

GCP seminar for inspectors participating in the WHO Prequalification Programme

**Trainer : Olivier Le Blaye PharmD
Inspector,
Clinical Trial Unit AFSSAPS**

Program

Thursday March 30, 2006

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|--|--|------------------------------------|
| 9.00 - 9.10 | Opening of the seminar | Laurent Moche, Director
AFSSAPS |
| 9.10 - 9.30 | Scope of the seminar and introduction of
the participants | Olivier Gross, WHO |
| 9.30 - 10.00 | What is a Bioequivalence study | Olivier LeBlaye,
AFSSAPS |
| <i>10.00- 10.15 Coffee break</i> | | |
| 10.15 - 10.45 Identification of key points | | |
| 10.45 - 11.15 Reference texts | | |
| 11.15 - 12.30 Investigational products | | |
| <i>12.30 - 13.45 Lunch</i> | | |
| 13.45 - 15.15 Clinical part of a BE study | | |
| <i>15.15 - 15.30 Coffee break</i> | | |
| 15.15 - 17.00 Questions and discussion | | |



Friday March 31, 2006

9.00 – 10.00 Bioanalytical methods used
Case study

10.00 – 10.15 Coffee break

10.15 – 12.30 Validation
Case study

12.30 – 13.45 Lunch

13.45 – 15.15 Study phase :
- Acceptance criteria
- QC samples

Case study

15.15 – 15.30 Coffee break

15.15 – 16.00 Study phase :
- Chromatogram integration
- Calculation of concentration
Case study

16.00 – 16.45 Questions and discussion

16.45 – 17.00 Closing of the seminar

Olivier Gross, WHO