

PROCESS ANALYTICAL TECHNOLOGIES

Summary

To support both innovation and efficiency in pharmaceutical development, manufacturing, and quality assurance, the FDA proposed its process analytical technology or PAT framework (2004). The framework is founded on process understanding to facilitate innovation and risk-based regulatory decisions by industry and the Agency.

During this course, a basic introduction will be given on the implementation of process analytical tools (PAT) in the field of the pharmaceutical industry. An overview will be provided on the PAT-tools which are commonly used in the field including both spectroscopic and non-spectroscopic sensors. In addition, attendants will learn how, when and where these tools can provide a benefit to the pharmaceutical manufacturing process. During a 2.5-day training, participants will learn to explore uni- and multivariate data and make predictive models using real spectroscopic data.

- 1) **Module 1: Basic course: Introduction to PAT (1-day)**
- 2) **Module 2: Basic data-analysis and modeling (1.5-day)**

MODULE 1: BASIC COURSE: INTRODUCTION TO PAT

Theoretical

General introduction to PAT

- a. Basic fundamentals
- b. What is the scope?

Choosing the appropriate PAT sensor

- a. Spectroscopic sensors
- b. Non-spectroscopic sensors (Univariate/Multivariate)

Basic understanding of hyperspectral imaging

- a. Basic fundamentals
- b. What is the scope?
- c. Sensors

How can PAT be used?

- a. PAT in R&D/Process Validation/QbD
- b. Process control based on PAT

Regulatory aspects and hurdles

- a. What is the current regulatory status?
- b. What hurdles are there currently?

Sneak-peak into Multivariate data analysis

- a. Basic fundamentals

Practical

Hands-on session: Use and implementation of NIR

- a. How to implement the system?
- b. What kind of data do you get out of it?

Hands-on session: Use and implementation of Raman

Hands-on session: Use and implementation of FLIR

REQUIREMENTS

Basic understanding of spectroscopy and pharmaceutical manufacturing techniques.

Basic understanding of coding and programming is recommended.

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MODULE 2: BASIC DATA-ANALYSIS AND MODELING

Theory through practice

Using spectroscopic data, the teacher will go through different aspects of PAT and model development together with the attendee.

General introduction to Python

- a. Basic coding principles
- b. How can we use Python for PAT data?
- c. Advantages compared to commercial software

Data preparation and exploration

- a. Data pre-treatment aspects
- b. Exploratory analysis

Introduction to modeling

- a. Overview of linear and non-linear univariate models
- b. Introduction to PCA
- c. Introduction to PLS
- d. Multivariate data-analysis
 - i. Introduction to modeling in SIMCA
 - ii. Introduction to modeling in Python

Process control based on PAT

- a. Looking at your data, which predictive models can you implement?
- b. How can you control the process based on your developed models?

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