

How to Successfully Navigate the FDA Site Inspection Process

BY IMPLEMENTING THIS COURSE STRATEGY 483 CITATIONS CAN BE AVOIDED

2019
November
MON-TUE
18th / 19th Hyderabad.

2019
November
WED-THU
20th / 21st Mumbai.



Introduction :

Commercialization of products in India that are destined for distribution in the US market will require inspection by the US Food and Drug Administration - FDA. Products will be licensed either as branded molecules through the New Drug Approval process (NDA), and generic's follow the Abbreviated New Drug Approval process (ANDA). Biological products also follow a variance of the NDA process through a BLA, biological license application process. **Both processes (NDA & ANDA) are rigorous and will require inspection of the material manufacturing site, including supporting sites, testing facilities and any third-party facility that provides a significant piece of the manufacturing process.**

Inspections follow two formats: Pre Approval Inspection (PAI) and general GMP inspection. The former tends to be more rigorous and it's a Pre Approval Inspection associated with a product and is therefore more focused and in depth in format. GMP inspections are a general review of the plant's GMP compliance status and can cover all products / intermediaries etc. produced at the site.

To successfully navigate these potentially difficult inspectional processes requires a good plan, a clear project commitment from management and staff as well as education and training in order to assure that the site has its GMP compliance commitments in order and in the case of products site approvals, that the site is in sync with the regulatory documents submitted to the FDA.

Cont.

Our Approach :

International Business Conferences delivers Training Programs that are designed according to latest trends and developments, it also believes in offering training inputs customized to an organization's unique business requirements.

The faculty for this workshop has domain expertise in the subject in addition to the practical experience of having applied the theories in the workplace and thus can address issues of participants on "application of learning".

Conceptual inputs are provided using a variety of techniques such as audio-visual aids, role plays, case studies, games, instruments etc. The "Action Learning" methodology is participant centered and practical work-place oriented.

Participants are treated as partners in co-discovery of learning that builds competitive edge in individuals according to their individual needs and aspirations.

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Introduction :

Site preparation is vital otherwise the regulatory authorities will develop a negative impression of the company, the site competency and commitments to compliance, with the result that the site might not receive the approval for the product, or it might receive several citations in the form of either 483 observations or a Warning Letter. **The goal for the site should be to leave** the FDA inspection team with a favorable impression of your site in terms of the facility, equipment, staff and its various processes, so that it can provide a positive Establishment Inspection Report (EIR), post the site inspection process. **The intent of this seminar is to review these processes and provide guidance on how to successfully navigate the FDA process. Covered will be key actionable items that the site needs to focus on to both avoid negative pitfalls and to assure a positive outcome.**

Benefit :

ROI will be achieved post the course through each individual participating in a site readiness team at their individual companies. Taking the material shared at the course will add value to their own situation by immediately facilitating a better level of preparation to enable a smoother FDA experience at their subsequent site inspections.

Joining or causing the formation of a new improved site readiness team at that own individual companies, so that they are better able to navigate the next FDA inspection without needless **483 citations that can be avoided** if they implement the strategy shared at the course.



Programme Schedule for two days

| | |
|---------------------|--------------------------|
| 09:30 am | Registration & Breakfast |
| 10:00 am | Course Commences |
| 11:30 am - 11:45 am | Tea Break |
| 01:00 pm - 02:00 pm | Lunch |
| 03:30 pm - 03:45 pm | Tea Break |
| 05:30 pm | Course Ends |

Would You Like to Run This Course In-House?



Our Customised Training Solutions team are veterans of in-house training with a portfolio of specialists unrivaled anywhere in Asia Pacific! To design your training project with significant business impact, **for More Details please contact.**

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Meet Your Expert Coach : Dr. Nigel Smart

Dr. Nigel Smart PhD is president of SMART Pharmaceutical Consulting, a Global Pennsylvania based consulting firm that provides technical and quality expertise to the pharmaceutical, biological and medical device industries. He has **+35 years'** experience in the business, in a corporate, development, manufacturing, quality, and executive capacities. **In both a corporate and consulting capacity, Dr. Smart has provided guidance to companies for multiple successful FDA inspections, both PAI and GMP.** This has included all pharmaceutical presentations, vaccines, biologicals (rDNA), cell systems, gene therapies and combination products.

Dr. Smart is a frequent course leader in cGMP compliance and **regularly teaches courses dealing with inspections, inspection readiness and cGMP remediation activities associated with failed inspections.** As an industry expert Dr Smart has provided courtroom legal testimony on cGMP compliance and has prepared readiness programs to successfully navigate FDA inspections for clients. This has included face to face meetings pre and post inspections. He is a frequently published industry commentator on cGMP compliance and how companies can avoid expensive remediation programs by building a **first-class inspection readiness program** as part of a wider strategic compliance continuous improvement initiative.

Dr. Smart is recognized as an industry expert for his innovative approaches to assuring quality compliance with simultaneous attainment of efficiency through Lean Process Excellence Processes. The SMART approach introduces the concept of Pharma 4.0 to achieve improved efficiency and compliance through digital integration with Lean System philosophy.

In addition to providing services to the global commercial industry, Dr. Smart provides consulting services to the US government as a pharmaceutical regulatory compliance expert. This includes the US FDA, Department of Defense Countermeasures Program and Federal Trade Commission.

As a consultant to the US FDA, Dr. Smart has provided expert counsel on GMP compliance and data integrity and his testimony has been used by the FDA with the Department of Justice in regulatory actions against companies failing in their responsibilities to meet US GMP regulations.

Dr. Smart is a frequent speaker on the compliant production and regulation of pharmaceuticals and life science products.

Recently Dr. Smart has given various papers on the compliant production of High-Quality Pharmaceuticals, both as a keynote speaker in Philadelphia and at CPHI in Shanghai, China.

FORENOON

Understanding what is needed for the Pharmaceutical company to prepare for the FDA inspection process :

- ✓ How to start the inspection- who accepts the inspectors.
- ✓ Organization of space.
- ✓ Escorts for FDA.

Developing a plan and strategy for inspection.

Selection of the Pharmaceutical Company's internal inspection readiness team. Who should be involved / how to select the team?

- ✓ Competency of SMEs.
- ✓ Performance under stress.
- ✓ Demeanor and attitude.
- ✓ Adaptability of SMEs.
- ✓ Backup plans for addressing questions.

Etiquette In answering questions is important so as not to generate difficulties with the FDA inspectors. It's important to:

- ✓ Ask for restatement of questions if the understanding by the readiness team is not clear.
- ✓ Watch what is said in a reply to a question. How much to say, what not to say.
- ✓ The importance of guarding against being tricked into revealing unnecessary information which could implicate a potential problem.

Do's and Don'ts in answering questions:

Do's :

- ♦ Answer ALL questions honestly.
- ♦ Say "I don't know, or I'll get the answer for you".
- ♦ Avoid such phrases as "I think" sometimes / often / usually, "never" and "next time".
- ♦ Avoid qualities such as "typically" "normally" generally and usually.
- ♦ Stop speaking once a question is answered.
- ♦ Ask for explanations or interpretations of what you do not understand.
- ♦ Maintain a friendly cooperative attitude.
- ♦ Maintain your composure, remain courteous and professional.
- ♦ Maintain eye contact.

Don't :

- ♦ Volunteer information or answer a question that has not been asked.
- ♦ Be sarcastic.
- ♦ Guess answers.
- ♦ Attempt to answer "what if" or hypothetical questions.

- ♦ Argue with the investigator.
- ♦ Philosophize, ramble or editorialize.
- ♦ Point out deficiencies or errors.
- ♦ Apologize for problems or comments made by an investigator.
- ♦ Feel the need to respond to every comment made.
- ♦ Become defensive or evasive.
- ♦ Look away, fidget or look nervous.
- ♦ Make statements about your personal opinion of the FDA.

AFTERNOON

Simulating investigator questions :

- ✓ Identifying what needs to be covered.
- ✓ Use of repetitive sessions - update approach.

BENEFITS :

The team will have a clear and detailed understanding of how to set up the organizational structure required to control the investigational process. It will also enable the pharmaceutical company staff / management to become familiar with non-controversial language that will effectively engage the FDA inspectors. The company Readiness team will learn the techniques to best handle the inspection process and the FDA inspectors' line of questioning without sabotaging themselves in the process. As a result, this presentation will help to facilitate a favorable impression with the FDA and enable the questions that arise to be answered smoothly and quickly to generate a satisfactory outcome.



FORENOON

The pharmaceutical company Readiness team will learn how the FDA will conduct its facilities tour and how they should handle that to maintain control of the inspectional tour without self-sabotaging the process:

- ✓ Where they'll start/why?
- ✓ What documents they'll look at/why?
- ✓ How to assure they stay together as an inspection team / the control process.
- ✓ Control of questions being asked for and answered by facility staff that might not be prepared.
- ✓ Adherence to SOP's for inspectors as well as your staff.
- ✓ Be prepared to show operational documents at each place of work.
- ✓ Have staff on hand that can answer questions who have been through the training process.
- ✓ Preparation by mock inspections with QA staff or consultants.
- ✓ Be able to explain issues that are being modified under a CAPA for example
- ✓ The FDA inspection team and company employees should follow the company procedures associated with gowning and personal protective equipment (PPE), to assure compliance and safety. PPE is always worn!
- ✓ Control documents and work spaces as prescribed by procedures.



AFTERNOON

Training for readiness :

- ✓ Understanding all roles/responsibilities of team.
- ✓ Functions in the front room with inspectors.
- ✓ Functions in the back room – preparation.
- ✓ Research reputation of inspectors and their specialties.
- ✓ Dealing with open ended questions.
- ✓ Developing a uniform mode of response.
- ✓ Anticipating questions - preparing answers.
- ✓ Practicing questions and responses.
- ✓ How to use role-play to test team's readiness.
- ✓ Common pitfalls.
- ✓ Avoiding generalizations.
- ✓ Learn to use silence to avoid checking oneself up by giving unnecessary information.
- ✓ Examples of questions by inspectors.
- ✓ Practice answers given to inspectors

Requesting daily summaries :

- ✓ Who should attend?
- ✓ Wrap up meeting at end of inspection.

Corrections of documents prior to end of inspection process.**Acceptance of inspection report and any citations.****Lessons learned from process:**

- ✓ Internal debrief post inspection.

BENEFITS :

The team should have a clear understanding of how to organize and conduct the physical part of the inspection around the facilities and connected with the pharmaceutical processing. The roles and responsibilities should be clear, and this should avoid any unnecessary mistakes which might precipitate difficult questions in the document review process. Also, having a clear understanding of the roles and responsibilities should enable both the front room, where the inspection is being conducted with the inspectors, and the back room, where documents and SME's are being prepared to function smoothly and efficiently. This should help to facilitate the inspection process and create a favorable impression with the inspection team.

CLOSING & CERTIFICATION

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