



Foundation

*Fostering harmonisation
of GMP/GDP regulations*

ECA Good Practice Guide – GMP Auditors Reference Handbook – Attachment 1: Audit Agenda Template –

Audit Agenda

Company to be audited	Address and contact information
Audit host	Name of contact person
Audit date	
Type of audit	Qualification / requalification / For cause
Audit scope	Warehouse / Production / QC, etc.
Auditors	Names of auditor and co-auditor
Regulatory basis	Contract and regulatory documents

Date day 1

time/h	Subject	Contact persons
09.00	Introduction and company and site presentation	
10.30	Site Tour	
11.30	<i>topic</i>	
12.30	Lunch break (flexible with regard to timing)	
13.15	Document review	
17.00	End of first audit day	

Date day 2

time/h	Subject	Contact persons
09.00	<i>topic</i>	
10.30	<i>topic</i>	
11.30	<i>topic</i>	
12.30	<i>topic</i>	
16.30	Wrap-up	
17.00	End of first audit day	

The times mentioned – except start and end time are indicative and may be adapted according to the actual needs.

Documents requested for preparation: