Master Aspetti Regolatori,Brevettuali ed Economici per lo sviluppo dei farmaci e dei dispositivi medici

4° settimana 24/10 to 29/10

Aula Levi - Dipartimento di scienze chimiche e farmaceutiche

Giorno	Orario	Argomento lezione	Docente
Sabato 19/11	9.00-13.00	Medical Devices	**Bertolasi**
Lunedì 21/11	9.00-18.00	Medical Devices	**Ing. Mosca,**
Martedì 22/11	9.00-18.00	Clinical Trial Methodology and Italian & International Regulation ICH GCP Quality Systems – Quality Assurance, Quality Control & Auditing	**Francesca Saracino** Societa' Faramaceutica Celgene **Federica Chiera** COVANCE
Mercoledì 23/11	9.00-18.00	Clinical Monitor responsibilities according to GCP and Italian Ministry of Health Decree 15 Luglio 1997 (paragrafo 5.18 dell'allegato 1) Good Manufacturing Practices Pharmacovigilance	**Francesca Saracino** Societa' Faramaceutica Celgene **Federica Chiera** COVANCE

Giovedì 24/11	9.00 -18.00	Electronic Health Records – FDA & EMA guidance EU Trial Master File – FDA & EMA Guidance	**Maria Grazia Pagano** COVANCE **Mauro Germinario** Director Clinical Operations, Country Head Italy COVANCE
Venerdì 25/11	9.00-18.00	Principal Investigator Responsibilities Managing Clinical Trials	**Maria Grazia Pagano** COVANCE **Mauro Germinario** Director Clinical Operations, Country Head Italy COVANCE
Sabato 26/11	9:00- 18.00	Enrolling Subjects in Clinical Trial The role of the Independent Ethics Committee ICH GCP	**Maria Grazia Pagano** COVANCE **Mauro Germinario** Director Clinical Operations, Country Head Italy COVANCE