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MHRA expectation regarding self inspection

News and hot topics

16 December 2013

The MHRA is setting an expectation that pharmaceutical manufacturers, importers and cc as part of their self-inspection programme must review the effectiveness of their governar data integrity and traceability.

This aspect will be covered during inspections from the start of 2014, when reviewing the inspection programmes in accordance with Chapter 9 of EU GMP.

It is also expected that in addition to having their own governance systems, companies ou should verify the adequacy of comparable systems at the contract acceptor.

The MHRA invites companies that identify data integrity issues to contact: [GMPInspector](#):