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Webinar on

Mathematics Of Terminal Sterilization - Probability Of Survival Approach -Vs- Overkill Approach

Areas Covered

From the topics listed above the areas covered provide the mathematical means of developing and proving the sterilization process is effective and does not generate a problem for heat liable products.

- *Survivor Curves to determine D-values and Z-values*
- *Linear Regression used to calculate the edge of failure*
- *Fraction Negative studies*
- *Correction factors associated with heating and cooling*

- *Cold spot determination - product and chamber - TD and HP*
- *Calculation of process lethality*
- *Biological Indicators to be used and how to make the selection*
- *Laboratory Studies needed to support Sterilizer Studies*
- *Identification of elements in the process that can affect D-value*

This webinar will discuss the definition of “Sterile” and how to get there by describing different sterilization methods.

PRESENTED BY:

Mr. Jerry Dalfors has extensive (40+ years) of business administration, consultative, technical and managerial experience in the development and manufacture of highly regulated biopharmaceutical products including injectables, biologics, medical devices and oral dosages. He has held permanent employee, temporary employee and company representative management positions with a multitude of the major pharmaceutical and biotechnology companies in the US.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

Heat sterilization is a PROBABILITY function dependent on heat exposure, the number of microorganisms, and the heat resistance of the microorganisms. Current regulations expect the sterilization process to provide a level of assurance of at least 1 x 10-6 probability (fewer than one non-sterile unit per million units) of survival (non-sterility) for terminally sterilized parenteral and medical devices. Since Regulations require that we generate in our sterilization processes a PROBABILITY of a NON-STERILE UNIT (PNSU), how do we use D-values, Z-values, and Foto calculate the probability and determine that we have essentially zero risk in our products due to lack of sterility?

D-value is the term used to describe the amount of time required to kill or destroy a microorganism. Spores are much more difficult to kill than vegetative cells which is why we use spores as our Biological Indicator for the effectiveness monitor of our sterilization process. D121 tells us how many minutes it takes to kill an organism at 121oC (or 250oF) - note the "F". The D-value is the time required to reduce a population of microorganisms by one log at the process temperature. From 1x106 to 1x105 – from 1,000,000 to 100,000 organisms.

Z-value of a microorganism is a measure of how heat resistance changes with changes in temperature. Z is defined as the number of degrees temperature change to change the D-value by a factor of 10. The Z-value allows integration of the lethal effect of heat as the temperature changes during the heating and cooling phases of a sterilization cycle. D121 tells us how many minutes it takes to kill an organism at 121oC (or 250oF) - note the "F"

And then we move on to lethality, the different elements that affect D-value and z-value and how to calculate the probability that a defined cycle is going to give us the SAL and PNSU that is needed to ensure that only or less than 1 in a million patients might have a problem due to sterility issues as well as reviewing what has caused a number of FDA Warning Letter due to inappropriate sterilization development, validation and on-going assessment of the process.

Different microorganisms in different environments during sterilization have different resistance to the destructive principles that causes the organism or spore to die (lethality). Some extreme thermophile organisms have their optimal growth temperature of 110°C, whereas most vegetative cells are killed at 60°C. Some species (not necessarily spore formers) are highly radiation resistant. The chemical environment causes significant variance in the death rate of a microorganism. Very dense cell walls, sports coats, or slime layers outside the cell can severely limit the ingress of what is being used to sterilize the product.

General principals used to kill microorganisms such as Steam and Dry Heat which causes denaturation of macromolecules, dissociation of tertiary and secondary structures, and protein agglutination along with the destruction of molecular arrangements in the cells caused by radiation. The generation of free radicals causes destruction and re-arrangement of chemical bonds in macromolecules. Chemical disinfection or sterilization causes modifications of macromolecules depending on the agent used.

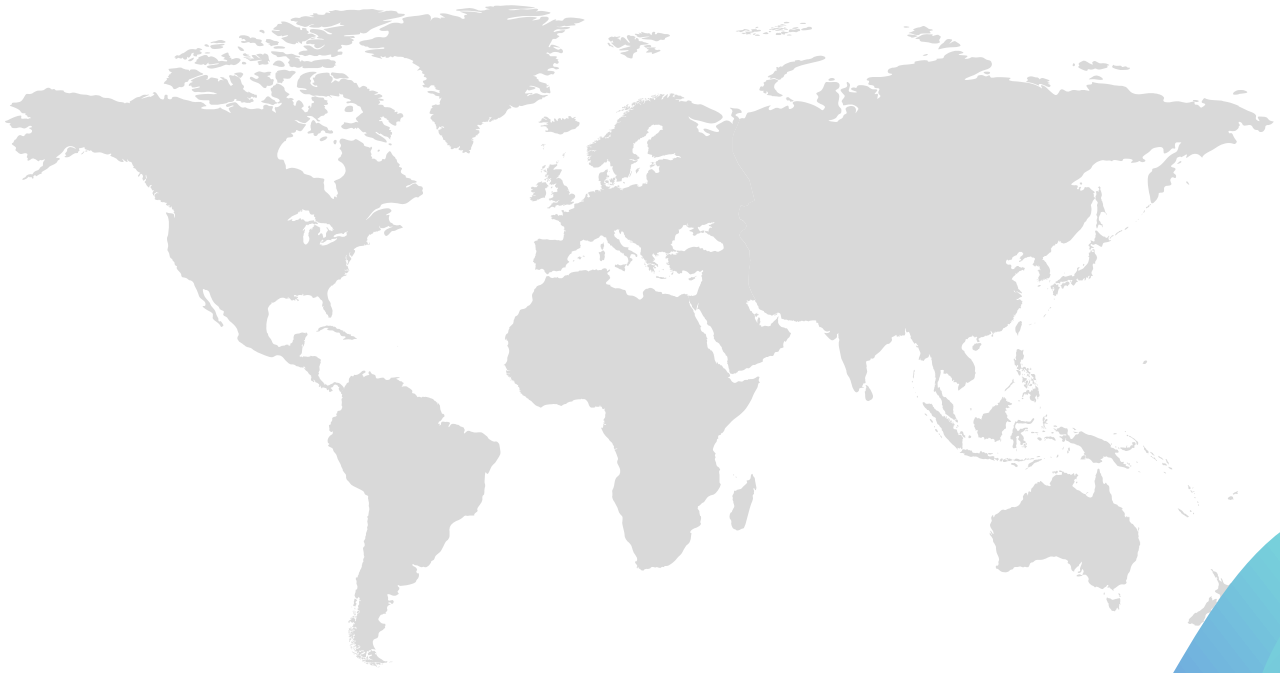
General Sterilization Terms

D-value – all types of sterilization
z-value – thermal sterilization processes
F-value – thermal sterilization processes that originated from 250oF
FBIO - thermal sterilization for specific organisms
Fo (F sub-zero) – moist heat sterilization
FH (F sub H) – dry heat sterilization & depyrogenation
L – Lethality (aka F value) used in various processes

How do we calculate and monitor these different variables in order to generate the required SAL and PNSU based on the bioburden that may be contaminating the product from an API or the process?

Who Should Attend ?

Manufacturing Operations, Formulation, Engineering, QA/QC, Product and Process Development, Regulatory Affairs, Research and Development, Sterility Assurance, Technical Operations and Validation Professionals as well as inspectors and auditors.



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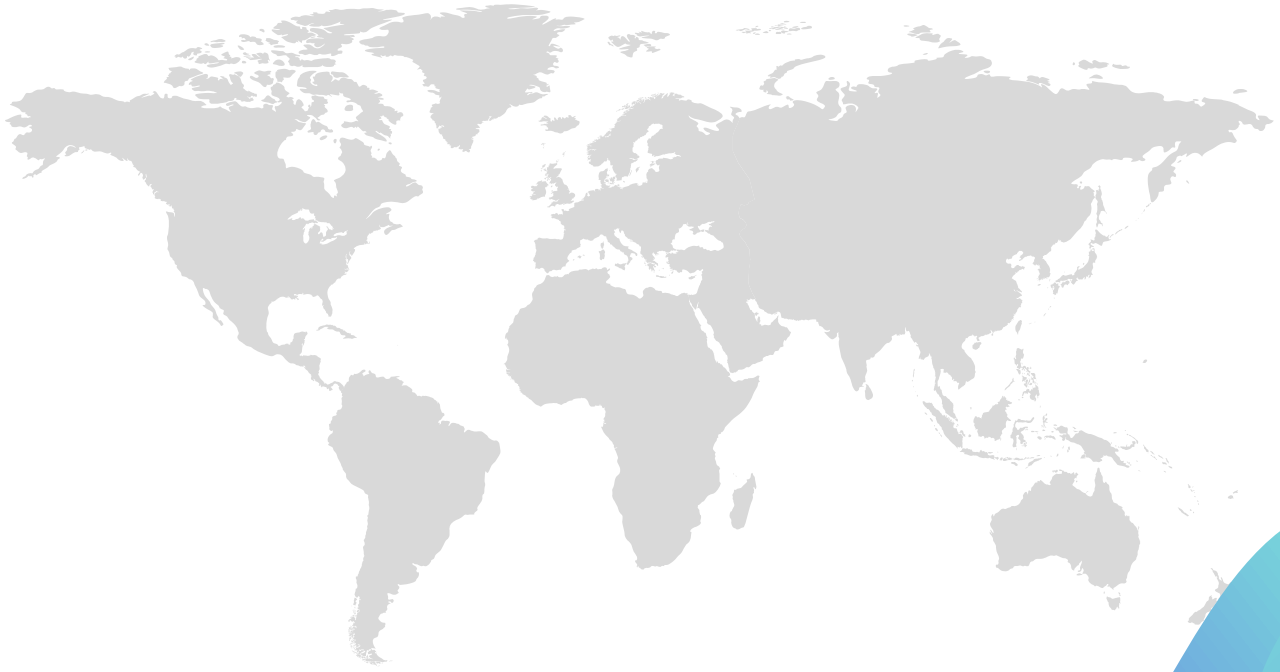
Why Should Attend ?

FDA wants me to teach this to their field inspectors. Since there is so much different interpretation of regulatory statements and because different agencies have different philosophies, those who do not have a deep comprehension of the sterilization design relative to the microbiological impact (why many sterilizers have been improperly designed), we will discuss the definition of "Sterile" and how to get there by describing different sterilization methods, various approaches to be used for the validation of a sterilization process using moist heat as template that can be used for other sterilization methods and what requirements for routine monitoring and control of sterilization are required.



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