

FDA inspection Passed with flying colours

Broughton Laboratories are delighted to announce that their recent FDA regulatory inspection was deemed a major success. On July 27, 2010, the FDA gave their verdict: Broughton Laboratories site complies with good manufacturing practises (GMP) and no 483's were issued.

Carried out in the summer, the two day inspection involved the heavy scrutiny of protocols, specifications, calculations, equipment records, workbooks and training records with very positive conclusions made by the visiting inspectors.

The lead FDA Investigator, considered an expert in GMP compliance and the second Investigator, an analytical chemist who focused upon data integrity, was particularly interested in the thoroughness of the company's current research into dissolution calibration.

Chris Allen, Broughton's Managing Director explained the process and throughout the discussion faced some quite searching questions relating to the proposed switch from chemical to mechanical calibration. Chris summarised the discussion 'The agreement was that once equivalence between the chemical and the enhanced mechanical calibration had been demonstrated the switch to mechanical calibration could be justified. The switch will provide a robust method of verifying the performance of our dissolution test stations whilst eliminating the difficulties many laboratories experience with the USP chemical calibration method and therefore reduce the time spent and eliminate costs associated with the USP calibrations. The result of this is reduced equipment downtime and reduced financial outlay allowing us to pass the savings onto our clients'.

The investigator also examined a great deal of raw data workbooks, HPLC chromatography and results. These records were expertly presented by Paul Moran, CEO and Yvonne MacLeod, QC Team Leader, with support from the US Sponsor.

The laboratory's GMP compliance was reviewed separately by the Lead Investigator, a seasoned professional with over 18 years experience in auditing. A great number of documents were presented by Lynne Hessel, Quality & Compliance Manager and Chris Allen, with particular attention being paid to record keeping, equipment qualification, stability study records and training.

Credit and great thanks go to the Broughton Laboratories personnel and their dedication to regulatory compliance, having completely satisfied the FDA investigators. BLL has the mark of compliance and can proudly announce that we were successfully audited by the FDA.

Broughton Laboratories take a great deal of pride in it's commitment to Quality and Compliance. The successful outcome of this audit enhances our confidence in our mission to provide a significant competitive advantage in the delivery of high product quality, customer satisfaction and people development. We enjoy listening and working with clients and regulatory bodies to continuously improve our services. We recognise the importance of demonstrating GMP compliance within the pharmaceutical industry.

In addition, we are extremely excited about the future opportunities this successful audit will make available to us. For further information on how Broughton Laboratories can help support your business then please contact Charlotte Wood on 01756 700 255 or cwood@broughtonlaboratories.co.uk.