ACTIVE PHARMACEUTICAL INGREDIENTS (API)
GOOD MANUFACTURING PRACTICE INTERIM UPDATE REPORT
GUIDELINES FOR COMPLETION AND SUBMISSION

Introduction

The following information is provided for general guidance for completion of the Interim Update report for API facilities. In order to ensure that there are no changes on site that would impact on the validity of the GMP Certificate MHRA require to be made aware of any significant changes that occur on the site during the period of validity of the GMP Certificate. *It is the responsibility of the site to judge what information/data indicates significant change however the following guidance is provided to assist sites.*

Specific Guidance

In order to complete this report sites should consider but not limit to the areas recorded below. Sites may wish to consider what is reported through change control, management review meetings or other strategic business meetings and considered significant by the site:

- API or Drug Product recall triggered in any market as a result of issues with the manufactured APIs named on the GMP certificate or other APIs manufactured on site under the same quality system.
- API site/company entered into financial administration (or equivalent financial status) or experiencing a financial difficulty that has/will result in budget cuts affecting good manufacturing practice compliance.
- Changes in the types of products manufactured/ handled in facilities that manufacture API/API Intermediates for EU Markets. Particularly introduction of hazardous contaminants to site such as non pharmaceutical molecules, Ectoparasiticides, highly sensitising materials, biological preparations containing living organisms, certain hormones, cytotoxics, other highly active/potent products e.g. teratogens.
- Addition of new manufacturing buildings within the current facility for manufacture of products named on the GMP certificate.
- Any other significant changes or issues that the site believes may indicate a step change in the risk to product quality or affecting patient safety.

The form (titled “API Interim Update”) can be found on the MHRA web site through the following link:

http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodManufacturingPractice/Risk-basedinspections/index.htm

The completed form should be sent by e mail to the inspector that last inspected your site with a copy to gmpinspectorate@mhra.gsi.gov.uk.