Innovating Cell and Gene Therapy Quality Control Conference 13 JULY 2022

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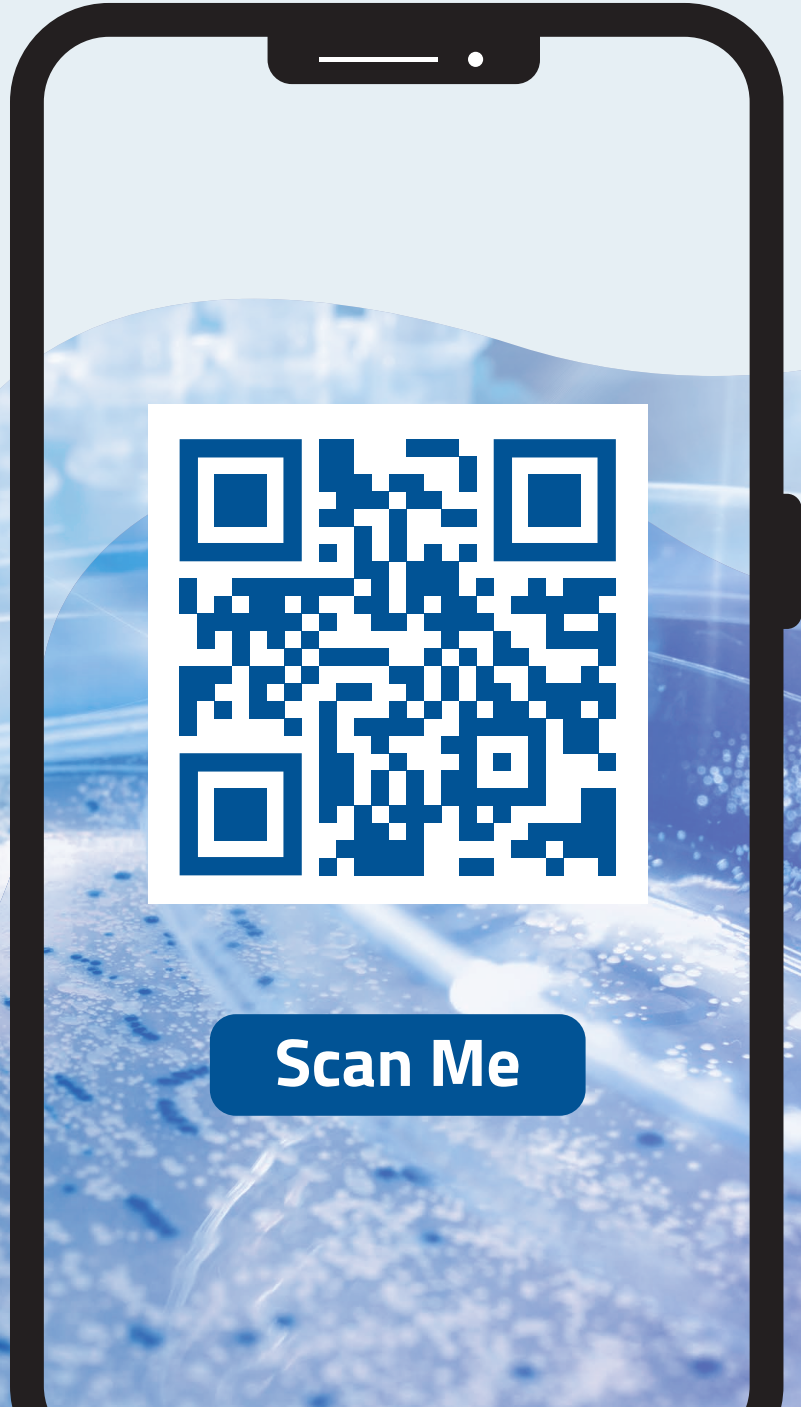
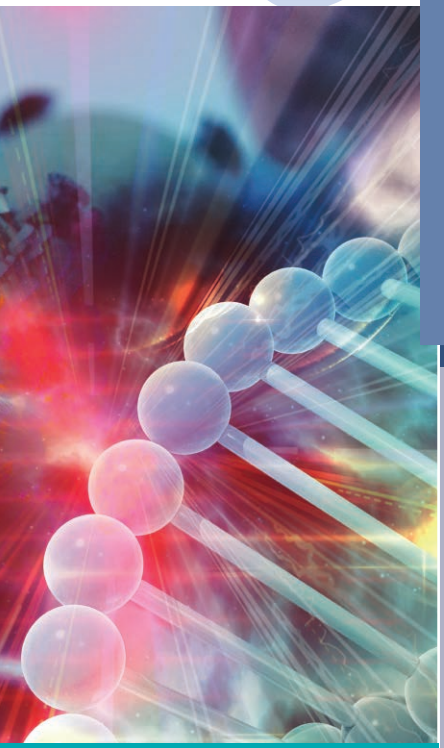


When we test the CGT product using BSC Class II cabinet under unclassified area, what sort of environmental monitoring would you recommend for BSC Class II when is use? Air plates, settle plate and contact plate or contact and Settle is enough? Also would you recommend any EM for unclassified area?

ACCUGENIX PRODUCT DEMO LAB DEMO

I think the networking was great as it was last time, we have had some unexpected but very positive conversations again

ACCUGENIX PRODUCT DEMO / LAB DEMO



From a regulatory perspective, how likely is it that an RMM will replace the compendial method for final product sterility testing? How much time do you predict it will take for regulatory acceptance?

CGT MANUFACTURING: A MICROBIOLOGICAL PERSPECTIVE

How much of an impact does contamination of reagents have on RMM accuracy?

Enzymes and other biological reagents are generated using bacterial vectors, and it is effectively impossible to purchase reagents without some level of contamination. How does that affect LoD for RMMs and what level is acceptable to the industry?

CGT MANUFACTURING: A MICROBIOLOGICAL PERSPECTIVE

Is it mandatory to Identify the EM isolate if its from Grade A area? or it depends on how critical the product or step or process it is?

PANEL DISCUSSION: ENVIRONMENTAL MONITORING AND MICROBIAL IDENTIFICATION

Where are there areas that I can gain efficiency and save costs with EM?

Q&A - QUICK FIRE REGULATORY UPDATE

How can the customer web portal help me identify where an organism came from during an investigation?

Q&A - ACCUGENIX PRODUCT DEMO / LAB DEMO

From a regulatory perspective, how likely is it that a RMM will replace the compendial method for final product sterility testing?

How much time do you predict it will take for regulatory acceptance?

Q&A - RAPID MICROBIAL METHODS

What are some of your best tips to ensure you have a robust training especially for those who have never aseptically gowned before?

ENVIRONMENTAL MONITORING AND MICROBIAL IDENTIFICATION

What limits can be applied for the Grade A BSC in Grade C background while in operation for CGT aseptic manipulations?

ENVIRONMENTAL MONITORING AND MICROBIAL IDENTIFICATION

How do you react if you find that you recovered mycoplasma in your product?

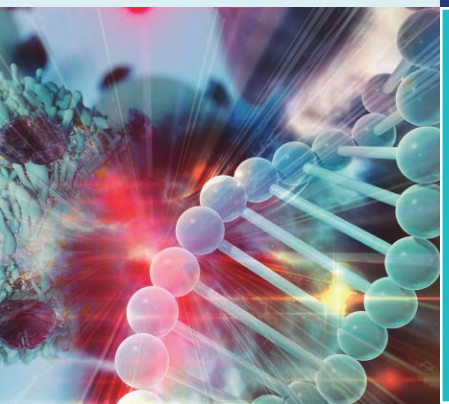
ENVIRONMENTAL MONITORING AND MICROBIAL IDENTIFICATION

How critical is it that a company's microbial ID strategy is harmonised across sites? What are the risks and challenges of each site using a different microbial ID platform?

PANEL DISCUSSION: ENVIRONMENTAL MONITORING AND MICROBIAL IDENTIFICATION

What are the typical roles of the various departments in a company (QA, QC Micro, Manufacturing, Facilities Management, etc.) with respect to the environmental monitoring program and during EM investigations?

ENVIRONMENTAL MONITORING AND MICROBIAL IDENTIFICATION



Is there a specific method that is recommended?

ENVIRONMENTAL MONITORING AND MICROBIAL IDENTIFICATION

How do microbial identifications fit into an EM program?

ENVIRONMENTAL MONITORING AND MICROBIAL IDENTIFICATION

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What kinds of cell lines have you tested using this technology?

CELSIS PRODUCT DEMO / LAB DEMO

How long does it take to detect very low C. acnes contamination, so maybe less than 10 CFU for example?

CELSIS PRODUCT DEMO / LAB DEMO

Is it mandatory to validate the disinfectant by suspension method as well as contact replicas for contact time if we are only product testing facility?

Or can we validate our cleaning/disinfection method to be used by Spray wipe-lightly spray and allow to dry? As we are more interested to remove the organisms from surfaces. of source disinfectant must be effective here?

MITIGATING MOULDS

What is the false positive rate?

CELSIS PRODUCT DEMO / LAB DEMO

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PANEL DISCUSSION: ENVIRONMENTAL MONITORING AND MICROBIAL IDENTIFICATION

What is the advantage of using this technology over established CO_2 detection methods?

CELSIS PRODUCT DEMO / LAB DEMO

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What disinfectant(s) would you recommend using on stainless steel?

MITIGATING MOULDS

Is BacT/ALERT (automated growth-based method) something considered by USP or any other chapter in USP? regulatory update?

QUICK FIRE REGULATORY UPDATE

What are the sterilant recommended?

Can you list them

MITIGATING MOULDS

What are the recommendations for the frequency of cleaning/disinfection and the use of sporicides?

MITIGATING MOULDS

Do you need a method qualification and method validation for the same assay?

At what stage do you need both? Should we do both the activity in QC?

QUICK FIRE REGULATORY UPDATE

Are there any regulatory guidelines available for QC testing for Cell and Gene therapy?

QUICK FIRE REGULATORY UPDATE

You mentioned various fungi that are a risk– is there a particular species that is most common to CGT environments?

MITIGATING MOULDS

Do you need a method qualification and method validation for the same assay?

At what stage do you need both? Should we do both the activity in QC?

MITIGATING MOULDS

Is there anything available for combining sterility testing with mycoplasma testing?

- what would be the benefit of this?

QUICK FIRE REGULATORY UPDATE

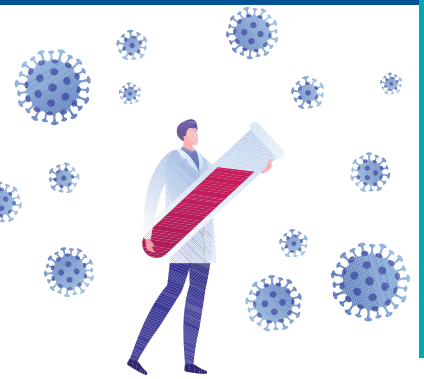
How can we reduce the amount of samples for sterility testing?

In case we do not have enough samples to carry out sterility control according to the quantities specified in EP or USP

QUICK FIRE REGULATORY UPDATE

Do you need a method qualification and method validation for the same assay?

FIRESIDE CHAT: MY JOURNEY AS A CGT START-UP



What is the most sensitive test for endotoxin detection?

FAST AND EFFICIENT ENDOTOXIN TESTING

Even low levels of endotoxin contamination can trigger strong immune activation in cell culture or animal models. What are your thoughts on quality control measures?

FAST AND EFFICIENT ENDOTOXIN TESTING

What should be the ideal Turnaround time for QC testing and batch release in Cell and Gene therapy?

FIRESIDE CHAT: MY JOURNEY AS A CGT START-UP

Are there any regulatory guidelines available for QC testing for Cell and Gene therapy?

FIRESIDE CHAT: MY JOURNEY AS A CGT START-UP

At what stage do you need both?

Should we do both the activity in QC?

FIRESIDE CHAT: MY JOURNEY AS A CGT START-UP

What should be the EM specification recommendation for BSC (grade A) when testing CGT product under BSC in unclasssified area?

FIRESIDE CHAT: MY JOURNEY AS A CGT START-UP

Once sample is ready to test in how much time sample must be tested by Endosafe?

Is ther any limit?

FAST AND EFFICIENT ENDOTOXIN TESTING

Can targetability be an issue with gene and cell based therapeutics?

Rapid microbial methods

How to interpret and report a test result obtained by the rapid diagnosis method when it is different from that of culture method, it can not perform antibiotic sensitivity tests, a problem of non-specific reaction, comparatively higher cost of rapid diagnosis kits.

RAPID MICROBIAL METHODS

According to EP or USP there is a certain amount of the gene/ cell product for conducting sterility control, depending on the size of the lot. Do you have any advice on how to reduce the amount of sample per control?

RAPID MICROBIAL METHODS

Celsis approach cannot be considered as compendial, right ?

RAPID MICROBIAL METHODS

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RAPID MICROBIAL METHODS

If the method is generically validated as it seems with your slides, does it mean that we need to do a complement of validation with product-specific matrix, to check that generically validated method remains fit for purpose with this specific matrix?

RAPID MICROBIAL METHODS

In cell based therapies how can the test be individualised as tests may vary a little from case to case?

RAPID MICROBIAL METHODS

If you get a positive result, how do you identify the organism to start an investigation? It looks like the microbes are destroyed in order to detect their ATP.

RAPID MICROBIAL METHODS

In the video, it seems PTS is a standalone reader. Why should we use ENDOSCAN V?

Is it really required?

ENDOSAFE PRODUCT DEMO / LAB DEMO

A previous speaker stated that they store cartridges at 2-8, whereas I have stored at ambient in a previous role. Is there any major difference between storing at these conditions?

ENDOSAFE PRODUCT DEMO / LAB DEMO

And how long does an analysis take?

RAPID MICROBIAL METHODS

Scan Me

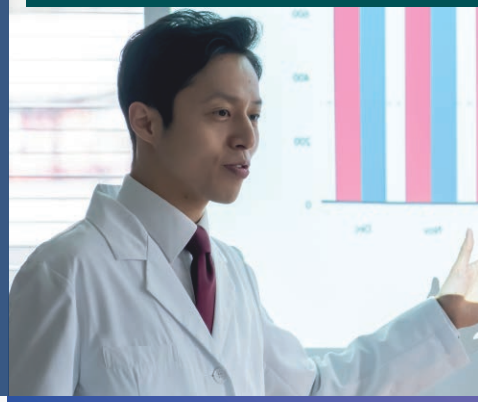
Endotoxin testing must be performed on clean bench or BSC II by Endosafe testing kit method?

ENDOSAFE PRODUCT DEMO / LAB DEMO

What do you think about Recombinant Factor C (rFC) approach for endotoxin testing?

How much time is needed for an analysis on the Endosafe?

FAST AND EFFICIENT ENDOTOXIN TESTING



What is involved in bringing a rapid method on site, getting regulatory approval, and routinely using the system?

RAPID MICROBIAL METHODS

Could you advise on expiry date on LAL water once opened?

Does it need to be validated internally?

ENDOSAFE PRODUCT DEMO / LAB DEMO

What does calibration code mean?

Why is it not enough only the batch code for performing a LAL test on PTS?

ENDOSAFE PRODUCT DEMO / LAB DEMO

When you talk about validating Endosafe, Do you mean a compendial verification about EP/USP method suitability with the product matrix?

ENDOSAFE PRODUCT DEMO / LAB DEMO

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RAPID MICROBIAL METHODS