Regulatory Inspections: The Good, Bad, and Ugly Experiences

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For all of us in Quality Assurance departments, on-site inspections are a regular occurrence. Our Quality Management System may be subject not only to the scrutiny of FDA Investigators, Health Canada Inspectors, and ISO Auditors, but also to the audits and inspections conducted by our clients. In addition, we may take on the roll of auditor when qualifying or inspecting our suppliers. With so many possible audits and auditors, the experience can vary greatly. No matter how well we prepare, the actual audit can range from a positive experience to one that leaves us with a bitter taste in our mouth. These are some of our experiences:

The Good

- Agenda is sent at least a week before the audit
- Interviews with key personnel go smoothly as per timelines
- Policies, procedures, and records are carefully reviewed and any potential issues are discussed
- The audit/inspection report is prepared during the audit and, therefore, has no surprises; any findings or observations are discussed prior to finalization of the report
- The closing meeting produces agreement on any issues and the next steps
- The response to any findings and/or observation is acknowledged

The Bad

- Agenda is delivered at the opening meeting, requiring documentation and personnel to be gathered on short notice

- Audit goes off track, time is wasted, regular daily activities are interrupted
- Objectives of the audit are defined during the audit and another visit or extension of the audit is requested
- The auditee is evasive or does not provide clear answers or evidence or the auditor jumps to conclusions and writes unsubstantiated observations without asking for evidence
- At the closing meeting, time is wasted in attempts to clarify the issues
- The Audit Report is prepared after the audit and more time is wasted in attempts to clarify any issues

The Ugly

- No agenda and no definition of the purpose of the visit
- The audit and/or the interviews are unstructured and haphazard
- There is no closing meeting to discuss the outcome of the inspection
- Weeks (or months) later, a report is produced that does not reflect what occurred during the audit requiring considerable wasted effort addressing misunderstandings
- A response is sent but not acknowledged
- Neither side benefits from the experience

To avoid unproductive audits and inspections, both parties need to be clear on the purpose and scope of the audit/inspection. For the host, a clear agenda for the visit will assist in assembling documents and records, and ensuring that the appropriate personnel are available on site. For the auditor, making the effort to clarify and discuss any findings before leaving the site will save wasted effort on both sides.

After inspection, it is important to consider not only the nonconformances, but also any suggestions and recommendations (opportunities for improvement). If we were successful in establishing a collaborative tone to the audit, the opportunities for improvement and the suggestions provided by the auditor can result in meaningful changes to the organization.

In a recent example, our reputation for being well prepared for inspections as a contract manufacturer helped our client with a successful factory inspection. The third party inspector was able to complete and close a factory inspection within 24 hours and our client was able to ship their products to the distributor without any delays. Happy client, happy inspector, happy host—how perfect is that!?