

Training Day 1 **09:00 to approx. 18:00**

Strategies, Suppliers and Sourcing Approaches

- General introduction to outsourcing
- Designing an outsourcing strategy
- Clinical research supplier market
- Insourcing/outsourcing
- Critical success factors for suppliers
- Set up of a typical CRO collaboration

Outsourcing Process

- Regulatory requirements and common inspection findings
- Process overview from study design to final payment
- The role of the outsourcing manager
- Basic negotiation principles

Financial Considerations

- Outsourcing costs
- Bid review and analysis
- Preparation for negotiation

Training Day 2 **09:00 to 16:45**

Legal Issues in Outsourcing

- Development of a contract
- Key documents
- Contract models and change in scope documentation
- Legal terms
- Typical legal issues and how to overcome them

Risk Management

- Introduction to risk management
- Using scenarios:
 - Consider areas of risk in outsourcing a project
 - What contingency measures can be put in place?
 - How can these be managed and measured?

Relationship Management

- How to establish a relationship
- Governance
- Key success criteria
- Understand key stakeholder requirements

Financial oversight during the study

- Financial tracking and contract management
- Change in scope
- Negotiation considerations

Oversight and Performance Management

- Study oversight
- Performance metrics/KPIs
- Issue management and resolution
- Using 'lessons learnt' to improve the future

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