Webinar on "How to Host a Virtual Audit"

15th Oct 2020

3.30pm – 5.00pmIST

INTRO:

In this new world of limited travel and Covid 9 precautions auditors, government regulators and especially customers, are looking at virtual audits as a way to fulfil the required Supplier evaluations that would normally be conducted on-site. While the items to be audited remain the same, there are challenges to hosting a successful audit. We will explore these differences and how you can provide the best audit experience possible so that your chances of keeping a current customer or adding a new one are maximized.

TOPICS

What is the same

Document review

Tour

Opening presentation

What is different

Set up before the opening day

Getting all the logistics in place

How documents are reviewed

Must have technology:

Open video call all day

A shared file box

A way to provide a live tour

What if there are 2 auditors

Profile

Owner and primary consultant for MFM GMP Consulting, conducting Mock FDA audits,

3rd party audits, FDA readiness evaluations and training in all aspects of GMP's for the

pharmaceutical, biologic and device industries.

•As a Global GMP/GLP Auditor for SGS, she was responsible for conducting GMP/GLP audits of their 20 Life Sciences Chemistry and Microbiological contract labs throughout the world including China, India, Europe and Canada.

US Food and Drug Administration Role

- Consumer Safety Officer (Investigator) – Atlanta and New Orleans Districts
- Promoted to New Orleans District Drug Expert in April of 2012.
- Obtained Level IISHE certification, in Drugs, in March of 2011 and became member of

  Pharmaceutical Inspectorate. (Highest level achievable)
- Obtained Level ISHE certification, in Drugs, in 2010.
- Member of the Dedicated Foreign Drug Cadre in 2009, 2010, 2013 and 2014.
- New-Orleans District Drug Pre-approval Manager from 2011 - 2013.
- Conduct Drug and Device inspections domestically and Drug inspections internationally.
- Well versed in cGMP's for Sterile, Biotech, finished dosage and APSHE drug substances.
- Wide experience in dealing with Microbiological issues including: environmental monitoring; water purification and testing; creation, characterization and maintenance of master cell banks and the maintenance of working cell banks.
- Experienced in aseptic techniques and media fills.
- Has led inspection teams of up to 6 persons.

•Twelve years as an FDA Investigator working in the Atlanta and New Orleans Districts with experience conducting investigations in areas regulated by FDA including pharmaceuticals, devices and food HACCP.

•SHE was one of only 2, Level IISHE certified, Drug Specialist, investigators in the New Orleans District. SHE obtained Level IISHE certification in March of 2011 and was a member of FDA's Pharmaceutical Inspectorate.

•SHE was attached to FDA's Dedicated Foreign Drug Cadre for 4 years performing 100% international drug work. She has performed more than 60 international inspections covering: sterile and non-sterile API's; and sterile and non-sterile finished dosage forms with over a third of the inspections being Drug Pre-approvals. My assignments has also included fermented and Biotech products.

•Countries in which She has conducted pharmaceutical inspections include: China, Japan, Taiwan, India, Germany, Italy, France, Switzerland, the Netherlands, Scotland, the UK, Ireland, Belgium and Austria.

•As a Microbiologist; she has wide experience in dealing with Microbiological issues including: environmental monitoring; water purification and testing; creation, characterization and maintenance of master cell banks and the maintenance of working cell banks.

• Experienced in aseptic techniques and media fills in relation to sterile Drugs and Devices.

•SHE has led team inspections both domestically and internationally and provided on the job training for new investigators.

•SHE has wide experience in explaining difficult GMP concepts such as root cause determination, CAPA and other risk assessment and investigation techniques to people to whom English is a second language.

• SHE served as the Drug Pre-approval Manager for the New Orleans District from

2011-2013, and as such, has researched and evaluated domestic firms for Pre- approval of their NDA and ANDA drug products. This included the evaluation of firm responses to FDA-483's as well as Warning letters.

•SHE audited manufacturing systems, procedures, and controls for packaging, labeling, inventory management, batch records and related documentation as well as laboratory procedures and test methods. SHE also audited failure investigations as well as CAPA's

•SHE was able to read P&ID diagrams, blueprints and schematics due to electronics background obtained while serving as an Aircraft Electronics Technician in the US Navy, which aids greatly in the evaluation of HVAC and water systems when inspecting drug facilities.

REGISTRATION FORM

REGISTRATION FORM

Company Name :

Address :

Nominated By: Invoice To:

Name :

Designation :

Email Id

Mobile No :

Registration Fees:

SINGLE DELEGATE FEES : Rs 5000

REGISTRATION FEES

Single Delegate Fees 5000/ INR