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| **Submission of EFPIA and EBE comments on Public consultation on COMMISSION IMPLEMENTING REGULATION (EU) …/... on the detailed arrangements for the good clinical practice inspection procedures pursuant to Regulation (EU) No 536/2014 of the European Parliament and of the Council** |
| **Author: EFPIA and EBE** star.png **Date: 28 October 2016** star.png **Version: FINAL** |

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1. General comments

| Comment no | General comment (if any) | Outcome (if applicable) |
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|  | EFPIA and EBE, herein referred as we, welcome the opportunity to provide comments on the Public consultation on COMMISSION IMPLEMENTING REGULATION (EU) …/... on the detailed arrangements for the good clinical practice inspection procedures pursuant to Regulation (EU) No 536/2014 of the European Parliament and of the Council. |  |
|  | This draft covers recognition of findings from other Member States and information sharing. In addition it describes the escalation pathways that should be initiated where Member States cannot reach agreement on an inspection outcome - which can only be positive for industry. We would also welcome the Commission to include a procedure describing how the consistency of inspection findings and the grading of those findings will be reviewed and ensured. |  |

1. Specific comments on text

| Line number(s)  | Comment and rationale; proposed changes*(If changes to the wording are suggested, they are highlighted)* | Outcome (if applicable) |
| --- | --- | --- |
| Preliminarypoint 4 | **Comment:**Preamble #4 implies reference to ICH GCP of 1995, without recognising that ICH GCP (R2) is about to be finalized. **Proposed Change:**To avoid any misunderstanding on which version of the guidelines should be applied. It is suggested the second sentence reads 'Pursuant to Article 47 of Regulation (EU) No 536/2014, the ***current*** ICH guidelines....' and the last sentence say '.....inspectors should refer to the ***applicable*** ICH guidelines.....  |  |
| Preliminarypoint 7 | **Comment:**“… inspectors should be granted the necessary powers to access premises and data.” It is not always possible to provide inspectors with direct access to electronic system, if inspectors do not have a user name and are not trained. In such cases access will be granted under a trained and authorized user.**Proposed change:**“ …inspectors should be granted the necessary powers to access premises and data ***directly or indirectly, as appropriate.***” |  |
| Article 3Paragraph 1 | **Comment:** It should be specified that the quality systems should be harmonized and standardised across the EU.**Proposed change :**Each Member State shall set up a properly designed quality system ensuring that the inspection procedures are observed and consistently monitored. Member States shall ***harmonise and*** maintain those quality systems up to date. |  |
| Article 4 | **Comment:** To ensure consistency between Member States, a set of minimum training requirements for inspectors defined by EMA is proposed to be enclosed in article 4.Although the article 4 lists the experience, qualifications and trainings an inspector should have, the training and subsequent competencies an inspector should acquire remain very unspecific. |  |
| Article 4Paragraph 2 | **Comment**: Typo to correct**Proposed change:**Inspectors shall receive appropriate training, including participation in inspections. Their training needs, necessary to maintain or improve their skills, shall be assessed regularly by ***a*** person appointed for that task.  |  |
| Article 4 Paragraph 5 | **Comment:** Typo to correct **Proposed change:** “Inspectors shall be familiar with the procedures ***and*** technical systems for the recording and management of clinical data”. |  |
| Article 5Paragraph 1 | **Comment :**It is understood that a number of inspectors have previously worked in the pharmaceutical industry. Consequently, it is expected that there is a definitive time period before which they are allowed to return to a company where they previously worked to inspect.**Proposed change :**Inspectors shall be free from any influence which could affect their impartiality or their judgement**. *Inspectors should not inspect an organisation where they were previously employed until a reasonable period has elapsed (5 years).*** |  |
| Article 7 | **Comment:** It is recommended to include a procedure describing how the consistency of inspection findings and grading of those findings will be reviewed and ensured.The procedures should specify the selection criteria and process to appoint an expert, the rules in terms of conflict of interest and impartiality, as well as all the roles and responsibilities of the experts. Same rules than for inspectors apply to the experts involved in an inspection.  |  |
| Article 7Paragraph 1b | **Comment:** Inspections in third countries should be notified to the third country inspectorate. It is proposed that this requirement for notification is included in Article 7 item (b).  |  |
| Article 9 | **Comment:**Although Article 9 refers to Commission/EMA developing and improving “ … commonly recognised standards of GCP inspections …” , member states still have considerable scope for creating their own procedures. It is proposed that Article 7 notes that member state procedures should follow the common standards laid down by the Commission/EMA. |  |
| Article 10 | **Comment:**  “When performing an inspection, the inspectors shall be empowered to enter into sites, other related premises, and to access to data, including individual patients' records.”It should be clarified that this is only a legal empowerment in the EU/EEA. Outside the EU/EEA, EU inspectors enter premises with the co-operation of the site.  |  |
| Article 10 Paragraph 4 | **Comment**: The possibility for Inspectors to make copies etc, may be limited to the extent necessary to document inspection findings in order not to compromise company confidential information.Unlimited taking of photos of premises and equipment is usually not in accordance to company standard operating procedures. **Proposed change:** Inspectors shall be entitled to **ask for** copies of records and hardcopies, print outs of electronic records ~~and~~. ***Photos of premises and equipment should be limited to the extent necessary to support inspection findings and in order to protect company confidential information and confidentiality/privacy of subjects.*** |  |
| Article 10 Paragraph 6 | **Comment:**The possibility for Inspectors to directly contact trial subjects should also be limited. Preliminary point 7 should be modified accordingly. **Proposed Change:**Inspectors “… should be empowered to contact trial subjects in justified cases ***of suspicion of GCP non-compliance..*** ”. |  |
| Article 13 | **Comment:** It should be clearly stated in the final text that the inspected party has the opportunity to respond to inspection findings before the report is published. The Sponsor of the trial(s) should receive a copy of the inspection report prior to the report being submitted to the EU portal.The inspection reports submitted via the EU Portal should include the responses of the Sponsors.Of note, it would be good as well to receive more details on the uploading of inspection reports from third country inspectorates by the sponsor.  |  |