

OMCL Network of the Council of Europe QUALITY MANAGEMENT DOCUMENT

PA/PH/OMCL (14) 39

SUB-CONTRACTOR QUALIFICATION

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Custodian Organisation	The present document was elaborated by the OMCL Network / EDQM of the Council of Europe
Concerned Network	GEON

ANNEX I
SUB-CONTRACTOR QUALIFICATION

1. Description

Sub-contractor	
Division	
Address	
Postcode / City / Country	
Contact person / Tel.	
Responsible / Qualified Person	
Title and professional training	
Type of test / Remarks	
Test parameter / Test method	

2. QS Status

<ul style="list-style-type: none"> – Test accredited according to ISO 17025 – Test covered by MJA – GLP certification – GMP certification – Pre-qualification programme of WHO 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Accreditation body / Certification company	
Accreditation number / Certification number	

If accredited or certified, please skip section 3 and continue to section 4. *Archiving*

3. Qualification of Sub-contractor

Quality system in place	<input type="checkbox"/> yes <input type="checkbox"/> no	Please specify.
Standard Operating Procedure (SOP) in place	<input type="checkbox"/> yes <input type="checkbox"/> no	SOP No. / version:
OOS procedure in place	<input type="checkbox"/> yes <input type="checkbox"/> no	
Method validation in place	<input type="checkbox"/> yes <input type="checkbox"/> no	VA No. / version:
Qualification of reference material	<input type="checkbox"/> yes <input type="checkbox"/> no	Type / method of qualification:
Qualification of the equipment	<input type="checkbox"/> yes <input type="checkbox"/> no	Calibration programme in place <input type="checkbox"/> yes <input type="checkbox"/> no
Qualification of laboratory personnel	<input type="checkbox"/> yes <input type="checkbox"/> no	Training programme in place <input type="checkbox"/> yes <input type="checkbox"/> no
Participation in proficiency testing studies or other collaborative studies?	<input type="checkbox"/> yes <input type="checkbox"/> no	
Scientific publications?	<input type="checkbox"/> yes <input type="checkbox"/> no	
References/reputation of the laboratory?	<input type="checkbox"/> yes <input type="checkbox"/> no	
Notes		

4. Archiving

Archiving of test results (records)	<input type="checkbox"/> yes <input type="checkbox"/> no	Retention time:
Archiving of samples	<input type="checkbox"/> yes <input type="checkbox"/> no	Storage time:

Responsible for accuracy of the declaration, i.e. the Responsible / Qualified Person	Date
	Signature
	Name

To be completed by the OMCL

5. Decision

Sub-contractor suitable?	
Evaluation of QS-Manager <input type="checkbox"/> yes <input type="checkbox"/> no	Date / Signature
Decision of Responsible Person <input type="checkbox"/> yes <input type="checkbox"/> no	Date / Signature
Remarks	