microrite, inc.

EU GMP ANNEX 1 DRAFT CLARIFICATION AND IMPACT

UNDERSTAND THE PROGRESSION OF REGULATORY THINKING AND HOW TO SUCCESSFULLY IMPLEMENT THE PROPOSED DOCUMENTED CONTAMINATION CONTROL STRATEGY

SAN FRANCISCO, CA
SEPTEMBER 27TH & 28TH, 2018
CROWNE PLAZA HOTEL

How will these changes affect your facility?

The Draft GMP Annex 1 represents an upgraded regulatory perspective by the application of QRM and PQS as they apply to the manufacture of sterile medicinal products as well as other products that are not intended to be sterile.

The principles and guidance put forth in the Draft GMP Annex 1 provide substantial expansion on virtually every topic covered in the 2008 version. Though not officially implemented yet, this draft represents current regulatory thinking on the manufacturing of all medical products.

Some of the significant changes include; the requirement to develop a documented contamination control strategy (CCS) and the use of airflow visualization for choosing risk based environmental monitoring sites.

In the past, risk assessment, risk monitoring and risk remediation were addressed as individual aspects such as cleanrooms, barrier systems, water systems, process flow etc. The Draft GMP Annex 1 suggests a more comprehensive and holistic approach as no system or process works independently.

Familiarize yourself with all aspects of the Draft GMP Annex 1 in preparation for implementing the finalized document at your facility.

EVENT OVERVIEW

Discussion on all the changes from the current EU Annex 1 and the New Draft version

- How will these changes affect your facility and operations
- Discussion on the concept of risk assessment in the draft version
- Relevance of the changes in relation to contamination control
- Developing a contamination control strategy as proposed in the Draft GMP Annex 1

Common mistakes made during risk assessment and ineffective use of QRM

- Case studies of retroactive risk assessment vs proactive risk assessment
- FDA 483 observations related to contamination issues and case studies where risk assessment did not address the issue

Executing a Contamination Control Strategy as proposed in the Draft GMP Annex 1

1. **Facility Design and Operations- Understanding the Risks**
   - Inadequate tools used for design verification
   - Cleanroom certification flaws
   - Smoke studies not capturing design and integration issues
   - Discussion of airflow patterns that lead to particulate and microbial contamination
   - Demonstration of failed smoke studies-reasons and solutions
   - New details on smoke studies and their use as proposed in the Draft GMP Annex 1
   - How to perform a facilities risk assessment
2. **Risk Assessment during Gown Choice, Maintenance and Gowning-reasons behind human borne contamination**
   - Current 483s related to compromised gowns
   - Common reasons for human borne contamination and how to mitigate the risk
   - Case studies related to gowning and ergonomics which have led to contamination and inadequate aseptic practices
   - Understanding the guidance's for gowning and gloving to perform a risk assessment
3. **Establishing and Mitigating Risk in Process-A Multipronged Approach**
   - Evaluate risk from incoming and in-process materials
   - Identify process risk by assessing critical control points-Use of airflow pattern analysis to address process contamination risk
   - Assessing gaps in equipment placement, cleaning and storage
   - Microbial reduction strategies in process
   - Considering the risk of bi-products of microbial contaminants
   - Adequacy of bioburden testing, specification and test methods
   - Discussion on 483 observations related to process failures
   - Case studies related to processing failures due to inadequate risk assessment
4. **Process Simulation Studies-Prediction of Product Contamination Risks**
   - Understand common media fill failures
   - Learning from 483 observations related to media fills
   - Defining interventions, without understanding airflows-a common error
   - Personnel comfort, gowning and technique risk
   - Case studies on avoidable media fill failures
   - Common issues when monitoring personnel
   - Assessing factors that can lead to contamination events in the fill line

5. **Contamination Issues (Seen and unseen) in Water Systems and Process Equipment**
   - Assessing microbial contamination risk in water systems:
     - Pre-treatment
     - Purification
     - Post-treatment
     - Storage and Distribution
     - Compliance
   - Discussion on ongoing issues with sampling that may be causing sporadic contamination events
   - Overview of new on line real time monitoring technologies
   - Guidance on documentation of risk in water systems
   - What is Alternative WFI
   - Similarities between water system and process equipment contamination
6. **Understanding Microbial Contamination of Process Equipment**
   - How can equipment placement contribute to microbial contamination
   - How planktonic cleanroom microorganisms can form biofilm in process equipment
7. **Novel Approach to choosing risk based EM Sampling Sites – Draft GMP Annex 1**
   - Why is airflow visualization proposed in the Draft GMP Annex 1 for selecting risk based sites
   - Discussion on RABs design related to hard wired sampling sites without understanding airflows
   - Risk mitigation during monitoring:
     - Media issues
     - Plans
     - Trends
   - Risk assessment during sampling equipment selection
   - Common errors in sampling that can increase failures or mask results
   - Missed risk in testing compressed gases
   - Continuous monitoring of risk, to process and product via EM trends
   - Laboratory related risks

Continuous Risk Assessment as proposed by Draft GMP Annex 1

- Simple tools to continuously assess risk to product
- Follow through on preventive and corrective actions and avoid excessive CAPAs
- Develop a mindset for monitoring risk instead of reacting to situations

GENRAL EVENT TIMELINE AND INFORMATION

Hotel: Crowne Plaza Foster City 1221 Chess Dr, Foster City, CA 94404 (650) 570-5700	**Airport: SFO** **Date: September 27th & 28th**
Registration and Breakfast	8.00 AM to 8.30 AM
Lunch	12.00 PM to 1.00 PM
Break	3.00 PM to 3.15 PM
Questions and answers and discussions	4.15 PM to 5.00 PM

REGISTRATION INFORMATION

Personal Information of One Registrant		
Last Name: Mr. Ms. Dr.		First Name:
Job Title:		Organization:
Mailing Address:		
Telephone:		
Email:		
Fee: $1800.00 per attendee (Includes 2 day workshop fee, breakfast, lunch, break, and course material)		
Additional Attendees		
First Name:	**Last Name:**	**Title:**
First Name:	**Last Name:**	**Title:**
First Name:	**Last Name:**	**Title:**
First Name:	**Last Name:**	**Title:**
Method of Payment: Credit Card and Check payments only. Attendees can register and make payments on Microrite's website-www.microrite.com or complete this form and fax to 408-445-1236. Check payments must be cleared before the workshop date. If you have any questions regarding payment methods feel free to contact Microrite at 408-445-0507 or send your enquiry to labraham@microrite.com.		
For credit card payment on website, a payment receipt will be considered as confirmation of registration. For credit card information faxed to Microrite an email confirmation will be sent with a copy of payment receipt. Please call 408-445-0507 in due time if confirmation is not received after payment.		
Cancellation must be received 15 business days prior to the workshop less a 10% service fee, cancellation requests will be accepted via email only.		

PAYMENT INFORMATION

Choose One (Place X) ►	☐ VISA	☐ Master Card	☐ American Express
Card Holder's Name ►			
Address of Card Holder:	Enter firm address for corporate card or personal address for personal card		
Street:			
City/State:			
Zip Code:			
Country:			
Contact Ph No & Email:			
Card Number:			
Expiration(Month/Year):			
Amount (US Dollars):			
Signature:			
Name of Attendee(s)			
Referred by:	Kindly note the name of the company or person that referred you to this workshop. We would like to thank them.		

SPEAKER OVERVIEW

Morgan has been involved with cleanrooms and contamination control since 1984. He has Worked in over 40 countries involved with projects ranging from cleanroom design, construction, validation, monitoring program development, particle counter design and product management for cleanroom related products and systems. He has addressed monitoring and control solutions in a wide variety of clean industries such as pharmaceutical, medical device, semiconductor, data storage, aerospace,, defense, automotive, optical and others.

MORGAN POLEN- CLEANROOM CONSULTANT **MICRORITE, INC.**

Ziva has over 25 years of academic, research, clinical and industrial experience in microbiology, and quality assurance. Ziva has received her Master's Degree in microbiology with a focus on Mycology and has conducted research on developing microbial Insecticides using entomogenous bacteria and fungi. Her career also includes founding and managing clinical laboratories for Maccabi Medical in Israel. She has trained personnel from various industries in microbiology techniques and methods. She uses her extensive experience to teach why assessing risk of microbial contamination should be in the forefront of any company that has products for human/veterinary use. Currently she is the President and Founder of Microrite, Inc., a California based consulting firm providing consulting and training services to pharmaceuticals, biotechnology, medical devices and in vitro diagnostics in the areas of quality assurance, quality control, microbiology, and validation.

ZIVA ABRAHAM- CEO
MICRORITE, INC.

Bob has 35 years of experience in Industrial Water Purification and application. Bob has worked in the design, production, application and monitoring of high purity water for most every technical Industry including Defense, Aerospace, Semiconductors, Pharmaceuticals, Biotechnology, Nanotechnology, Hospitals and Research. Bob's work has focused on all aspects of high purity water including trace analytical chemistry, water system design, system manufacturing, instrumentation, regulatory expectations, system failure investigation, and design remediation and application assistance.

ROBERT LIVINGSTON- CTO
ARION WATER