

GCP INSPECTION FINDINGS CLASSIFICATION

Critical:

- a) Where evidence exists that significant and unjustified departure(s) from applicable legislative requirements has occurred with evidence that
 - i) the safety or well-being of trial subjects either have been or have significant potential to be jeopardised, and/or
 - ii) the clinical trial data are unreliable and/or
 - iii) there are a number of Major non-compliances (defined in (c) and (d)) across areas of responsibility, indicating a systematic quality assurance failure, and/or
- b) Where inappropriate, insufficient or untimely corrective action has taken place regarding previously reported Major non-compliances (defined in (c) and (d))

Major:

- c) A non-critical finding where evidence exists that a significant and unjustified departure from applicable legislative requirements has occurred that may not have developed into a critical issue, but may have the potential to do so unless addressed, and/or
- d) Where evidence exists that a number of departures from applicable legislative requirements and/or established GCP guidelines have occurred within a single area of responsibility, indicating a systematic quality assurance failure.

Other:

- e) Where evidence exists that a departure from applicable legislative requirements and/or established GCP guidelines and/or procedural requirement and/or good clinical practice has occurred, but it is neither Critical nor Major.