milestones and measures?

- > Stop manufacturing?
- > Quarantine product?
- > Recall product?
- > Replace equipment?

How will short-term corrective actions be monitored and measured for effectiveness? What resources will be dedicated to successful implementation?

## Step 6: Identify the Error Chain

What caused this to happen? Why didn't you pick this up and fix it? This step is vital. A detailed review of all contributing factors (error chain) that led to the deficiency is essential. Take, for example, failure to set the correct specification for environmental monitoring.



The questions the regulatory agency want answered include:

- > Why did your own internal surveillance systems fail to pick this up?
  - Self-inspection program
  - QA (in general)
  - Corporate audit
  - Deviation and CAPA system
  - Plant reviews and more
- > Why did people throughout your organization fail to implement the correct standard?
  - Ignorance of poor GMP requirements
  - Poor training or education
  - Fear
  - Etc
- > Why did the quality system allow this to happen?
  - Why did policy documents and SOPs fail to include the right standard?

### Step 7: Prevention

Preventive actions are key to rebuilding trust and respect. They communicate your commitment to prevention and improvement rather than the quick fix. Who will do what, when and how? What are the timelines and milestones? How will effectiveness be monitored, measured and reported? Have you engineered out the primary causes. How have you addressed the cultural and behavioral issues?



### Step 8: Your Cover Letter is Vital

The first thing the regulator will read is your cover letter. Usually written by you and signed by a member of your senior leadership team. The more serious the audit report, the more senior the signature. It must convey:

- > How serious you are about addressing the issues raised
- > The immediate actions you have taken to reduce risk to patient safety
- > Your commitment to fixing the underlying causes
- > The resources that will be mobilized to enable this to happen
- > Your willingness to work collaboratively with the agency

## RESPONDING TO SEVERE REGULATORY CRITICISM?

1. Think first. Let logic rule over emotion
2. Your focus is to satisfy the emotional needs of the regulator by removing fear and rebuilding trust and respect. It's about style and content
3. Correct any misunderstandings but never attempt to justify the unjustifiable
4. If you feel any criticism is not justified, respectfully defend your position using science, data and common sense
5. Make sure your response focuses on prevention, not short-term reaction, and that your plan is credible and fully resourced
6. Ensure your response is simple to understand, and easy to read and navigate. It must communicate your sincerity and commitment to address the underlying causes, not just in words but by the actions of leadership

If you need assistance or have questions, please contact us at [pharmamail@nsf.org](mailto:pharmamail@nsf.org)



Many of these same principles apply to medical device manufacturers when they receive FDA warning letters. Kristen Grumet, Executive Director at NSF International's medical device business published an article in the Medical Design and Outsourcing publication on six key steps manufacturers can take in response to a FDA Form 483 and Warning Letter.

Please download a copy of this article by visiting [www.nsf.org/info/formfda483md](http://www.nsf.org/info/formfda483md)

For more information on NSF's medical device services visit [www.nsfmedicaldevices.org](http://www.nsfmedicaldevices.org)

## ABOUT THE AUTHOR



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