**Attachment 2:** National orders, guidelines and laws with respect to GCP inspections

| Order/Guideline | Short description | Content with respect to GCP inspections | Comment | Source/Link |
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| German Drug Law ("Arzneimittelgesetz [AMG]) and GCP-order (GCP-V) | § 42a AMG in connection with § 9 Abs. 5 GCP-V pre-study/on-study GCP-inspection within the approval procedure/in the course of clinical trials. | The cited paragraphs govern GCP inspections within the approval procedure of clinical trials. The responsible higher authority has the possibility, in the course of preparing a decision on approval of a clinical trial, to verify the information within the application, at the investigational site, in participating laboratories, at the sponsor or in other institutions. Further the higher authority may withdraw the approval during the course of a clinical trial. | Targeted inspection, commonly directed to clinical trials.<br>The authors are not aware of any such inspection in Germany to date. | Drug Law version of December 12th 2005 (BGBl. I S. 3394;), last modification by means of article 2 of the law of June 14th 2007 (BGBl. I S. 1066)"<br><br>http://bundesrecht.juris.de/amg_1976/index.html<br><br>Order on the application of Good Clinical Practice in conducting clinical trials with drugs for use in humans (GCP order, GCP-V)<br><br>http://bundesrecht.juris.de/gcp-v/index.html |
| German Medicines Law (AMG) and GCP-order (GCP-V) | § 25 Abs. 5 AMG pre-approval, post-approval GCP-inspections within the approval procedure/in the course of clinical trials. | These inspections are conducted by the responsible federal authority as part of the registration procedure. They may be conducted in advance or cause specific after registration. Inspected are the adherence to international standards (the existence of an ethics committee votum and authoritative approval) and the credibility and validity of clinical data on efficacy and safety of the registrational dossier. | Targeted inspection related to a registration dossier. Procedural requirements for this kind of inspection have not been published to date. | |
| German Medicines Law (AMG) and GCP-order (GCP-V) | §§ 64–69 AMG in connection with § 15 GCP-V:<br>Routine or cause specific inspections of sponsors, investigational sites and other participating institutions. | The cited paragraphs describe the surveillance of sponsors and of institutions taking part in clinical trials. The responsibility for these GCP inspections is with the federal state authority and comprises the compliance with national legal requirements for clinical trials and the provision of the participant rights.<br>Inspected is the positive opinion of the ethics committee as well as the approval by the responsible federal higher authority, the appropriate information and written consent of the trial participants and the quality assurance of the sponsor, the investigational site or other institutions being part of the trial.<br>Surveillance inspections in ongoing clinical trials are usually either routine or cause specific to assure appropriate measures in case of issues recognized during the inspection. | Concise definition of the scope of inspection in the law or the order. Procedural requirements for this type of inspection are published on the ZLG website (see below). | |

**Attachment 2 (continued):** National orders, guidelines and laws with respect to GCP inspections

| Order/Guideline | Short description | Content with respect to GCP inspections | Comment | Source/Link |
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| AMGVwV as of March 29th 2006 | Common administrative instructions for the implementation of the Medicines Law. | § 4 (Inspections) contains a detailed description of different types of inspections with regard to respective legal regulations as well as a selected number of rules for inspections.<br><br>Section (5): "Inspections within the surveillance of clinical trials are to be conducted in accordance with the guidance, that have been developed for the mutual recognition of inspections results of clinical trials within the European Union. "<br>§ 8 describes the necessary expertise of staff involved in the surveillance and conduct of inspections. | Useful because of the detailed description of of inspection types. | Published in "Bundesanzeiger" No. 63 as of March 30th 2006. Available as a download on the ZLG website:<br><br>http://www.zlg.de/download/AM/rechtsquellen/bund/AMGVwV_2006.pdf |
| Procedural requirement of the „Zentralstelle der Länder für Gesundheitsschutz (ZLG)" for drugs and medicinal products | Procedural requirement 07114601 for inspections of clinical trials of drugs subject to approval. | The document describes in detail aims, basic documents and the procedure of GCP inspections. The appendices I–III contain detailed checklists for I. Routine inspections at the investigator site, II. Routine inspections at the sponsor/representative of the sponsor/CRO site and III. Inspections of laboratories. | Useful for investigators, monitors and quality assurance staff for preparation of investigator, sponsor and laboratory inspections. | Published on the ZLG website:<br><br>http://www.zlg.de/download/07114601_VAW.pdf |