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EVENTS LIST

Essentials Of USP Microbiology - USP General and Information Microbiology...

Date : Feb 22, 2018 - 08:30 AM - Feb 23, 04:30 PM

Event URL : http://www.sfbayeventslist.com/events/essentials-of-usp-microbiology-usp-general-and-information-microbiology

Organizer : METRICSTREAM INC - NewYorkEventsList

Venue :

Location : San DiegoSan Diego, CAUnited States,
San Diego, CA , US, ZIP: United States

Description

Essentials Of USP Microbiology - Reading Between the Lines of the USP General and Information Microbiology Chapters

***** LIMITED TIME OFFER: FREE $100 AMAZON GIFT CARD! *****
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The objective of this two day "Essentials of USP Microbiology" seminar is to explore USP General and General Information Chapters to learn which are available and to confirm that those that you are using are being used correctly. USP documents that will be reviewed include USP , , , , , , , and others. Various team exercises will be conducted to allow the participants to use these USP documents to solve "real life" problems. Plan to bring a cross-functional group of your personnel to attend this invaluable two day seminar.

Learning Objectives:

- The various General and General Information USP Chapters that apply to microbiology
- The focus of the chapters to include those that primarily involve non-sterile and sterile applications
- Chapters that involve the environment
- Examining the changes within the various Chapters that have recently occurred and how to interpret them
- Review areas that are often overlooked
- Study issues that continue to exist between the USP, EP and JP
- Examine the new regulatory attitude that is occurring with non-sterile products
- What now constitutes a "specified" and “objectionable” microorganism
- Explore Form FDA 483s and Warning Letters for microbiological applications

Seminar Fee Includes:

Lunch
AM-PM Tea/Coffee
Seminar Material
USB with seminar presentation
Hard copy of presentation
Attendance Certificate
$100 Gift Cert for next seminar

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Who Will Benefit:

- Manufacturing
- Product Development
- Project Management
- Quality Assurance
- Quality Control
- Regulatory Affairs
- Regulatory Compliance

Topic Background:

Microbiology plays a role throughout the manufacture of pharmaceutical products. Whether the final product is non-sterile or sterile, the bioburden exists from the raw materials, throughout the process and/or within the product's environment (water and HVAC) to the final product. A critical review of the overall microbiological process will determine whether the critical "in-process" points permit the final product to meet its acceptance criteria. In addition, any "objectionable" or "specified" microorganisms that may be encountered during the procurement of raw materials and the processing must be considered.

Whether you are testing a starting material (component), an in-process sample, the Active Pharmaceutical Ingredient (API), final product (whether non-sterile or sterile), the environment to include controlled and classified areas or the HVAC, you should be aware of the critical role the microorganisms play throughout. You should be aware of the various microbiological related documents, e.g., raw material sampling criteria, in-process, API, final product, environmental and utilities, (many of which have USP microbiological documents as the "bedrock" for building these documents, to determine whether the SOPs, validations as well as government and other regulatory body document requirements are being maintained to assure the control required to permit the final product to enter the marketplace as safe.

Event Categories :