

## A Practical Application of Monitoring in a Healthcare Setting Agenda

## DAY 1

- Introduction /Course Objectives
- The Scope & Purpose of Monitoring
- The Role of the Monitor / Approaches to Monitoring
- Risk Assessment / Development of a Monitoring plan
- Site Selection/Initiation / Preparation for a visit Monitoring Activities
- Monitoring Activities /Study closedown visit

## DAY 2

- Workshop: Monitoring of Study TMF and Pharmacy File
- Workshop: Monitoring of Study Source Data Verification
- Monitoring visit review/ Completion of Corrective Action Preventative Action
   Plan
- Escalation and none compliance processes
- End of study reports