Regulatory Interactions for Statisticians

presented by
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26-27 September 2018
Crowne Plaza, Heathrow

The course objective is to inform statisticians about the likely interactions they might have with regulatory agencies, both during a submission and at other times during drug development, and give advice on how to make these interactions most effective.

The course will focus on clinical development.

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The course is primarily targeted at project statisticians who interact with regulators, but would also be suitable for those who may move into this role in the near future.

The course will be presented by experienced statisticians from the MHRA, FDA and those with expansive pharmaceutical company employment and representatives from a company regulatory affairs department. The course will consist of lectures, practical examples and discussions. There will not be any computer exercises.

Key Topics

- Introduction to the regulatory agencies
- Interactions between EU and US regulators and statisticians at each stage of development
- Overview of regulatory practices in other regions

Registration

Registration on or before 15th August:
£595 + VAT (PSI Members)
£690 + VAT (PSI Non- Members)

Registration after 15th August:
£695 + VAT (PSI Members)
£790 + VAT (PSI Non- Members)

Register at: http://psiweb.org/events/psi-events
Please contact the PSI secretariat on psi@mci-group.com if you have any queries.