

**Form B Quality Questionnaire for Critical Suppliers**

Please answer ALL of the questions on this survey. If a question does not pertain to the product or services provided by your company please select No and add justification if required.

Please provide the following documentation to assist us in completing our assessment:

Documentation	Attached
A copy of your Quality Policy	<input type="checkbox"/> Yes <input type="checkbox"/> No
A copy of your ISO Certification/Accreditation	<input type="checkbox"/> Yes <input type="checkbox"/> No
A copy of your Complaints Procedure	<input type="checkbox"/> Yes <input type="checkbox"/> No

Please return signed and dated to the Neogen contact. A scanned copy is acceptable.

Company Information	
Company Name and Address:	Click here to enter text.
Company Telephone Number:	Click here to enter text.
Company Website:	Click here to enter text.
Year Founded:	Click here to enter text.
Total Number of Employees:	Click here to enter text.
Number of Employees within Quality functions:	Click here to enter text.
Are there other Manufacturing/ Service Locations that provide product/services to Neogen:	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, list other locations: Click here to enter text.
Products or Services provided to Neogen:	
Click here to enter text.	

Quality Management System	
Questions	Answers
Does your Company have a Quality Management System?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Are you ISO Certified or Accredited? Please select all that apply  <b>Please provide a copy of your certificate(s) and/or scope of accreditation.</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <small>IF NO, CONTINUE TO NEXT BOX</small> <input type="checkbox"/> ISO 9001 <input type="checkbox"/> ISO 17043 <input type="checkbox"/> ISO 17025 <input type="checkbox"/> ISO 17034 <input type="checkbox"/> ISO 13485 <input type="checkbox"/> ISO 27001 <input type="checkbox"/> Other <a href="#">Click here to enter text.</a>
Does your Company have a Quality Manual?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does your Company have a Quality Policy? <b>Please provide a copy of your quality policy.</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No
Do you have a main contact for Quality Issues?  Please provide the contact information:	<input type="checkbox"/> Yes <input type="checkbox"/> No <small>IF NO, CONTINUE TO NEXT BOX</small> Name: <a href="#">Click here to enter text.</a> Title: <a href="#">Click here to enter text.</a> Email: <a href="#">Click here to enter text.</a>
Does your Company have a Business Continuity Plan?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Would you be prepared to accept a quality audit visit by a representative from Neogen Europe Ltd?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Process Control	
Does your Company have a Document Control System?	<input type="checkbox"/> Yes <input type="checkbox"/> No <small>IF NO, CONTINUE TO NEXT BOX</small>
Does your Company have a change control procedure for Documents and Records?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Are procedures in place to prevent use of obsolete documents?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does your Company have version control?	<input type="checkbox"/> Yes <input type="checkbox"/> No

<p>Does your Company have established retention times of Documents and Records?</p>	<p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p>
<p>Does your Company have documented inspection procedures?</p> <p>Are incoming goods inspected using approved procedures/specifications?</p> <p>Does your Company have in-process testing/inspection points?</p> <p>Does your Company have documented final inspection processes?</p>	<p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p> <p><small>IF NO, CONTINUE TO NEXT BOX</small></p> <p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p> <p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p> <p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p>
<p>Does your Company have a process for control of Non-Conforming material/services?</p> <p>Is Non-conforming material quarantined to prevent unintended release?</p>	<p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p> <p><small>IF NO, CONTINUE TO NEXT BOX</small></p> <p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p>
<p>Does your Company have a documented Change Control process/procedure?</p> <p>Does your Company notify customers of any critical changes to products or services?</p> <p>What notice period do you give your customers of changes?</p>	<p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p> <p><small>IF NO, CONTINUE TO NEXT BOX</small></p> <p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p> <p><small>IF NO, CONTINUE TO NEXT BOX</small></p> <p>Click here to enter text.</p>
<p>Are production/test activities defined by documented procedures?</p>	<p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p>
<p>Does your Company use batch records or operating instructions?</p> <p>Are production/test records maintained?</p> <p>Are you able to provide a Certificate of Analysis (CoA) for each Lot of product supplied or a report detailing testing/calibration activities?</p>	<p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p> <p><small>IF NO, CONTINUE TO NEXT BOX</small></p> <p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p> <p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p>
<p><b>Supplier Management</b></p>	
<p>Does your Company outsource any of your activities/processes for Neogen Products/Services?</p> <p>Does your Company have a documented Supplier Approval Program?</p>	<p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p> <p><small>IF NO, CONTINUE TO NEXT BOX</small></p> <p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p>

<p>Does your Company have a maintained Approved Supplier/Subcontractor list?</p> <p>Is there a Supplier Complaints procedure?</p> <p>Does your Company monitor supplier performance?</p> <p><b>Please define the procedure/process for monitoring supplier performance standards.</b></p>	<p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p> <p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p> <p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p> <p>Click here to enter text.</p>
<b>Management Review and Internal Audits</b>	
<p>Does your Company have documented Management Review Meetings?</p>	<p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p>
<p>Does your Company conduct scheduled Internal Audits?</p>	<p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p>
<b>Complaints</b>	
<p>Does your Company have a documented Customer Complaint procedure?</p> <p>Is this available to customers?</p> <p>What is your target response time in relation to receipt of a complaint?</p> <p><b>Please provide a copy of your complaints procedure</b></p>	<p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p> <p><small>IF NO, CONTINUE TO NEXT BOX</small></p> <p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p> <p>Click here to enter text.</p>
<p>Does your Company have a documented Corrective Action process?</p> <p>Are Corrective Actions assigned and reviewed before closure?</p> <p>Are Corrective Actions periodically reviewed for effectiveness?</p>	<p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p> <p><small>IF NO, CONTINUE TO NEXT BOX</small></p> <p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p> <p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p>
<p>Are customers notified of complaint outcome and corrective actions?</p>	<p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p>
<b>Product Recall</b>	
<p>Does your Company have a documented Product recall procedure?</p> <p>Can the lot/batch number of the finished product be traced back to the raw material?</p> <p>Do you regularly test the product recall process?</p> <p>If Yes please specify how often?</p>	<p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p> <p><small>IF NO, CONTINUE TO NEXT BOX</small></p> <p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p> <p><input type="checkbox"/>Yes    <input type="checkbox"/>No</p> <p>Click here to enter text.</p>

Training	
<p>Does your Company have a documented training program?</p> <p><b>Briefly describe how personnel are trained/qualified to carry out duties?</b></p> <p>Are employees training records maintained and periodically reviewed?</p>	<p><input type="checkbox"/> Yes    <input type="checkbox"/> No</p> <p><small>IF NO, CONTINUE TO NEXT BOX</small></p> <p>Click here to enter text.</p> <p><input type="checkbox"/> Yes    <input type="checkbox"/> No</p>
Equipment Management	
<p>Does your Company have a documented procedure for equipment calibration and maintenance?</p> <p>Do you have a preventative maintenance program for equipment/machinery?</p> <p>Are documented procedures for equipment use and maintenance available to manufacturing/test personnel?</p> <p>Is there a documented calibration program in place to assure the equipment being used is within specification?</p>	<p><input type="checkbox"/> Yes    <input type="checkbox"/> No</p> <p><small>IF NO, CONTINUE TO NEXT BOX</small></p> <p><input type="checkbox"/> Yes    <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes    <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes    <input type="checkbox"/> No</p>
<p>Does your Company have a procedure to manage failed/defective equipment?</p> <p>Is the equipment removed from use until fixed?</p>	<p><input type="checkbox"/> Yes    <input type="checkbox"/> No</p> <p><small>IF NO, CONTINUE TO NEXT BOX</small></p> <p><input type="checkbox"/> Yes    <input type="checkbox"/> No</p>
<p>Are validations performed and documented for new equipment or processes where the results cannot be or are not fully verified?</p>	<p><input type="checkbox"/> Yes    <input type="checkbox"/> No</p>
<p>Are records retained and reviewed for calibration performed by a third party?</p>	<p><input type="checkbox"/> Yes    <input type="checkbox"/> No</p>

Additional Comments

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Supplier Questionnaire Approval	
Questionnaire completed by (print name)	
Signature	
Date	
Job title	

**For Internal Use only**

<b>Supplier Approved</b>	Yes/No
<b>Additional Comments</b>	

Signature	
Date	