FEATURED ARTICLES

- Japanese New Pharmaceutical Affairs Law, 'Pharmaceuticals and Medical Devices Law (PMDL)'
- Draft Addendum to ICH E6 meets ALCOA: Moving Toward a Practical Definition of Data Integrity
- Risk Assessment Tools for Auditing
- Adding Value to Biomedical and Life Sciences Research: The qPMO Way
- Usage of Local Depots in Russia and Ukraine: Some Practical Tips
- Quality Focus of Clinical Studies in Nutrition
- How does the Safe Harbour Ruling Affect Clinical Research? A Case Study of hVIVO’s Response to the News
Good Laboratory Practice

Good Laboratory Practice Committee

GLP Committee Presentations at the 2015 RQA Annual Conference

Pathology Peer Review

Mark Goodwin, GSK, presented on his experiences of implementation of the new guidance at GSK GLP Pathology Peer Review: A Blessing or a Curse? Mark suggested that the catalyst for production of the guidance was the issue of the OECD consensus document on multi-site study studies several years ago, raising questions within industry on how best to manage pathology peer review personnel and processes.

Mark suggested that there are two main lines of thinking on what a peer review is: an SOP driven QC process; or an integral part of the GLP study similar to any other part. These two stances are driving opinion on whether the guidance is seen as a useful addition to the industry or a hindrance.

The guidance document was initiated by the UK MHRA several years ago following industry request for guidance. The FDA also found it necessary to answer a series of questions on pathology peer review and it was subsequently agreed that the OECD GLP working group would progress the issue and draft a guidance document.

Following industry consultation the controversial requirement to appoint the peer-reviewing pathologist as a Principal Investigator was removed and does not appear in the finalised and amended version issued 15 December 2014. Other key messages in the guidance include the need to clearly describe the process and personnel in the study plan and the requirement for the peer review to be performed under GLP regulation.

Whether or not the guidance was welcomed universally, it offers advantages including providing clarity on regulatory expectations that will lead to greater industry consistency. However, it is recognised that some areas of the guidance are still open to interpretation.

The Society of Toxicologic Pathology in collaboration with global societies of toxicologic pathology initiated a document review to facilitate consistent interpretation. It should be remembered that although useful, the driving document remains the OECD advisory document. Mark highlighted some of the areas of contention or ambiguity in the advisory document and how the pathologist's document review addressed or attempted to clarify these.

During implementation at GSK, key internal stakeholders reviewed the guidance and performed a gap analysis. Adjustments to the GSK procedures and document templates were performed where necessary including an impact assessment of these changes. Following this, the updated procedure was released for use. In addition to updating the processes to conform with current guidance, it offered an opportunity to review and improve the pathology peer review procedures generally.
In OECD news it was stated that Malaysia is the most recently accepted country in the Mutual Acceptance of Data (MAD) agreement (April 2013).

GLP update
Vanessa Grant provided an update on recent events and news in the GLP environment.

In OECD news it was stated that Malaysia is the most recently accepted country in the Mutual Acceptance of Data (MAD) agreement (April 2013). Brazil has expanded its involvement in the MAD agreement to include pharmaceuticals. The UK GLPMA has reiterated that it will not accept claims of GLP compliance from non-OECD MAD adherents. The OECD also issued a position paper describing the relationship between ISO 17025 and GLP.

The OECD discussion group continues to progress with three projects:
- QA activities: frequently asked questions (FAQ) have been added to the OECD website.
- Characterisation of Test Item: the latest information available indicates that guidance can be expected in 1-2 years.
- iT; draft advisory document 10 The application of GLP Principles has been issued to industry for comment. A final document is expected in spring 2016.

The EMA is considering advanced therapies and how they affect GLP.

The FDA are updating their GLPs. They are currently in a period of government review, and there have been no further updates.

Inspection metrics for the FDA and MHRA were presented, providing some insight into what the monitoring authorities activities had been and the type of issues that had been found during 2014. There were clear commonalities in finding types between the FDA and MHRA.

An MHRA guidance document on final report amendments was issued in April 15.

The MHRA held a GLP and clinical laboratory seminar in September 2015; there was a clear focus from the MHRA on data integrity, as well as an introduction to the MHRA risk-based GLP QA programmes guidance published in September 2015. The MHRA welcomed two new GLP inspectors in 2015.

Subcontracting GLP Studies to China
Rachel Hodges, AstraZeneca, outlined the pleasures and pitfalls of establishing an OECD GLP Compliant facility in China.

Rachel explained how AstraZeneca managed the situation once it was clear that the UK GLP Monitoring Authority had said that they would not be accepting OECD GLP studies conducted in China.

Comparing the OECD GLP Regulations with those of the Chinese FDA (CFDA), it was easy to see why:
- Different requirements for signing the study plan and final report.
- No reference to Multi-site studies in CFDA.
- SOP management is different.
- Study Director and Test Facility Management responsibilities are different.
- Little mention of computer system validation, etc. in CFDA.
- QA to provide solutions to problems according to CFDA.
- Little definition around record management in CFDA.

There was an assessment by an OECD Inspector to Shanghai, which was extremely useful but no guarantee of submission, and the MHRA conducted their own study audit (2 Inspectors for one week) on a pivotal study prior to CTA approval.

Currently it is considered unlikely that China will become part of the OECD anytime soon. The Chinese culture can also be a challenge when operating in compliance with OECD GLP. The advice is to conduct studies in China for the Chinese market and not for the Rest of the World, do your due diligence and talk to regulators as early as possible when you have studies claiming compliance with OECD GLP conducted in China as part of an application.

Committee activities
- Guidance booklets are nearing completion.
- Study Director eLearning course in development.
- Webcasts introducing key regulatory topics are continuing to be produced.
- The Field Studies Forum was well attended.
- The Committee continues to be represented on the focus group.