Attachment 3: Further useful sources of information on GCP inspections

Reference	Short description	Content with respect to GCP inspections	Comment	Source/Link
EMEA	EMEA website on inspections.	The EMEA website on inspections contains information pertaining to the guidance (EC) 726/2004, in particular within the context of compliance assessments with GMP, GCP and GLP and further aspects in the surveillance of drugs registered in the EU.	Contains numerous useful links and documents for GMP, GLP and GCP inspections.	http://www.emea.europa.eu/Inspections/index.html
EMEA	EMEA website on Standard Operating Procedures (SOPs).	Website with all EMEA-SOPs and Working Instructions (WINs). *Confidential documents are listed only and can not be accessed.*	SOPs for inspections are found at the bottom of this page.	http://www.emea.europa.eu/htms/general/sop/sop.htm
EMEA	EMEA SOP/INSP/2004	EMEA-SOP for GCP Inspections structured Purpose, Scope und Responsibilities (1–3), List of forms (4), references and related documents (5), paragraph with definitions (Inspection, Reporting Inspector, Lead Inspector, Summary Inspection Report) (6), detailed description of procedures (7) and workflow (8).	Useful document for quality assurance staff with detailed information and flow-charts for the conduct of inspections.	http://www.emea.europa.eu/Inspections/docs/SOP2004.pdf
Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) – Information on inspections	Introduction of the GCP-Inspectorate at the BfArM.	Short description of the scope and different types of inspections as well as links to the most important national and international regulations.	The website contains no detailed descriptions of requirements for GCP sponsor inspections by the BfArM.	http://www.bfarm.de/cln_012/nn_421158/DE/Arzneimittel/1__vorDerZul/klinPr/gcp/gcp-home.html__nnn=true
Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) – Information on inspections	Memorandum on pharmacovigilance (PV) inspections as of January 15th 2007. Besides the legal requirements for PV inspections in Germany and the course of a PV inspection the website contains detailed templates for preparation.	Headlines of the template: 1. General information; 2. Qualified person for pharmacovigilance in the EU/EEA; 3. Short description of the company; 4. Pharmacovigilance system; 5. Electronic data management; 6. Quality assurance system; 7. Educational system; 8. Archiving; 9. Drug related safety issues; 10. licensing agreements; 11. Statistics on fulfillment of authoritative registration obligations; 12. List of drugs.	Detailed description of requirements for pharmacovigilance inspections.	Notification: http://www.bfarm.de/cln_043/nn_421158/DE/Pharmakovigilanz/mitteil/mittl-phvig-inspektion.html__nnn=true Sample documentation: http://www.bfarm.de/nn_1109152/DE/Pharmakovigilanz/mitteil/mittl-phvig-inspektion-muster.html

Attachment 3 (continued): Further useful sources of information on GCP inspections

Reference	Short description	Content with respect to GCP inspections	Comment	Source/Link
Paul-Ehrlich-Institut (PEI) – Information on inspections	Information as of November 1st 2006 for the preparation and conduct of inspections by the PEI and of inspections with experts of the PEI.	List of inspection types conducted by the PEI (within the course of registration, authoritative inspection of charges, approval of clinical trials and pharmacovigilance inspections) as well as inspections conducted with the help of experts (centralised registration, granting a manufacturing licence, legal surveillance relating to drugs, inspections in states outside the EU for the approval of import/the issue of a GMP certificate).	The website contains no detailed descriptions of requirements for a GCP-sponsor inspection by the PEI.	http://www.pei.de/cln_049/nn_154580/sid_99769B9284C3F43830F504EFCC538096/DE/infos/pu/03-zulassung-human/09-inspektionen/02-eigene/eigene-inhalt.html?__nnn=true
ZLG	"Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten".	Founded in 1994 and located in Bonn, this institute coordinates responsibilities within the medical devices and drug sector (http://mv.juris.de/mv/gesamt/ZLP_MV.htm#ZLP_MV_rahmen).	Premium site for information on inspections, many useful links.	http://www.zlg.de/cms.php?PHPSESSID=494f44e5dd501419b90cc338931e009e&mapid=2&hmp=1
Addresses and contacts for drug surveillance	Homepage of the federal ministry of health (Bundesministerium für Gesundheit, BMG). Website published by the "Bundesverband der Apotheker im Öffentlichen Dienst (BApÖD)".	An official and recent directory of the authorities and experts for the conduct of the medicinal law (pdf-format) can be found at the website of the BMG. The directory published by the BApÖD additionally contains specific contact persons including telephone numbers.	As to our experience the most recent information regarding the competence for inspections.	http://www.bmg.bund.de/cln_110/nn_1168682/SharedDocs/Standardartikel/DE/AZ/A/Glossarbegriff-Arzneimittel.html#doc1183650bodyText1 http://www.bapoed.de/Arzneimittel%fcberwachung/amueberwachung.htm