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## MHRA expectation regarding self inspection and data integrity

### News and hot topics

16 December 2013

The MHRA is setting an expectation that pharmaceutical manufacturers, importers and contract laboratories, as part of their self-inspection programme must review the effectiveness of their governance systems to ensure data integrity and traceability.

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

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

The MHRA invites companies that identify data integrity issues to contact: [GMPInspectorate@mhra.gsi.gov.uk](mailto:GMPInspectorate@mhra.gsi.gov.uk)

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製薬会社、医薬品輸入業者、委託ラボが、自己点検の一環として管理の有効性を見直し、データのインテグリティとトレーサビリティを確実なものとするのを、MHRAは期待している。

2014年の査察から、自己点検のレビューにおいてこの期待を確認する。

業務委託を行っている企業は、委託先の同様な仕組みが適切であるか確認すべきであると期待している。

Page last modified: 03 January 2014

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