Appendix 2: Supplier Selection check List		
Key Selection Criteria (Minimum)	**Non Critical raw materials**	**Critical Materials**
Specifications	X	X
Price	X	X
Manufacturing information	X	X
Packaging, Labelling information	X	X
Material Safety Data Sheets	X	X
Logistic information (Lead time to produce, delivery time, supply route, ...)	X	X
Certificates (GMO, BSE/TSE, Residual solvents, ...)	X	X
Analytical test method		X
Key Selection Criteria (Advanced)	**Non Critical raw materials**	**Critical Raw Materials**
I. Assurance of Supply		
I.A. Capacity		
What is the capacity of the plant ?		X
Is the capacity of the company sufficient to meet the long term needs ?	X	X
What is the maximum volume that can be manufactured and delivered on yearly basis?		X
What is the maximum batch size for the products within scope?		X
What would be the typical batch size for commerical manufacture?		X
Does the supplier has alternative sites to manufacture the products within scope?	X	X
Has the company industrial experience with the chemistry involved?		X
Does the company intend to manufacture in a dedicated plant?		X
Does the supplier has the capability to handle specific technology?		X
How soon can a validation campaign be started?		X
What is the expected yield and yield range for the products within scope?		X
I.B. Safety/Health/Environmental risk		
Does the company have the necessary manufacturing permits/licenses available ?	X	X
What is the validity of the permits?	X	X
Is there a REACH program in place?	X	X
What are the EHS standards employed at the site of manufacture?	X	X
Has the facility undergone EHS audits?	X	X
I.C. Financial/business stability		
Is the supplier willing to share data on the financial performance?	X	X
Is the company in good financial health?	X	X
What is the evolution of the financial KPIs during the last three years?		X
Is there a stable shareholder structure in place?		X
What is the shareholder's long term investment strategy?		X
What was the turnover for the last three years?		X
What percentage does the intended spend represent versus the total turnover?		X
I.D. Delivery performance		
Does the supplier has tools in order to track and evaluate their delivery performance?	X	X
II. Quallity /Regulatory Compliance		
II. A. cGMP Compliance & Regulatory track record		
Were there any cGMP inspections by local authorities or other regulatory authorities?		X
Were there any observations or objectionalbe observations from Health authorities?		X
Is the site classified as a US FDA, EU, TGA etc. acceptable site?		X
Where there ISO 9001 certifications?	X	
Will the product(s) within scope be manufactured in an inspected an approved facility?		X
II. B. Recalls & Complaints		
Are there adequate procedures in place for complaint handling & recalls?	X	X
How many recalls were there in the last three years? If not zero, indicate the reason for the recall		X
How many quality critical complaints were there in the last three years.		X
II. C. Change & Deviation management		
Does the supplier has effective change controls in place?	X	X
Does the suppliers allows the involvement and participation of the customer?		X
Is there a system in place for non-conformity evaluation	X	X
Are there effective procedures in place for deviation reporting?		X
II. D. Materials Management		
Is appropriate testing performed on the incoming raw materials including the availability of the manufacturer's CoA?	X	X

Is the site of manufacture verified on receipt of the raw material?		X
Is there a supplier qualification program in place?	X	X
Are there any materials of animal origin used?	X	X
Is it a requirement for the suppliers to provide completed TSE/BSE questionnaires?	X	X
Is it a requirement for the suppliers to provide a residual solvent questionnaire?		X
II.E. Quality Systems/ Agreement/Culture		
Does the supplier has quality systems in place in line with the requirements for the product(s) within scope?	X	X
Is the company willing to establish a Quality Agreement in accordance with your requirements and policies?		X
Is there a quality culture in the organisation driven and supported by top management?	X	X
Are there regular quality management review meetings?	X	X
II.F. Production facilities and equipment		
Are there appropriate environmental controls in place appropriate to the product type ?		X
If applicable to the API, has the supplier facilities in place to carry out microbiological testing on site or is this outscourced ?		X
If the product is manufactured in multi-purpose equipment how is ensured for product change-overs that the residues are below an acceptable level ?		X
How are the cleaning verification controls performed on the plant ?		X
Are the process support laboratories for the product located on the same site of the manufacturing site?		X
If applicable to the API, can stability studies following ICH conditions be performed on site?		X
II.G. Product Quality Review		
Is there a system in place to make periodic quality reviews?		X
Does the company use statistical tools ?		X
Is there a program for continious improvement?		X
II. H. Security of the supply chain?		
What measures are taken to ensure the safety of the supply chain?		X
Is there a full visibility on the origin of the raw materials?		X
II. I. Process Validation approach		
What is your process validation approach?		X
Are there adequate procedures in place for process validation?		X
III. Producurement/Cost		
III.A. Cost Management		
Is there a willingness to provide open book costing details for the products within scope?		X
Does the cost of goods calculation take into account the use of recycled solvents?		X
Is there a potential for price reduction based on increased efficiencies?		X
Are development costs included in the price?		X
Will a CAPEX program be required for the project wihtin scope?		X
Have development costs been taken into account for the price setting? If yes how much can be attributed to the cost of goods?		X
What are the total costs, timelines and resources required for pilot plant scale and developmment work ?		X
What are the costs for the validation campaign ?		X
Are there initiatives taken to lower cost of goods and work on price improvements?		X
III.B. Presence in Low Cost Countries (Emerging markets)		
Has the company easy access to LCC raw material sources?		X
Is there an Asean platform to manage local sourcing?		X
IV. Innovation/Technical		
Are there areas where the company can bring innovation?		X
What is the native language spoken in the company? What is the level of understanding of English on different levels in the organisation?	X	X
Are there resouces available to support continuous improvment activities? If yes, how many FTEs versus total?		X
What is the company's view on sharing detailed process information?		X
What is the level of competence in lean and 6S techniques?		X
Is there a structured approach to resolve business problems?		X
What is the approach to process trending and evaluation? Is plant and analytical data trended in real time or retrospectively?		X
What kind of advanced analytical and process chemistry equipment is available to carry out process investigation work?		X
What are the capabilities of the development lab? What type of specialist laboratory equipment is available and in use to support the process?		X
Are there plans to invest in laboratory equipment? If yes provide more details		X
rovide details of material of construction of the plant that will be used for the products within scope?		X
What milling technology and capacity is available?		X
Is there cold storage capacity on site ?		X

Are there project management capabilities present?		X
Provide the background on the number of staff and their qualifications		X
What level of parameter monitoring (eg. Temperature, pressure, weight, flow rate, etc) is there on the processing equipment?		X
V. Responsiveness & Communication		
V. A. Responsiveness		
What is the standard lead time following receipt of the purschase order?	X	X
What is the company's responsiveness for new inquiries?	X	X
What is the production flexibility?	X	X
What is the lead time for project assessment?	X	X
V. B. Communication		
Are there well defined functional contacts?	X	X
Does the supplier communicate pro-actively?	X	X
Is there a willingness to share detailed information on a voluntary basis?		X