



**PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME**

PS/W 1/2005 (Rev.)
13 December 2007

AUDIT CHECKLIST

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Summary of the Audit Checklist				
Component	Sub-component	Importance	Evaluation method	Comments
1 - Legislative and Regulatory Requirements and Scope	1A - Empowering legislation	Critical	Documentation review	
	1B - Conflict of interest	Very important	Documentation review On-site evaluation at Inspectorate	
2 - Regulatory directives and policies	2A - Procedures for designating inspectors	Very important	Documentation review	
	2B - Enforcement Policies	-	Evaluated as part of sub-component 7B	
	2C - Code of conduct/ Code of ethics	Very important	Documentation review	
	2D - Training certification policies/guidelines	-	Evaluated as part of sub-component 4C	
	2E - Alert/crisis management policies/procedures/guidelines	-	Evaluated as part of sub-component 8A	
	2F - Organisational structure	-	Evaluated as part of sub-component 11A	
3 - GMP Standards	3A - Details/ scope of GMP	Critical	Documentation review	
	3B - Process validation	-	Evaluated as part of sub-component 3A	
4 - Inspection resources	4A - Staffing: Initial qualification	Very important	Documentation review On-site evaluation at Inspectorate	
	4B - Number of inspectors	Very important	Documentation review On-site evaluation at Inspectorate	
	4C - Training programme	Very important	Documentation review On-site evaluation at Inspectorate	
	4D - QA mechanism to assure effectiveness of training program	-	Evaluated as part of sub-component 4C	
5 - Inspection procedures	5A - Inspection strategy	Very important	Documentation review On-site evaluation at Inspectorate	
	5B - Pre-inspection preparation	Very important	Documentation review On-site evaluation at Inspectorate Observed inspections	
	5C - Format and content of inspection reports	Very important	Documentation review Observed inspections	
	5D - Inspection methodology	-	Evaluated as part of sub-components 5E	
	5E - SOP for conducting inspections	Critical	Documentation review Observed inspections	
	5F - Inspection procedures - Post-inspection activities	Very important	Documentation review On-site evaluation at Inspectorate Observed inspections	
	5G - Inspection procedures – Storage of inspection data	Important	Documentation review Observed inspections	
6 - Inspection performance standard	6A - Performance standards	Very important	Documentation review On-site evaluation at Inspectorate	

Summary of the Audit Checklist				
Component	Sub-component	Importance	Evaluation method	Comments
7 - Enforcement powers and procedures	7A - Provision for written notice of violations	-	Evaluated as part of sub-component 7B	
	7B - Non-compliance management	Critical	Documentation review On-site evaluation at Inspectorate	
	7C - Appeal mechanism	Important	Documentation review On-site evaluation at Inspectorate	
	7D - Other measures	-	Evaluated as part of sub-components 7B	
8 - Alert and crisis systems	8A - Alert mechanisms	Critical	Documentation review On-site evaluation at Inspectorate	
	8B - Crisis management mechanisms	-	Evaluated as part of sub-component 8A	
	8C - Alert performance standards	Important	Documentation review	
9 - Analytical capability	9A - Access to laboratories	Critical	Documentation review On-site evaluation at Laboratory	
	9B - SOPs for analytical support (not obligatory if an audit report made by a recognised organisation (as the EDQM) is available and satisfactory)	Very important	Documentation review On-site evaluation at Laboratory On-site evaluation at Inspectorate	
	9C - Validation of analytical methods (not obligatory if an audit report made by a recognised organisation (as the EDQM) is available and satisfactory)	Very important	Documentation review On-site evaluation at Laboratory	
10 - Surveillance programme	10A - Sampling and audit procedure	Very important	Documentation review On-site evaluation at Laboratory On-site evaluation at Inspectorate	
	10B - Recall monitoring	-	Evaluated as part of sub-component 7B	
	10C - Consumer complaint system	Very important	Documentation review On-site evaluation at Inspectorate	
	10D - Adverse reaction reporting system/ procedures	-	Not evaluated - not considered within the scope of a GMP compliance programme.	
	10E - Drug product defect reporting systems/ procedures	-	Evaluated as part of sub-component 10C	
11 - Quality management system	11A - Quality management system	Critical	Documentation review On-site evaluation at Inspectorate On-site evaluation at Laboratory	

PIC/S AUDIT CHECKLIST

Indicator Number	Indicators	Method of Evaluation DR: Documentation Review OSEI: On-site Evaluation at Inspectorate OSEL: On-site Evaluation at Laboratory OI: Observed Inspection				
		DR	OSEI	OSEL	OI	COMMENTS

Sub-component 1A Legislative and regulatory requirements and scope - Empowering legislation (Critical)						
1	The legislation identifies a key official in the organisation/ regulatory authority assigned for overall responsibility of the compliance with the requirements of the Scheme.	[
2	The authority to designate inspectors is vested in legislation.	[
3	The identity of designated inspectors and scope of jurisdiction of legislation are available to companies being inspected.	[
4	There is legal authority for an inspector to enter at any reasonable time in any place where drugs/medicinal products are manufactured, imported, exported, packaged, released, stored or tested.	[
5	There is legal authority for taking samples and submitting them to designated laboratory (such as OMCL or other recognised organisations).	[
6	There is legal authority for making copies of documents and photographs of drug/medicinal product premises and equipment.	[
7	There is legal authority to open and examine any receptacle or package that contains articles subject to legislation.	[
8	There is the legal authority to seize or detain a drug/medicinal product or related article believed to be in violation.	[
9	The legislation allows entry to a private dwelling.	[
10	Legislation requires that the manufacturer cooperate and not obstruct an inspector.	[
11	Legislation requires a marketing authorisation holder to report to the regulatory authority any serious adverse drug/medicinal product reactions and manufacturer to report any product defect.	[
12	Legislation requires the manufacturer to notify a competent regulatory authority upon commencement of a recall and to submit pertinent product information.	[
13	All companies that manufacture (total or partial), package/label, import, export (including export only), distribute and test drugs are required to hold a manufacturing authorisation (or equivalent).	[

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Indicator Number	Indicators	Method of Evaluation				COMMENTS
		DR	OSEI	OSEL	OI	
14	The holder of the manufacturing authorisation (or equivalent) is required to notify the regulatory authority of significant changes or of conditions, which may affect the quality, safety or efficacy of a drug/medicinal product.	[
15	Legislation requires that the manufacturing authorisation (or equivalent) include: the address of each site, the manufacturing activities, the category of medicinal product and the pharmaceutical form.	[
16	Legislation prohibits the sale and processing of drugs/medicinal products under unsanitary conditions or leading to adulteration.	[
17	GMPs are legal requirements.	[
18	The legislation specifies that a manufacturer and / or a person is liable for a defective product and provides for prosecution and/or penalties upon conviction.	[
19	There is legislative authority to suspend, revoke or amend a manufacturing authorisation (or equivalent).	[
20	Exported drugs/medicinal products (including export only) are covered in the legislation.	[
Sub-component 1B Legislative and regulatory requirements and scope - Conflict of interest (Very important)						
21	A policy/guideline exists that details the situations regarded as conflict of interest.	[
22	Employees are required to declare their compliance with the conflict of interest policy.	[[[
Sub-component 2A Regulatory directives and policies - Procedures for designating inspectors (Very important)						
23		[
Sub-component 2B Regulatory directives and policies - Enforcement Policies						
Included under sub-component 7B. Enforcement powers and procedures - Non-compliance management.						
Sub-component 2C Regulatory directives and policies - Code of conduct/ Code of ethics (Very important)						
24	A policy/guideline exists that details situations regarded as Code Of Conduct/Code Of Ethics.	[
Sub-component 2D Regulatory directives and policies - Training certification policies/guidelines						
Included under sub-component 4C. Inspection resources - Training programme.						

PIC/S AUDIT CHECKLIST

Indicator Number	Indicators	Method of Evaluation DR: Documentation Review OSEI: On-site Evaluation at Inspectorate OSEL: On-site Evaluation at Laboratory OI: Observed Inspection				COMMENTS
Sub-component 2E Regulatory directives and policies - Alert/crisis management policies/procedures/guidelines						
Included under sub-component 8A. Alert and crisis systems - Alert mechanisms.						
Sub-component 2F Regulatory directives and policies - Organisational structure						
Included under sub-component 11A. Quality management system						
Sub-component 3A GMP Standards - Details/ scope of GMP (Critical)						
25	GMPs are covered within a regulatory framework.	[]			
26-39	The GMP regulatory framework covers all PIC/S GMP requirements and annexes.	[]			
Sub-component 3B GMP standards – Process validation						
Included under sub-component 3A GMP Standards - Details/ scope of GMP.						
Sub-component 4A Inspection resources - Staffing: Initial qualification (Very important)						
40	The minimum qualifications for GMP inspection staff are defined.	[]			
41	Duties of staff involved in the GMP compliance program are defined.	[]			
42	Evidence exists that the GMP inspectors meet the minimum qualifications.	[]			
Sub-component 4B Inspection resources - Number of inspectors (Very important)						
43	The number of inspectors dedicated to the GMP inspection programme is sufficient to meet the prescribed inspection frequency.	[]			
Sub-component 4C Inspection resources - Training programme (Very important)						
44	A training program for inspectors is established and records are maintained.	[]			
45	A mechanism to evaluate the effectiveness of training exists.	[]			
Sub-component 4D Inspection resources - QA mechanism to assure effectiveness of training programme						
Included under sub-component 4C Inspection resources - Training programme.						

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Indicator Number	Indicators	Method of Evaluation				COMMENTS
		DR	OSEI	OSEL	OI	
Sub-component 5A Inspection procedures - Inspection strategy (Very important)						
46	Documents that describe the work expected (e.g. job description), anticipated results (e.g. objectives for the incoming year) and resources applied to fulfil the functions of GMP inspections are available.	[
47	A scheduling system identifies companies due for inspections within a set time frame.		[
Sub-component 5B Inspection procedures - Pre-inspection preparation (Very important)						
48	A procedure details the requirements for pre-inspection activities, and is followed.	[
49	The inspection plan is based on the company's GMP compliance history, critical activities and type(s) of dosage forms manufactured (including, if any, the site master file).		[
Sub-component 5C Inspection procedures - Format and content of inspection reports (Very important)						
50	A procedure for the format and content of inspection reports is available.	[
51	Observations are factual and are based on proper interpretation of applicable legislation.					[
52	Observations are classified/ categorised according to risk.	[
53	Assessment of the company's overall compliance rating is in line with the inspection findings.					[
54	Inspection reports are completed in the required reporting format.					[
Sub-component 5D Inspection procedures - Inspection methodology						
Included under sub-components 5E. Inspection procedures - SOP for conducting inspections						
Sub-component 5E Inspection procedures - SOP for conducting inspections (Critical)						
55	A procedure details the requirements for conducting inspections, and is followed.	[
56	Critical stages and parameters of manufacturing processes are assessed.					[
57	Validation is assessed.					[
58	The inspection plan is adjusted, where warranted, based on the findings of the inspection.					[
59	The depth of the inspection is in line with the inspection findings.					[

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Indicator Number	Indicators	Method of Evaluation				COMMENTS
		DR	OSEI	OSEL	OI	
Sub-component 5F Inspection procedures - Post-inspection activities (Very important)						
60	A procedure details the requirements for post-inspection activities, and is followed.	[[[
61	Inspection findings and conclusions are subject to an internal review.	[[
Sub-component 5G Inspection procedures - Storage of inspection data (Important)						
62	A policy/procedure is available for the storage of inspection data.	[
63	An inspection report database is maintained in a secure and controlled manner.			[
Sub-component 6A Inspection performance standard – Performance standards (Very important)						
64	Inspection performance standards are established.		[
Sub-component 7A Enforcement powers and procedures - Provision for written notice of violations						
Included under sub-component 7B Enforcement powers and procedures - Non-compliance management -						
Sub-component 7B Enforcement powers and procedures - Non-compliance management (Critical)						
65	There is provision for written notice of violations to be sent to the company.		[
66	Recall procedures/mechanisms and records are available.		[
67	Manufacturing authorisation (or equivalent) and related GMP certificate suspension procedures/mechanisms are available and a list of suspended authorisations is maintained.		[
68	Seizure procedures/mechanisms and records are available.		[
69	Prosecution procedures/mechanisms and records are available.		[
Sub-component 7C Enforcement powers and procedures - Appeal mechanism (Important)						
70	Appeal procedures/mechanisms and records are available.		[
Sub-component 7D Enforcement powers and procedures - Other measures						
Included under sub-components 7B Enforcement powers and procedures - Non-compliance management						
Sub-component 8A Alert and crisis systems - Alert mechanisms (Critical)						
71	Alert procedures/mechanisms and records are available.		[

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Indicator Number	Indicators	Method of Evaluation				COMMENTS
		DR	OSEI	OSEL	OI	
Sub-component 8B Alert and crisis systems - Crisis management mechanisms						
Included under sub-component 8A Alert and Crisis systems - Alert mechanisms						
Sub-component 8C Alert and crisis systems - Alert performance standards (Important)						
72	An alert performance standard is available.	[
Sub-component 9A Analytical capability - Access to laboratories (Critical)						
73	The regulatory authority has access to laboratories (such as OMCL or other recognised organisations) capable of conducting necessary analyses.	[[
74	Contract laboratories are qualified according to a recognised standard.	[[
Sub-component 9B Analytical capability - SOPs for analytical support (Very important)						
75	Documents are available that detail the work expected, anticipated results and resources applied to fulfil the functions of the laboratories.	[[
76	Procedures covering all elements of laboratory operations are available and are followed.	[[
77	All product failures are documented and investigated.	[[
Sub-component 9C Analytical capability - Validation of analytical methods (Very important)						
78	The test method validation guideline is equivalent to the ICH standard and records are available.	[[
Sub-component 10A Surveillance programme - Sampling and audit procedure (Very important)						
79	The surveillance programme covers dosage forms of different drug/medicinal product types, and is risk based.	[[
80	Programme performance is reviewed annually and records of review are available.	[[
Sub-component 10B Surveillance programme - Recall monitoring						
Included under sub-component 7B Enforcement powers and procedures - Non-compliance management						
Sub-component 10C Surveillance programme - Consumer complaint system (Very important)						
81	A consumer complaint system/procedure and records are available.	[[
82	Issues of high risk are investigated immediately.	[[

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Indicator Number	Indicators	Method of Evaluation				COMMENTS
		DR	OSEI	OSEL	OI	
83	Compliance staff can access complaint information.		[
Sub-component 10D Surveillance programme - Adverse reaction reporting system/ procedures						
Not evaluated - not considered within the scope of a GMP compliance programme.						
Sub-component 10E Surveillance programme - Drug product defect reporting system/ procedures						
Included under sub-component 10C Surveillance programme - Consumer complaint system						
Sub-component 11A Quality management system - Quality management system (Critical)						
84	The quality system is based on a recognised international standard.		[
85	The quality manual covers all elements of the selected quality standard and of the GMP compliance programme.		[
86	The quality system has been implemented and is followed.		[[
87	A documentation control system is in place.		[[
88	Quality audit plans and records are available.		[[
89	Management reviews the performance of the quality system on an annual basis.		[[