Manual 014

5.9 Audit Reporting Figure: 1

CAT	No	OBSERVATION	PROPOSED FOLLOW-UP ACTION	BY WHOM	WHEN	PROGRESS COMMENTS	DATE OBSERVATION CLOSED OUT	CLOSED OUT BY

The report should clearly identify agreed deviations/deficiencies and indicate their classification, i.e. "CAT" in the first column above (critical, major, other) in accordance with the following table:

Class	Supplier Type			Action required from supplier
	Pharmaceutical active ingredients and pharmaceutical contractors	**Pharmaceutical excipients, printed and primary packaging components**	**Chemical materials and miscellaneous packaging components**	
Critical	Serious non compliance with cGMP/regulatory requirements that results in a significant risk to the patient/business	Serious failure of a procedure that results in a significant risk to the patient/business	Serious failure of a procedure that results in a significant risk to the customer's process or product/business	Immediate corrective action is mandatory. A time schedule for CAPA implementation is required
Major	Significant non compliance with cGMP/regulatory requirements NOT directly offering a risk to the patient/business	Significant failure of a procedure NOT directly offering a risk to the patient/business	Significant failure of a procedure NOT directly offering a risk to the customer's process or product/business	A time schedule for CAPA implementation is required
Minor (Other)	Failure to follow cGMP practise or specific AstraZeneca's requirement	Failure to follow an appropriate procedure	Failure to follow an appropriate procedure	A time schedule for CAPA implementation is recommended

CAPA = Corrective And Preventive Action

Note: several majors can be collectively added to make a critical.

5.12 Audit Standards Figure 2

Supplier of	Audit Standards							
	ICH Q7A	IPEC - GMP Guide for Bulk Pharmaceutical Excipients	EU – GMP and/or PIC/S GMP	21 CFR – parts 210 & 211	21 CFR – part 820	ISO 9001:2000	PS 9000/PS9100	Other standards and guidances e.g. Aseptic processing
Finished Drug Products (sterile and non-sterile)			X	X				X
General Services*			X	X				X
Sterile API	X		X	X				X
API	X		X	X				X
Intermediate	X			X				X
API starting materials (CRM)						X (with appropriate Q7a level of GMP)		X
NCRM						X		X
Excipient		X				X	X**	X
Sterile EX		X	X	X				X
PCC					X	X	X***	X
PCNC						X		X
Microbiological supplier			X	X		X		X