Webinar on

Thermal Characterization As Part Of An Empirical Process For Developing Optimized Formulations And Lyophilization Cycles

Date : September 17 ,2019

Areas Covered

- *Applications of thermal analysis and freeze-dry microscopy techniques for solutions and solids*
- *Freeze-dry microscopy equipment and techniques*
- *Crystalline vs. amorphous vs. mixed systems*
- *Eutectic melting, glass transition, and collapse temperatures*
- *Thermal analysis equipment and techniques: DSC, DTA, TEA*
- *Partial collapse vs. meltback*
- *Examples of failed products*
- *Principals of thermal analysis*

This webinar will begin with a discussion of the physical properties of materials that are commonly used to formulate freeze-dried products, and the impact that these materials can have on how products freeze-dry.

PRESENTED BY:

J. Jeff Schwegman, Ph.D. is currently the founder and chief executive officer of AB BioTechnologies (www.ab-biotech.com) where he develops formulations, lyophilization cycles, determines residual moisture by Karl Fischer, and provides thermal characterization studies including freeze-dry microscopy and DSC.

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Date : September 17, 2019

Time : 01 : 00 PM EST

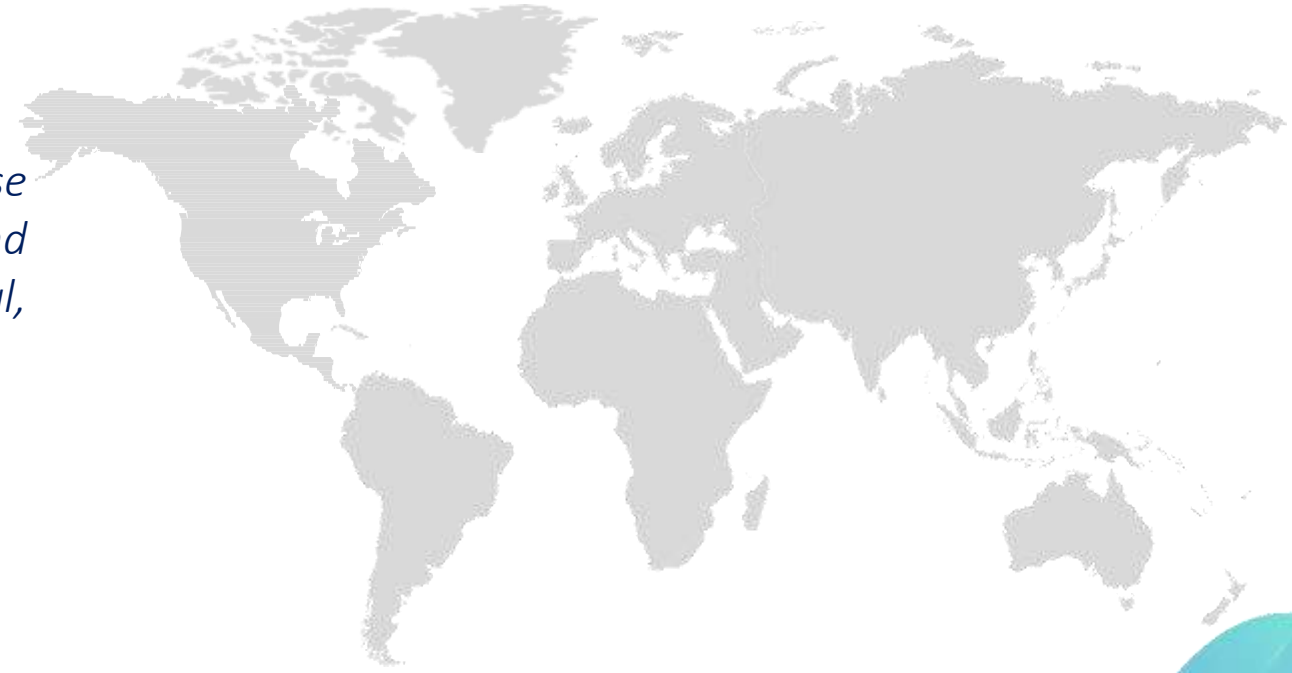
Duration : 90 Minutes

Price: $179

Webinar Description

This webinar will begin with a discussion of the physical properties of materials that are commonly used to formulate freeze-dried products, and the impact that these materials can have on how products freeze-dry (in regards to the physical and chemical integrity). Understanding if a crystalline, amorphous, mixed, and or metastable system is present in our products, is critical in developing a sound, stable formulation that can easily be freeze-dried. Choosing excipients based solely on their stability imparting characteristics, without taking into account their thermal properties, can result in disastrous results both in the physical structure of the solids and on the long term stability. Next, there will be a thorough discussion of the analytical techniques used to characterize the thermal properties of the formulated product. These techniques allow the development scientist to understand not only what types of materials are present, but also the critical temperatures that are associated with these materials (glass transition temperature, eutectic melting temperature, annealing temperature, etc.). Finally, the webinar will conclude with a brief discussion of some of the specialized analytical techniques that can be employed to characterize the lyophilized solids. Understanding the physical properties of the dried solids allows the development scientist to be able to troubleshoot, diagnose, and correct a problematic formulation and or lyophilization cycle.

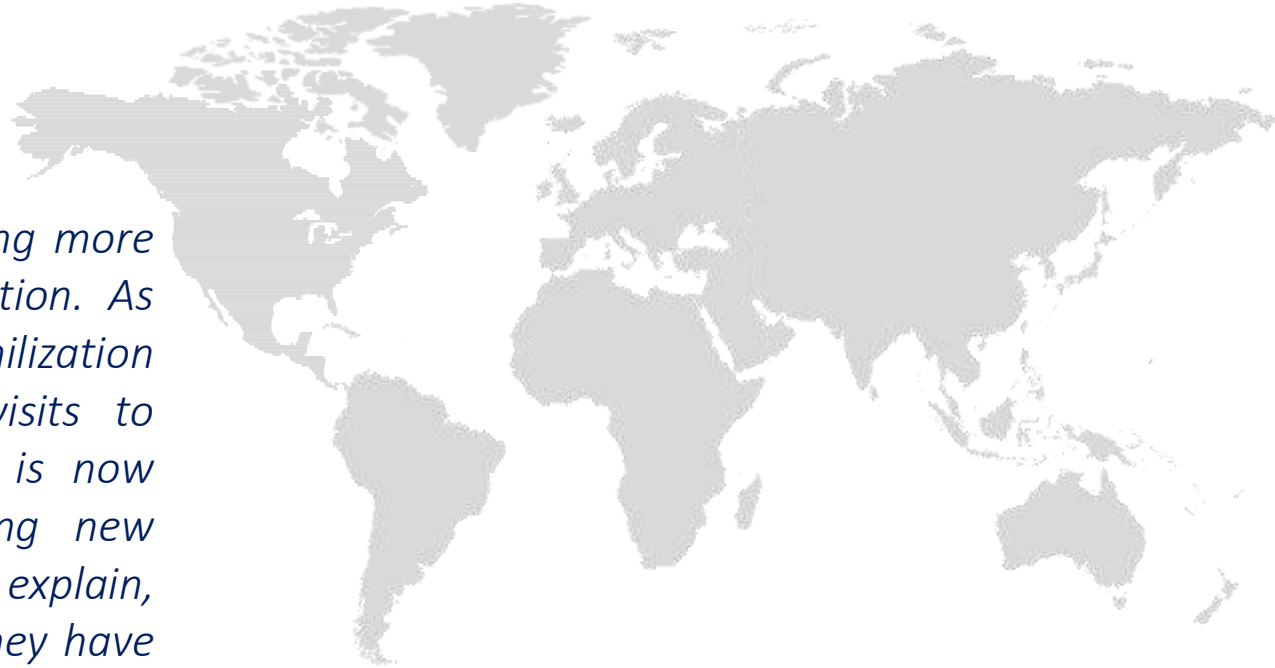
Who Should Attend ?



This webinar will provide valuable assistance to those companies involved in the development and manufacture of lyophilized pharmaceutical, diagnostic, and food products

- *Quality Control Scientists*
- *Development Scientists*
- *Production Management*
- *Quality Assurance*

Why Should Attend ?



The Food and Drug Administration (FDA) is becoming more educated in the practice and science of lyophilization. As such, they are asking more questions about lyophilization during NDA or ANDA document reviews, site visits to companies producing lyophilized products, etc. It is now expected by the FDA, that companies developing new formulations and lyophilization cycles must be able to explain, scientifically, why they have chosen each excipient they have added to a formulation, why they are using as much as they have added, what are the critical temperatures of the products (glass transition temperature, Tg' or eutectic melting temperature, Te), etc. Companies that cannot produce this type of information run the risk of being delayed in getting their products approved and on the market, which can have a dramatic impact on their profit margin.

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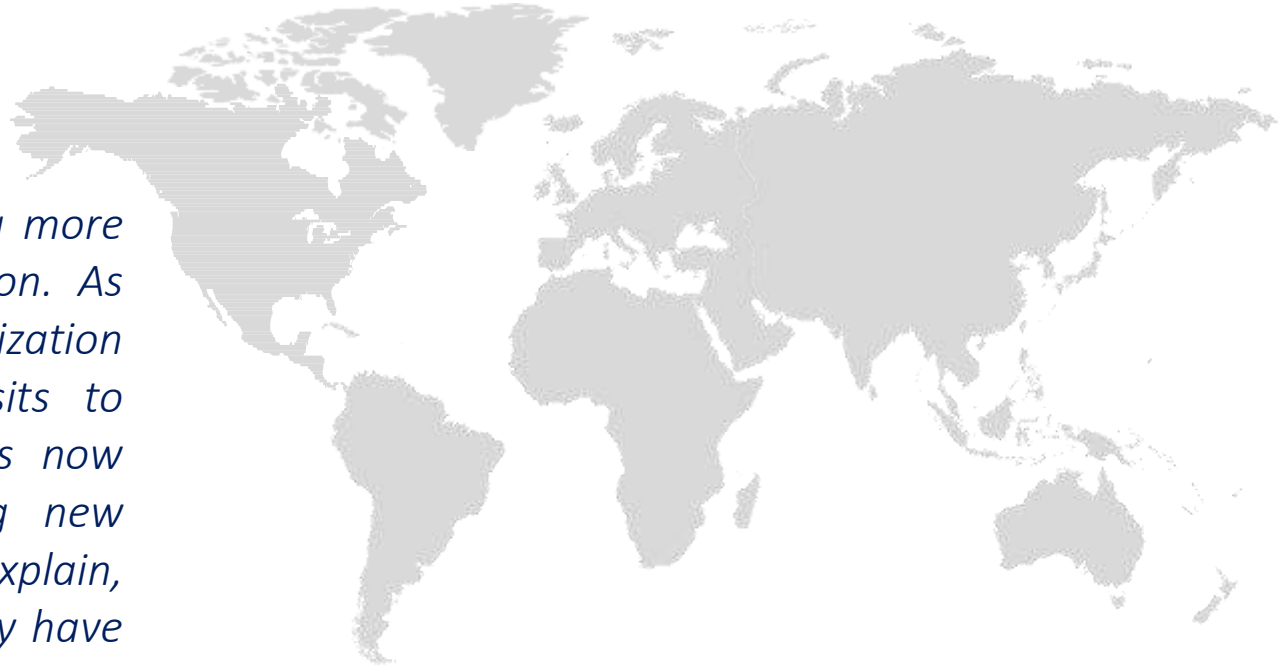

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