

## New arrangements for MHRA Good Practice (GxP) inspections due to coronavirus (COVID-19)

As part of our response to the coronavirus outbreak, we have decided to conduct only essential Good Practice (GxP) inspections of Laboratories, Clinical Trials, Manufacturing, Distribution and Pharmacovigilance until further notice.

Other MHRA inspections will be deferred to a later date.

Our Good Practice inspections monitor compliance with the MHRA's UK standards in sites engaged in laboratory studies, clinical trials, manufacturing, distribution, and pharmacovigilance (safety monitoring of medicines). They are conducted both in the UK and overseas.

We are expecting organisations to maintain GxP compliance, and will support the industry and NHS to focus on service continuity by using alternative approaches for routine regulatory oversight, such as office-based assessment and the sharing of information within the international regulatory network.

We will prioritise essential on-site inspections linked to the UK Government's COVID-19 response or any other potential serious public health risk, where these sites cannot be assessed remotely. Essential clinical trial authorisation applications will not be affected by this change and will remain prioritised.

We understand current challenges, and are acting in line with UK Government recommendations to minimise the impact of any such inspections on industry and agency personnel wherever possible.

This situation remains under review and we will provide further information as it becomes available.

If you have any questions on GxP-related issues, please email: