

<http://www.pharmacompass.com/pharma-news/the-2015-data-integrity-cheat-sheet-5-questions-every-drug-maker-needs-to-answer>

5 Questions You Need to Answer

For several years now, data-integrity violations have been the main reason why the US Food and Drug Administration (FDA) has issued warning letters to pharmaceutical manufacturers. And 2015 was no exception.

PharmaCompass set out to uncover what exactly went wrong at these facilities. In order to understand compliance failures, we referred to Barbara Unger's compilation of "[Data Integrity and Enforcement Actions](#)" which focuses on data integrity observations of the FDA and EU inspectors through the past year. Unger is the founder of [Unger Consulting Inc.](#), which provides Good Manufacturing Practices (GMP) consulting services to the pharmaceutical industry.

"Regulators continue to identify the same set of shortcomings," says the Unger Consulting review. In fact, for the last 15 years, regulatory agencies have cited the same deficiencies – related to data integrity and data management. "Yet it appears that the industry as a whole has made limited progress in self identifying and remediating these deficiencies," the review adds.

In an effort to demonstrate the recurring pattern, [PharmaCompass tabulated the observations listed in various warning letters issued in 2015](#). And based on our tabulation, we have chalked out five questions that the management of every pharmaceutical company needs to ask itself and take remedial action in order to consistently come up trumps in regulatory inspections. Here are the five questions:

1. Are you duplicating your testing efforts?

Our tabulation observed that companies which get warning letters are duplicating efforts. Since duplication of activities add to costs of a manufacturing unit, it is worth asking why companies need multiple testing of the same product?

Is duplication done because there is a lack of confidence in the manufacturing process? Could this be the reason why "test" or "trial" injections are performed to ensure the "actual" result will pass when GMP documents have to be completed?

Or could it be that there is a big gap between the commitments made to regulatory authorities and the actual process being performed on the shop floor?

If your company is making these mistakes, look at how to reduce duplication of activities. Elimination of duplication improves compliance and also brings about cost efficiencies.

2. Does your company lack real-time documentation?

PharmaCompass also observed that several companies that faced regulatory action last year did not document operations in real-time. Why go through the added effort to duplicate documentation once the activity has been completed?

Are the questions which need to be answered the same as those for duplicate testing? Is it also a possibility that companies are not manufacturing the product but only manufacturing paper?

3. Do you have problems configuring audit trails?

Problems with audit trail configuration was the most frequent observation made by the FDA. Interestingly, the observation was made across brands of software and equipment, reinforcing the fact that the problem had more to do with improper set-up than access to the appropriate solution.

The right configuration is important to track audit history, especially in organizations with multiple operators and administrators. How should companies configure audit trail functions in any software used to acquire data that can impact product quality?

This is definitely an area that companies need to address. *PharmaCompass* plans to cover this issue in the coming weeks. So watch this space.

4. Are you getting to the root of quality failures?

In many cases, where products routinely failed quality standards, the FDA inspectors found the firms had not conducted thorough investigations to get to the root-cause of the problem.

Do companies differentiate between a one-off product quality problem coming from the manufacturing line and a recurring process failure with the potential of dispatching a contaminated product to the market? Without a thorough investigation that gets to the root cause of failing a quality standard, no company can hope to be GMP compliant.

5. Have your employees been adequately trained for inspections?

When inspectors arrive on site, panic creeps in. That's a common observation and employees definitely need training to handle regulatory inspections.

However, before you begin training employees for rigorous interviews from inspectors, check if your training procedures are effective, whether or not your GMP procedures are overly complicated and if employees are following common unwritten practices?

Lack of proper employee training can be detrimental to the image of your company, as employees often end up giving ill-informed answers to inspectors. Remember – regulators are just doing their job. They have a governing body to answer to. They will report issues they find weighty and incompliant to GMP and quality norms.