

*<Out of specification investigations seminar> Syllabus  
Rev.1*

## Day 1

### Module

### Topics

#### Session Kick-Off

- Introductions
- Course objectives and expectations

#### Guides session

- A brief overview of FDA guide “ Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production” May, 2022
- A brief overview of MHRA “Out of Specification & Out of Trend Investigations” October 2017
- General instructions and some tips for high-quality, exhaustive and comprehensive investigations

#### Inspections review

- Review of regulatory inspections (FDA & MOH) findings from several last years
- Hot topics to be prepared

#### Team work

- Practical experience in investigational thinking – work in teams

#### Session Wrap-Up

- Feedback