

19. Detailed questionnaire for Third Party Audit

1. Third Party Audit Details

1.1 Company Address Information

Name of company:	
Address:	
Postcode:	
Country:	
Website:	

1.2 Contact Information (Please provide details of an available contact)

This information should be filled into the General Questionnaire.

2. General information

2.1 Information about provided services

2.1.1	What are the auditing standards that you are able to offer to your customers?	☐ GMP – API ☐ GMP – Finished Product ☐ GDP ☐ GLP ☐ ISO 9001 ☐ IPEC ☐ Other (please in "comments")
2.1.2	What are the audit types that you are able to perform?	☐ Physical audit ☐ Remote audit
2.1.3	How many audits does your company perform on a yearly basis?	
2.1.4	How many audits will you be able to perform on the behalf of our company on a yearly basis?	

COMMENTS:

Commenté [VD1]: add to each paragraph a line for comments

Commenté [RT2R1]: That is already there, right?

Commenté [VD3]: add excepients standards

Commenté [HG4R3]: IPEC

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2.2 Service Management		
2.2.1	What are the geographical areas covered by your company?	
2.2.2	In which geographical area your auditors located?	
2.2.3	Is the qualified auditor systematically native of the country in which the audit has to be performed?	Yes ☐ No ☐
2.2.4	If no, for which countries do you apply native auditors systematically?	
2.2.5	The auditing service includes: • Exclusive audits for one customer only • Audits combining requests for multiple customers • Selling existing audit reports • Other (please specify)	Yes ☐ No ☐
2.2.6	Is confidentiality assured in case of audits covering multiple customers?	Yes ☐ No ☐
COMMENTS:		

3. Auditor Management

3.1 Auditor information

3.1.1	Are the auditors' employees of your company or do you work with freelance auditors?	☐ Own employees ☐ Freelance auditors
3.1.2	In case you work with freelance auditors, do contracts include clauses covering...	☐ Confidentiality? ☐ Conflict of interest?

3.1 Auditor qualification

3.2.1	Do you share auditors CV with customer prior to the audit performance?	Yes ☐ No ☐
3.2.2	Please specify your minimum requirements for qualification of auditors:	
3.2.3	Do you offer regular auditor (re-)training on the auditing standards referred in 2.1.1?	Yes ☐ No ☐
3.2.4	If yes, what is the frequency? Please specify.	
3.2.5	In general, how many audits does an auditor perform on a yearly basis?	
3.2.6	How do you avoid a potential conflict of interest of the selected auditor(s)?	
3.2.7	How do you maintain consistency among auditors?	

Commenté [RT5]: 3. Auditor Qualification & Competence

Auditor Selection

Describe the criteria for auditor qualification:

Minimum experience required:

Relevant education requirements:

Training Program

Is there an initial training program? ☐ Yes ☐ No

Is continuous training performed? ☐ Yes ☐ No

Frequency of requalification:

Expertise

Expertise areas available:

☐ Sterile manufacturing

☐ APIs (chemical)

☐ Biotech/biologics

☐ Packaging/labelling

Provide CVs of key auditors (upon request)

Commenté [HG6R5]: Agreed in meeting of 24.08.2026: We leave the open question 3.2.2, do not specify potential details or minimum requirements.

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COMMENTS:

4. Audit execution

4.1 Audit documents

4.1.1	Do you have templates for audit documentation?	Yes ☐ No ☐
4.1.2	If yes, for what documents? Please provide the document template(s) in attachment of this questionnaire.	☐ Audit agenda ☐ Preliminary audit summary ☐ Audit summary ☐ Audit report ☐ CAPA plan evaluation ☐ CAPA plan follow-up
4.1.3	If yes, are you willing to customize your standard templates for reporting?	Yes ☐ No ☐
4.1.4	What is the deadline after audit execution to provide initial audit feedback to customer (in days)?	
4.1.5	What is the deadline after audit execution to provide the audit report, to customer (in days)?	
4.1.6	How much time do you allow the audited company to provide a CAPA plan (in days)?	
4.1.7	What is the deadline after CAPA plan receipt to provide the CAPA plan evaluation to customer (in days)?	

Commenté [HG7]: GEROLD: Add tickboxes

Commenté [HG8]: GEROLD: Add yes/ no and correct numbering

COMMENTS:

4.2 Audit findings information

4.2.1	Do you have a standard evaluation table to classify (e.g. major, minor, recommendation) the audit findings? If yes, please share this information in attachment of the questionnaire	Yes ☐ No ☐
4.2.2	Are the auditor findings peer reviewed internally to ensure appropriate classification?	Yes ☐ No ☐
4.2.3	Do you have a specific process to follow in case of critical finding(s) are detected during an audit? If yes, please explain in "comments".	Yes ☐ No ☐
4.2.4	Does your service include CAPA plan evaluation and follow up until audit closure?	Yes ☐ No ☐

COMMENTS:

3. Comments

Please list all references and enclosures that you make to this questionnaire and specify the reference number given to each document. Use one list for all sections of the document and extend it if needed.

[illegible]

Completion Signatures

- Confirmation that enclosed information is correct and relevant to the product(s) in scope.
- Confirmation that you will inform us in case of any changes to the product status

Site Operations Lead Representative:

Name (Print):

Position:

Signature:

Date:

Head of Quality Assurance or representative; person who completed the questionnaire:

Name (Print):

Position:

Signature:

Date: