

EurAHP Biotechnology Educational Summit

3–5 October 2007 The Radisson SAS Bay Point Resort, Malta



Key points Day 2

- Administration, storage, patient reaction are all unique to Biopharmaceuticals.
- Handling issues are complex for Biopharmaceuticals giving rise to education requirements, and as always patient's practices will give surprises.
- There may be a mismatch between the prescribed 'requirements' and capacity to ensure quality, such as observation of particulates and physical visualisation.
- We must not forget the practical supply-chain issues. The technology gives us a sterile, fully-functional Biopharmaceutical but that does not guarantee the patient will receive it.
- "How similar is biosimilar"
- Issues of substitution by hospital pharmacy? Traceability an issue, monitor-by-batch.

Key points Day 2

- Clinical Governance is what 'we' do already as Professionals. In the UK this is being monitored and by government who by 2009 will determine Education, Registration and Discipline as it appoints to the governing General Pharmaceutical Council.
- Large molecules are not constant, in individuals they change, unlike small molecules.
- How much experience does the company have in production of a biosimilar – its in the process
- Going from big to small helps with issues of pharmacokinetics.