FDA COMPLIANCE & PLANT INSPECTION MANAGEMENT 2018

3 Day Masterclass

14th - 16th March 2018

Sheraton Shanghai Pudong Hotel & Residence, China

Quest Masterclass

OVERVIEW

Deploying and creating an arsenal of compliance knowledge and rankings of priorities that should be at the top, with regards to your preparation for your next FDA visit. Simulated exercises that include role playing for both the FDA regulators and your company's representatives, will prepare you for your next real inspection. You will learn the best ways along with the best resources to improve your compliance. You will be prepared with the latest guidance and strategies for inspection readiness – at any time, announced or unannounced.

Attendees will learn and comprehend how to respond to FDA questions – what to say and how to say it. Everyone will comprehend the importance of FDA Inspections from both sides of the process. You will improve your compliance, enjoy the activities and be much better prepared for the next time FDA "visits" with you.

Learn from the very best expert who wrote the rules, teach FDA inspectors, train industry Quality specialists, and who themselves were expert FDA investigators.

"Unravelling The FDA – Deliverables & Expectations"

COURSE LEADER

Brian G. Nadel

Brian G. Nadel has over thirty years of diverse experience in: Pharmaceutical Quality Assurance and Quality Systems; FDA Pre-Approval and Inspection Readiness Inspections; International CGMP Auditing for finished drug products, Active Pharmaceutical Ingredients, Fermentation, Process Validation and botanical extraction.

He worked as an FDA Drug Specialist Investigator and at the Center for Drug Evaluation and Research (CDER) as Compliance Officer at FDA Headquarters. At CDER, his main responsibility was reviewing recommendations from FDA's District Offices for regulatory actions such as Warning Letters, Seizures, Consent Decrees and Injunctions.

Mr. Nadel was formerly a Senior Director responsible for Supplier Quality, Risk Management and Anti-Counterfeiting, in the Corporate Quality and Compliance department at Sanofi's US headquarters in Bridgewater, NJ. Before that, he was the Senior Manager at Forest Laboratories in NY and NJ responsible for Pre-Approval Inspection Readiness and Internal and External audits. At Forest Laboratories, he managed teams that were responsible for receiving first-pass approvals of two blockbuster NDA drug products.

He has consulted pharmaceutical biologics, and device facilities with NDA, ANDA, DMF, BLA and OTC product manufacturers across Asia, Europe, and North America; and also conducts CGMP training for FDA, Industry to train them to proactively prevent problems and respond to "issues" with the US FDA.

BOOK NOW & GET DISCOUNTS

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BENEFITS OF ATTENDING

- Managing Your FDA Inspection: Before, During and After
- Bad Things Happen, But it Can Get Worse – Understanding FDA Post Market Regulations
- Understanding FDA and Avoiding Inspections Leading to Warning Letters, Seizures, Injunctions and Prosecutions
- Understanding the FDA's Regulation of HCT/Ps and Successful Product Development Strategies
- Where and how the CAPA feedback loop improves your overall quality system
- Deficiencies in Corrective and Preventive Action (CAPA) systems continue to trigger the largest number of FDA 483s and Warning Letters
- Why data integrity has become one of FDA's top concerns -- and how you can avoid being an enforcement target
- Examples of FDA Warning Letters citing documentation and change control failures
- What are those tools and Where do you find the best data that FDA wants in your CAPA system in order to monitor continuously and improve quality throughout your product's lifecycle
- Essential FDA Guidelines and other FDA documents, along with references will be provided
- The differences between the generic drug approval process and the innovator drug approval process will be presented
- There will be role dynamic playing simulations and discussions on the positive and negative consequences of your interactions with FDA
- Comparisons to improper behaviours and responses will be made with appropriate and positive communications
- Attendees will learn and comprehend how to respond to FDA questions – what to say and how to say it
- Everyone will comprehend the importance of FDA Inspections from both sides of the process
- Everybody will learn how to control the pace and the outcomes of these FDA Inspections
- You will improve your compliance, enjoy the activities and be much better prepared for the next time FDA "visits" with you

WHO SHOULD ATTEND

- Executive Management
- Facilities Management
- Plant Head
- Factory Head
- Production Head
- Manufacturing Head
- Regulatory Affairs Head
- Internal & External Auditors
- Documentation Management
- Validation Management
- Quality Assurance
- Quality Control

OUR PAST ATTENDEES

• Abbott • Abbvie • Actavis • Alcon • Amgen • Aspen • Astellas • Astra Zeneca • B Braun • Baxalta • Baxter • Bayer Pharma • Biocon • Bio Nexus • Biofarma Pharmaceutical • Boehringer Ingelheim • Bristol Myer Squibb • CCL • CCM • Cipla • Daiichi Sankyo • Dexa Medica • DKSH • Dompe • Dr Reddys • Eisai • Eli Lilly • Fresenius Kabi • Galderma • GSK • Hyphens • Inter Pharma • J L Morison • Janssen • Johnson & Johnson • Kalbe Farma • Laurus Labs • Lundbeck • Lupin Limited • Martin Dow • Menarini • Merck • Merck Sereno • MSD • Mylan • NDA Regulatory Service • Neo Pharma • Novartis • Novo Nordisk • Pfizer • Pharma Niaga Quintiles • Roche • Sanofi • Square Pharma • Swiss Medic • Takeda • Teva Pharmaceutical • Themis Medicare • UCB • United Laboratories • Vifor Pharma • Wockhardt • Zuellig • IPI Pharma • AJ Pharma • Kimia Pharma • Sanbe Pharma • Kotra Pharma • Bangkok Drug • Renata • Howards Pharma • Amneal Pharmaceuticals • Radiant Pharmaceuticals • UPHA Pharmaceuticals • Cadila Healthcare • Oncogen Pharma • Winwa Medical • Sydenham Laboratories Inc. • Serum Institute • OLIC • Hilton Pharma • LF Asia •ACME Laboratories

PRE-CLASS QUESTIONNAIRE (PCQ)

To ensure that you gain maximum benefit from this event, a detailed questionnaire will be sent to you to establish exactly what your training needs are. The completed forms will be analyzed by the course trainer. As a result, we ensure the course is delivered at an appropriate level and that relevant issues will be addressed. The comprehensive course material will enable you to digest the subject matter in your own time. This training course is designed specifically for participants to work through a dedicated strategic planning process. It is a high-level, intensive and vigorous programmed that will move rapidly. The trainer will introduce the sessions and then participants will have the opportunity to develop their own plan. It is an extremely practical training course where participants will spend considerable time working on their own ideas that will enable them to achieve superior performance within their personal work domains. This training course will contain case studies and learning principles fromvarious organizations, which will enable participants a frame of reference fromwhich they can then launch into their own activity.

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DAY 1

Identifying The Differences Between The Generic Drug Approval Process & The Innovator Drug Approval Process

SESSION 1

The Generic Drug Approval Process

- What is a generic drug?
- What is an ANDA?
- What is generic exclusivity?
- Will there be an increase in the availability of new generic drugs?
- What are the FDA guidelines and definitions for generic drugs?

SESSION 2

Supplemental References, Social and Economic Implications

- What are the FDA guidelines, FDA reference documents and definitions for generic drugs?
- How do the companies make these generic "copies"?
- Why do we need generic drugs?
- How will this help the patients that use these drugs?
- Why will we continue to need generic drugs
- How will the economies of countries be affected by the proliferation of generic drugs?
- Case Study and Group Exercises

SESSION 3

The New Drug Approval Process

- What is a new drug?
- NDA - What does the mean?
- What is the new drug approval process?
- What or who is the Innovator?
- Why do we need new drugs?
- What are the benefits of new drugs?

SESSION 4

Supplemental References, Social And Economic Implications

- Why are new drugs so expensive?
- What are the processes and investments needed to get new drugs approved?
- Why will people always need new drugs?
- How could we afford to pay for these new drugs?
- Will generic drugs eventually replace the need for new drugs?
- Review of applicable guidelines and other FDA reference documents
- Case Study and Group Exercises

SESSION 5

Tips and Requirements for Auditing Design Controls

- Differences between design verification and design validation
- Defining and documenting essential design inputs and outputs
- Ensuring accurate transfer of product design to production
- Examples of FDA Warning Letters citing Design Control failures

SESSION 6

Regulatory Enforcement: The Consequences of Non-Compliance

- Helping your suppliers prepare for an inspection or audit
- Can you shield your audit reports from FDA?
- Responding to 483s and Warning Letters
- Latest FDA enforcement priorities and targets

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DAY 2

SESSION 7

How To Prepare for The FDA Investigator Using A Simulated Inspection With Real - World Scenarios

- Will FDA notify you when your next inspection is going to be?
- What should you do to prepare for this inspection?
- Should you clean your facility?
- Should you gather, prepare and organize all the relevant documents?
- Where should you keep these documents?
- Can you let the FDA representatives walk around your facility by themselves?
- Can FDA just go to the washrooms by themselves?
- Who should be talking and interacting with FDA?
- How should you behave during an inspection?
- How should you answer FDA's questions?

SESSION 8

Supplemental legal, behavioural & clerical factors that will increase your confidence and knowledge

- How should you answer FDA's questions?
- Do you have to answer all of FDA's questions?
- Can you just give the FDA photocopies of **ALL** your documents?
- What things are you not required to provide FDA with?
- Should you be taking notes of everything that FDA does?
- Is it time to go home right after FDA leaves every day?
- Review of applicable guidelines and other FDA reference documents

SESSION 9

Interactive Preparation Activities For Becoming More Experienced, Confident And Stress Reducing Methods

- Simulated inspection
- Selection of role players
- Reviewing the scripts
- Actual simulated inspection
- Discussion on how the simulation proceeded
- Was everything conducted using the correct behaviors?
- What was wrong with some of the role players?
- What was correct / good with some of the role players and their responses?
- What improvements could have been made?
- Case Study and Group Exercises

SESSION 10

Where and how the CAPA feedback loop improves your overall quality system Key points in picking the right CAPA tracking tools to match your needs

- Key objectives and phases of effective failure investigations
- How to conduct a proper failure investigation to its root cause
- 00S (Out-of-Spec) investigations -- special considerations and rules
- Failure Investigations tools
  - What they are and how best to apply them
  - How to document and report your findings (and to whom)

SESSION 11

FDA wants your CAPA system to use a variety of tools and data resources to continuously monitor and improve quality throughout your product's lifecycle

- What are those tools?
- Where do you find the best data?
- How do you prevent the same quality problems from happening again and again?
- FDA's requirements for Corrective and Preventive Action systems
- Role of CAPA in meeting global rules and standards

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DAY 3

SESSION 12

Comprehend The Key Strategies to Achieve Compliance: Use of Outsourced Assistance, Internal Audits, and The Drug Development and Approval Process, Quality by Design, Reliance on Electronic Submissions, Remediation Plans and Proper FDA Communication

- What are the best ways to prepare for an FDA Inspection?
- Should you hire outside consultants to assist you to prepare?
- What is inspection readiness training?
- Do you have a Standard Operating Procedure (SOP) for FDA Inspections?
- How can you use your internal audits to prepare for an FDA Inspection?
- Should you review all your Out of Specification (OOS) and Deviation Investigations?
- Should you make sure you have completed all your promised corrections to the previous inspection by FDA?
- What is Quality by Design (QBD)?
- What is Continuous Quality Improvement?
- What ICH Guidelines are useful to prepare for FDA Inspections?
- What is an FDA-483?
- Do you need to send written responses to the FDA Observations?
- How much time do you have to respond to the FDA-483 observations?

SESSION 13

FDA Inspection Process As Applicable To Foreign Inspections

- Will FDA announce these inspections to your company?
- How much notice will they provide you with?
- Do people need to postpone their vacations or other scheduled travel?
- Review of FDA Guidelines and guidance documents
- How can we prepare for these foreign inspections?
- Proven methods to politely take control of inspection and influence results positively
- Methods to boost your confidence and increase your control of outcomes
- What are the differences between FDA domestic inspections and foreign inspections?
- How long will these inspections last?
- Can FDA decide to extend their inspections?
- Case Study and Group Exercises

SESSION 14

Tips and Requirements for Auditing Records, Documents and Change Control

- FDA rules for electronic records and signatures
- Expectations for validating computerized systems
- Critical importance of audit trails
- Examples of FDA Warning Letters citing documentation and change control failures

Course Concludes

TESTIMONIALS

Forces you to think outside the box and it has widened my view of quality

Pfizer

Great experience, networking, exposure to new ideas, or different twists on old ideas

Sanofi

It is a great opportunity to learn and see what the rest of the world is thinking

Sun Pharma

It was great exposure to new quality ideas and other quality professionals

Abbott