Warning Letters

Finding a path forward

SMART
CONSULTING GROUP

So you've received a warning letter...

what do you do now?

It's important to get a clear understanding of the message that the regulatory authority (FDA), is trying to send to your company.

It's not just about the words, it's more about what the intent of the observations listed is trying to convey.

More often than not, the observations are illustrative of wider compliance concerns, so you need to look past just answering/addressing observational deficiencies. This is a trap that many fall into and it's often a big mistake!

It's important that you look at this in terms of total quality management of the manufacturing operations and assess what the relative risks of the individual operations are for product quality and product safety.

Patient safety is of paramount importance to regulatory agencies, so process and product quality will be high on their list of agency responsibilities when inspecting manufacturing and testing facilities.

In addressing these severe regulatory compliance situations, it's important to clearly understand the intent of the regulatory agency and to focus the scope of any remediation response to rectify those deficiencies to produce a sustainable compliance condition.

Having a plan and appropriate methodology are required to do this effectively and efficiently together with an experienced team to manage and execute the process.

How do we structure things?

One of the first things we do is to assess all the areas involved to see whether they can meet the appropriate standards. We do this by developing a gap analysis profile for the situation and supplement this with a SWOT analysis to fully understand the scope of what's involved. This will act as a Current State profile for the remediation situation.

We also will set up a core team to develop key quality attributes and apply these against the gaps for individual Quality System deficiencies. By ranking these as critical, major, and minor we can develop the working project timeline for the remediation activities and extend appropriate resources to execute each task. Each task will be identified by the resource being used to complete it.

This new Work Plan will provide a snapshot of what the future remediated state will look like; it's important to challenge that prior to the commencement of the plan. Using a SIPOC analysis is often a helpful tool for this process.

Once completed, the Work Plan will itemize each task/issue by quality system element with a timeline for completion and the resources needed to close out and neutralize the situation. Upon completion, each task will have a closeout checklist which Quality Assurance can refer to during follow-up system maintenance audits.

Why is a consultant helpful in this process?

When your own company credibility with the FDA has been damaged due to a Warning Letter or other serious compliance situation, it is difficult to effectively negotiate reasonable solutions and terms for delivering those solutions. That's when you need the help of a third party consultant that you can lean on that will help advocate reasonable points on your behalf. With the appropriate skill sets, resources and credibility, it is often easier for a third party to advocate the solution. The client company can leverage that situation to its best advantage with the regulatory agency.

What makes Smart Consulting Group a suitable resource to help you with this process?

Experience and track record!

In Smart Consulting Group you have an experienced team with a proven track record that can help you navigate the regulatory compliance process.

Specifically, what does Smart Consulting Group bring?

- Access to a diverse quality and technical team that has complimentary skill sets.
- A team that has an outstanding reputation with the FDA.
- Programs that are tightly project managed to assure the best use of resources and life-cycle management.
- Internal quality assessment capability to assure the needs of the client are being met.
- Robust Quality System driven approaches that encompass **quality by design** and **risk management** across every facet and phase to deliver sustainability.
- A ruthless appetite for assuring **Lean Compliance** so that resources are appropriately used when needed.
- Flexible approaches that cater to evolving needs.
- A receptive responsive partner to customer needs and requests.

Let our experience and track record work for you!

What does Smart Consulting Group provide to meet these challenges?

- A customized solution to meet immediate needs and future objectives. This includes the right strategy, methodologies and approach to deliver a successful resolution.
- A definition of key points that need to be addressed in logical sequence to maintain an interim level of control until the end-game solution is deployed.
- A creative team that is sensitive and responsive to the "Ground Zero" situation; advice on how to meet and maintain sustainable compliance using a cost-effective approach.
- A critical mass of expertise to make an immediate and sustainable impact that will mesh with FDA expectations.
- Specialists that meet the needs of your issues.
- Experienced leaders that can guide the program.
- A level of certainty that the situation can be recovered that will restore confidence in both management and staff.
- Feedback mechanisms to senior management so they are in tune with ongoing remediation plans and efforts.

What type of work product can be expected from Smart Consulting Group?

- We deliver a creatively generated work product that meets the objectives of the Customer Driven Project Management Work Plan.
- Solutions that are custom tailored to meet the specific issues related to your situation.
- Practical solutions, policies and procedures that are easy to follow and maintain.
- Visually driven procedures that provide for efficiency and a high level of compliance.
- Training ideas and approaches that will leverage off visual management philosophy to provide cost-effective and reliable operational performance.

What happens when the project ends?

Analyzing the situation and deploying a solution to fix a Warning Letter is only part of the real answer. The best approach is to provide ongoing monitoring capability to assure that the situation remains on track once a remediation program has been instituted.

Smart Consulting Group provides a periodic assessment check to support and supplement the new ongoing QA oversight that any Smart Consulting Group program puts in place as part of the Warning Letter remediation Work Plan.

In brief, we serve as a safety net through an ongoing pre-agreed plan to assure that standards and commitments are being maintained and continuously improved.

Call us today to learn how we can help your organization!

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