Highlights from “Managing Your FDA Inspection: Before, During and After”
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Organised by ComplianceOnline

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For most in the the pharmaceutical industry, an FDA (Food and Drug Administration) inspection is regarded as THE audit to pass and companies spend much time and efforts in their preparation leading up to the inspection. In fact, an attendee flew from Europe to Singapore just for this 2-day seminar, to prepare for her company's impending audit by the FDA. Glad to say that this event was quite worth the trip.

As per the title, this seminar covers the lifecycle from before to after an FDA audit.

Some key takeaways are:

- It is essential to be aware of the legal authority of the FDA, which could lead to various legal and practical consequences should the company have any refusals – before/during/after the audit.
- Be familiar with the type of inspection relevant to your company. The audit will be conducted according to the applicable Compliance Program Guidance Manual (CPGM).
- Be aware of the critical observations.
- As expected, product approval inspections will be prioritized, as compared to routine inspections. However, other factors such as your management's conduct during a previous inspection and product recalls may trigger followup inspections.
- The FDA does not have to explain the type of inspection which they are planning to perform.
- Establish a procedure on how audits are to be conducted to prepare your company and the teams involved.
- Always take the auditor's observations seriously, but do not under- or over-promise. Be logical.
- Ensure that you fully understand the observations or the content of Warning Letter.
- The timeline is important. Ensure that your response to the 483 or Warning Letter reaches FDA within 15 US working days.

A few interesting points:

- Do not read too much into the auditor's actions during the inspection – they may not be relevant.
- A 483 is not the end of the world! To the inspector, it is just a form.
- If required, the FDA usually issues a Warning Letter within 6 months from the end of the inspection. You may be safe after; or a followup inspection may be scheduled.

It has been an engaging and informative seminar, and being able to directly discuss with an ex-FDA official offers more insight into how the agency view and conduct inspections. At the end of the day, the FDA is not trying to make things difficult, but just to help and ensure the industry to make things r i g h t ,