**MHRA PHASE I ACCREDITATION SCHEME: VARIATION FORM**

Please submit this notification to phase1accreditationscheme@mhra.gov.uk

**Section 1: To be Completed by Accredited Unit**

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| --- | --- |
| **Organisation Name**  |  |
| **Full Address**  |  |
| **Contact Name**  |  |
| **Contact Telephone Number**  |  |
| **Email**  |  |

|  |  |
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| **Last accreditation inspection dates** |   |
| **Accreditation certificate expiry date**  |  |
| **Provide details of the proposed variation** |
| *Explain the proposed variation including timelines*  |
| **Provide details of the impact of the proposed variation**  |
| *Discuss the impact on facilities, trials, QMS i.e. SOPs, training etc*  |
| **Provide confirmation of the actions taken to ensure compliance with scheme is maintained.** ***Evidence of actions completed should be provided (please ensure documents are clearly indexed for ease of review)*** |
| *Provide list and evidence of actions including timelines (e.g. SOP updates, tests of facility changes prior to use, additional emergency scenarios, training etc), if any actions are in progress please make this clear.*  |

**Section 2: To be Completed by MHRA**

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| **Reviewing Inspector** |  |
| **Inspector Review Comments**  |  |
| **Review Outcome**  | [ ]  Approved, new certificate not required [ ]  Approved, new certificate required [ ]  Inspection required – onsite [ ]  Inspection required – remote[ ]  Not approved  |

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| **MHRA Review and Approval Signatures** |
| **Name, Head of GCP / Expert / Lead Senior / Senior / GCP Inspector** | **Date** |
| **Name, Head of GCP / Expert / Lead Senior / Senior GCP Inspector** | **Date** |