

General Sessions – Abstracts

ECU Spring Break 2020 Pharma Conference
March 10-11th, 2020

Drug Development Process from Discovery to Market

Wael Elmasri, Thermo Fisher Scientific

Drug development is the process of bringing a new pharmaceutical drug to the market. It starts with identifying a lead compound through the process of drug discovery. Once identified, preclinical research on microorganisms and animals then clinical trials on humans takes place followed by filing for regulatory status through United States Food and Drug Administration. Upon obtaining regulatory approval on the drug application, the drug launched to the market.

It's Not Working! What will work? The Lifecycle Approach for Methods

Jane Weitzel, Independent Consultant

The Lifecycle approach to analytical procedures is new. Why is it needed? To quote Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER); "It's not working, and it won't work in the future, I don't want to bum everyone out, the science is fabulous, but that's not enough." What is enough? For analytical procedures the lifecycle approach which uses measurement uncertainty is enough.

This talk will review the concerns of regulatory bodies regarding the state of the pharmaceutical industry. Then the Lifecycle approach to analytical procedures will be described. Its benefits will be identified, specifically the use of Measurement uncertainty when making decisions with the reportable value. The way in which the lifecycle approach is "enough" will be explained.

Test Methods in Common: An "Analytical Formulator's" Prospective

Michael DeHart, CMP Pharma

This talk will focus on the relationship between analytical methods and the manufacturing process. A brief review of the current guidance that helps determine the quality, safety, and efficacy of a drug product will be provided. Several scenarios are discussed where analytical results impact the manufacturing process and vice versa. In the end, the pharmaceutical scientist should have a greater understand of how intertwined analytical and manufacturing are and that you just don't "throw it over the wall."

The USP Organization

Alan Potts, Thermo Fisher Scientific

[Pending]

Biopharmaceuticals – An Overview of Process Manufacturing and Analytical Testing

Janet Davis, Thermo Fisher Scientific

The pharmaceutical industry has seen a rapid expansion in recent years of proteins, peptides, vaccines, and nucleic acids used as therapeutic products. This talk will provide a broad overview of biologic drugs to include categories, expression at scale (Upstream Bioprocessing), purification (Downstream Bioprocessing), unique formulation / storage / handling properties, and typical testing methods to release for clinical use.

What's Hot? A Survey of Recent Warning Letters

Angela Corbin, Thermo Fisher Scientific

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