Vendor Audit Questionnaire

(Ref. SOP QMS-045; QMS-080)

Vendor Company Name:			
Supplier Site Address:	**Supplier Business Address (if different):**		
Phone No:	**Phone No:**		
Fax No:	**Fax No:**		
E Mail:	**E Mail:**		
Material supplied to Sydco, covered by this questionnaire:			
Is the Company a division/subsidiary of another corporation?	**Yes**	**No**	**N/A**
If Yes, Please Specify			

This questionnaire was completed by:
Name:
Job Title:
Date:
Signature:

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For "Yes" / "No" answers; Please tick the box for the one which applies, or select "N/A" (Not Applicable)			
Management Responsibility			
Is an organization chart available? If yes, please enclose a copy.	Yes	No	N/A
Are there any written job descriptions defining each individuals responsibilities	Yes	No	N/A
How many shifts of operation are there in the Production Area? How many shifts of operation are there in QC Laboratory?			
Approximately how many employees do you have? - Site total			
- QA/QC			
- Production			
To whom does the QA/QC Manager report?			
Does the company have a policy on EHS (Environmental, Health & Safety)?	Yes	No	N/A
Does the company have a policy on Quality?	Yes	No	N/A
Who is responsible for contacts with Sydco with regards to the following areas: Quality: Technical: Commercial:			
Are subcontractors (if used), used for significant steps or components in Preparation of Sydco's products? The term subcontractors includes both contracted operations within Production and the Laboratory	Yes	No	N/A
If "Yes", please list and explain:			

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Can you please provide full Supply chain(s) for the referenced material(s) (i.e. Manufacturer, Testers, Providers of C of A / C of C, Packers / Repackers and Storage & Distribution)	Yes	No	N/A
If "Yes", please list & explain:			

Quality Management System

What is the basis of your quality system, i.e. ISO?			
Please state your Certificate/Registration reference and appropriate dates:			
Have any regulatory agencies inspected your facility in the last five years?	Yes	No	N/A
If 'Yes', by whom, when and what were the results?			
Are all procedures documented and approved?	Yes	No	N/A
Are there change control procedures in place?	Yes	No	N/A
Is there a procedure to notify customers of change?	Yes	No	N/A
Are QA/QC responsibilities well defined and independent?	Yes	No	N/A
Does QA/QC approve all analytical specifications and methods?	Yes	No	N/A
How is a batch (standard quantity) defined?			
What is the batch numbering system? (Please explain in detail)			

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Do you assign shelf/expiry/retest-lives for all materials (incoming & produced)?	**Yes**	**No**	**N/A**
If "Yes", please provide details.			
Which department reviews and approves production procedures?			
Are reference samples retained?	**Yes**	**No**	**N/A**
If "Yes", for how long?			
For how long are records retained?			
Is there a self-audit program?	**Yes**	**No**	**N/A**

Incoming Goods			
Is a list of approved suppliers used?	**Yes**	**No**	**N/A**
Is there a documented procedure for approval of suppliers?	**Yes**	**No**	**N/A**
Does this include audit of suppliers?	**Yes**	**No**	**N/A**
If bulk tankers are used, are they dedicated?	**Yes**	**No**	**N/A**
If not, is a cleaning certificate required?	**Yes**	**No**	**N/A**
Is there a system for monitoring or reviewing suppliers' performance?	**Yes**	**No**	**N/A**
Are there documented procedures for: **- Inspecting material**	**Yes**	**No**	**N/A**
- Testing material	**Yes**	**No**	**N/A**
Are established Purchase Specifications used?	**Yes**	**No**	**N/A**
What is the basis for acceptance of raw materials, i.e. testing, receipt of suppliers C of A or both?			
Is a sampling plan in place?	**Yes**	**No**	**N/A**
Is a testing plan in place?	**Yes**	**No**	**N/A**

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Warehouse			
Are storage facilities/equipment/ rented or personnel contracted?	Yes	No	N/A
If "Yes", please provide details.			
Are receipt and release procedures documented?	Yes	No	N/A
Is the supply chain documented?	Yes	No	N/A
How is material status controlled? (i.e. Physical, system or labelling)			
How is rejected material controlled? (i.e. Physical, system or labelling)			
Is there an identified sampling area?	Yes	No	N/A
Are all containers identified?	Yes	No	N/A
Is a First-In-First-Out or First-Expiry-First-Out system in use? (Identify)	Yes	No	N/A
Are shelf life/expiration dates used?	Yes	No	N/A
Is Temperature (T°), controlled and documented?	Yes	No	N/A
Comments:			
Is Relative humidity (RH%), controlled and documented?	Yes	No	N/A
Comments:			

Production			
Is there more than one site or plant used for the manufacture of the specified material(s)?	Yes	No	N/A
If "Yes", please provide details.			
Is plant equipment labelled as to its status and contents?	Yes	No	N/A
Is Pipe work labelled?	Yes	No	N/A
Are critical processes validated?	Yes	No	N/A
Does process documentation include: Process instructions	Yes	No	N/A
Cleaning instructions	Yes	No	N/A
Cleaning records	Yes	No	N/A
Area clearance	Yes	No	N/A
Are cleaning processes validated?	Yes	No	N/A

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Is there traceability throughout the process?	**Yes**	**No**	**N/A**
Is there an in-process monitoring system?	**Yes**	**No**	**N/A**
Is there an equipment use log?	**Yes**	**No**	**N/A**
Are all critical instruments calibrated?	**Yes**	**No**	**N/A**
Is there a preventative maintenance program?	**Yes**	**No**	**N/A**
Is reprocessing allowed?	**Yes**	**No**	**N/A**
Is there a non-conformance procedure?	**Yes**	**No**	**N/A**
Is the yield checked against defined limits?	**Yes**	**No**	**N/A**
Are different grades of material produced?	**Yes**	**No**	**N/A**
If 'Yes', how and at what stage are these differentiated/selected?			
Is the plant dedicated or multi purpose?			
If the plant is multi purpose, what other types of materials are produced in the unit(s)?			
Please list any hazardous materials that are manufactured on your site (whether in dedicated or multi purpose facilities). E.g. herbicides.			
If available, please enclose a brief process flow, and if possible include where in-process controls are performed.			

Packing			
Are packing operations segregated from production?	**Yes**	**No**	**N/A**
Are barcode readers in use?	**Yes**	**No**	**N/A**
Are areas labelled with the product being packed?	**Yes**	**No**	**N/A**
Are re-usable containers used?	**Yes**	**No**	**N/A**
Are cleaning procedures in place?	**Yes**	**No**	**N/A**
Are controlled procedures used for issuing labels and labelling?	**Yes**	**No**	**N/A**
Are label details checked?	**Yes**	**No**	**N/A**
Are there label reconciliation procedures?	**Yes**	**No**	**N/A**

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Are there label disposal procedures?	Yes	No	N/A
How are containers security sealed?			
Is material clearly labelled, including waste and reject material?	Yes	No	N/A

Computerized Systems			
Do you have a list of the Computerized systems used by this facility?	Yes	No	N/A
If "Yes", do you identify the Computerized systems that are considered to have an impact on Quality of Product, or Service offered?	Yes	No	N/A
If "Yes", how is this documented?			
Does your Quality system cover the quality of Computerized systems?	Yes	No	N/A
Do you have procedures in place for disaster recovery and restoring of data archives?	Yes	No	N/A
Do you have access security levels for the Computerized systems?	Yes	No	N/A
Do your procedures for validation cover the Computerized systems?	Yes	No	N/A
Do you have anti-virus protection?	Yes	No	N/A
Does the Change Control procedure include Computerized systems?	Yes	No	N/A

Laboratories, QA & QC			
Is an equipment use log in place?	Yes	No	N/A
Are all instruments qualified (IQ, OQ, PQ)?	Yes	No	N/A
Are all instruments calibrated?	Yes	No	N/A
Is there a preventative maintenance program?	Yes	No	N/A
Are there documented procedures for: Sampling	Yes	No	N/A
Sample handling	Yes	No	N/A
Sample labelling	Yes	No	N/A
Re-testing / Re-sampling	Yes	No	N/A
Specification generation	Yes	No	N/A
Analytical method generation	Yes	No	N/A
Control and review of analytical methods	Yes	No	N/A

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Investigation of rejected material	Yes	No	N/A
Product complaints	Yes	No	N/A
Handling out of specification results	Yes	No	N/A
Are manual calculations checked by a second person?	Yes	No	N/A
Are data transcriptions checked by a second person?	Yes	No	N/A
Is all raw-data retained?	Yes	No	N/A
Are all standards traceable to their preparation and the reagents used?	Yes	No	N/A
Are analytical methods validated?	Yes	No	N/A
Do you perform stability testing on materials and/or products?	Yes	No	N/A
If so, what shelf life / retest dates are available for the referenced product(s)?			
Do you perform annual product reviews or campaign reviews on products?	Yes	No	N/A

Material Release

Is the decision to release/reject product made by a person or function independent from production?	Yes	No	N/A
Is the final status recorded?	Yes	No	N/A
Are certificates issued for each batch?	Yes	No	N/A
Are certificates signed by QA/QC?	Yes	No	N/A
If not, who signs certificates?			
Is shelf life or retest dates or expiry date provided on the "C of A " OR "C of C's"	Yes	No	N/A
Is there a documented recall procedure?	Yes	No	N/A

Transport

Is a list of approved hauliers in use?	Yes	No	N/A
Is temperature controlled transports used?	Yes	No	N/A
If "Yes", are temperature records reviewed and retained?	Yes	No	N/A
If bulk tankers are used, is a cleaning certificate required?	Yes	No	N/A
If bulk tankers are used, are they dedicated?	Yes	No	N/A
If not, what other substances could be transported in the tankers?			

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If Agent/Distributor involved, is the pipe work used on delivery to the agent/distributor dedicated?	**Yes**	**No**	**N/A**
Are the Agent/Distributor storage facilities dedicated?	**Yes**	**No**	**N/A**
If "No", what other substances are stored in the facilities?			
Does the Agent/Distributor use dedicated filling lines?	**Yes**	**No**	**N/A**
What instructions are given to the haulier for delivery to a Sydco site e.g. dedicated hoses, dedicated tanks, dedicated pumps, temperature control, and paperwork to accompany delivery?			

Facilities & Housekeeping			
Are there procedures for health and hygiene?	**Yes**	**No**	**N/A**
Are rest/change/wash facilities separated from production areas?	**Yes**	**No**	**N/A**
Are access restrictions implemented as needed?	**Yes**	**No**	**N/A**
Do any production areas have special containment needs?	**Yes**	**No**	**N/A**
Are waste disposal systems in place?	**Yes**	**No**	**N/A**
Are there procedures documenting a pest control program?	**Yes**	**No**	**N/A**
Are material Safety Data Sheets maintained?	**Yes**	**No**	**N/A**

Training			
Is there a written training program?	**Yes**	**No**	**N/A**
Are job-training needs evaluated?	**Yes**	**No**	**N/A**
Is completed training evaluated and approved?	**Yes**	**No**	**N/A**
Are there completed written training records for all employees?	**Yes**	**No**	**N/A**

Questionnaire reviewed for Buyer lead audit site by:
Name:
Title:
Date:

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