THIS COURSE INTRODUCES THE PARTICIPANT TO SPONSOR RESPONSIBILITIES AND GOOD CLINICAL PRACTICE IN INVESTIGATOR-INITIATED AND/OR COMMERCIALLY SPONSORED CLINICAL TRIALS

Good Clinical Practice: Sponsor Responsibilities

RCSI Education and Research Centre

Smurfit Building, Beaumont Hospital

7th September 2015

Agenda

09:30	**Introductions**
09:40	Research Governance - Background - Rules and Regulations
10:30	**Workshop 1**
10:45	Principles of ICH GCP
11:00	**Coffee Break**
11:30	ICH GCP Section 5: Sponsor Responsibilities
12:30	**Workshop 2** ICH GCP Section 5: Sponsor Responsibilities (Continued)
13:15	**Lunch**
14:00	Other Sponsor Responsibilities ➢ Essential documents ➢ Indemnity and Insurance ➢ Safety Reporting
15:15	**Workshop 3**
15:30	GCP Audits and Inspections
16.00	GCP Quiz and Conclusion

To reserve a place please contact: caroleschilling@rcsi.ie or dhyland@rcsi.ie