SUPPLIER APPROVAL QUESTIONNAIRE

The purpose of this questionnaire is to assist Pharmaxis in assessing suppliers for inclusion in our approved supplier list for provision of material, service and computerised system providers which are essential to the quality of our products.

All information will be treated in the strictest confidence.

We would be grateful if you could take the time to complete this questionnaire, and return it as soon as possible to the Pharmaxis contact below.

SECTION A) TO BE COMPLETED BY THE PHARMAXIS REQUESTOR

Name of Pharmaxis Contact:		**Position:**	
Address	**Pharmaxis Ltd.** **20 Rodborough Road** **FRENCHS FOREST NSW 2086 AUSTRALIA**		
Phone No.		**Date**	
E-mail			
Supplier Name			
Supplier Address			
Material / Service Required			
Specification			
Manufacturer/Principle Supplier Name and Address *(if not the direct supplier)*			

REQUESTOR NOTE. If the supplier is a consultant they must provide evidence to show they have adequate education, training, and experience, or any combination thereof, to advise on the subject for which they are engaged. A request for copies of these documents should be entered in the additional questions section of this form.

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Prior to sending to the supplier ensure additional questions, if required, are entered in the allocated area at the end of this form.

Sections A and B is to accompany sections C or D as applicable.

Section C is to be completed by material and service providers.

Section D is to be completed computerised system providers.

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SUPPLIER APPROVAL QUESTIONNAIRE

SECTION B) TO BE COMPLETED BY THE MATERIAL/SERVICE SUPPLIER/COMPUTERISED SYSTEM REPRESENTATIVE

Supplier Name		
Questionnaire Completed By	**Name:**	
	Position:	
	E-mail:	**Phone No.**
	Date Completed:	

LICENCING / CERTIFICATION

What ***critical*** licencing or certification does your company require in order to supply the specified material, service or computerised system to Pharmaxis.
Please provide the following details:

Issuing Authority Name :.....

Licence / Certificate No.:.....

Scope of Licence / Certification :.....

Please attach a copy of the certificate(s).

If there is more than one ***critical*** licence /certification required please provide further details below:

.....

.....

.....

.....

.....

What ***other*** licencing or certification has your company obtained.

Please attach a copy of the certificate(s).

SUPPLIER APPROVAL QUESTIONNAIRE

SECTION C) TO BE COMPLETED BY THE MATERIAL/SERVICE SUPPLIER

Complete each question by circling the applicable answer. If the question is not relevant to your business enter N/A and move on to the next question.

Please do not hesitate to contact the Pharmaxis Requestor via the contact details on page 1, should you have any queries regarding the questions.

Please attach scanned pdf copies of required documentation in your Email response.

QUESTIONNAIRE	Circle Applicable Answer
GENERAL	
Can you manufacture / supply the material or service required as defined in Section A) meeting all specified requirements?	**Yes / No**
Would you have to subcontract any or all of the material manufacture /service being supplied to Pharmaxis. If yes Please provide details:…… ……	**Yes / No**
Do you have a procedure for the selection of subcontractors	**Yes / No / N/A**
Do you agree to obtain written consent from Pharmaxis via the Pharmaxis contact before subcontracting any work relating to this material/service?	**Yes / No / N/A**
Does your company have a Quality department. If yes, how many Quality staff:	**Yes / No / N/A**
Does your company have training records for Quality department staff.	**Yes / No / N/A**
CALIBRATION PROVIDERS	
If you provide calibration services, do you have applicable certification to perform these services? (Please attach certification)	**Yes / No / N/A**
If you are not certified to perform calibration, how are the reference standards maintained used for calibration of clients equipment.	
EVIDENCE OF QUALITY SYSTEM	
Do you have current, documented work instructions for each process associated with the material / service required?	**Yes / No / N/A**
Do you have a documented system for control, calibration and maintenance of measuring and test equipment?	**Yes / No / N/A**

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QUESTIONNAIRE	Circle Applicable Answer
Do you operate documented procedures for investigating non-conformities (including customer complaints) and taking corrective action?	Yes / No / N/A
Do you have documented procedures for handling deviations	Yes / No / N/A
Do you have documented procedures for change management	Yes / No / N/A
Do you have documented procedures for storage and maintenance of records?	Yes / No / N/A
Do you retain records for a minimum retention period of 5 years.	Yes / No / N/A
Is there a procedure for creation, review, approval and maintaining procedures.	Yes / No / N/A
Do you have an internal audit program	Yes / No / N/A
Contact name and position for Pharmaxis to contact when requesting for current documentation (e.g. licences, certifications, Agreements) **Name:** **Position:**	
SUPPLIER SPECIFIC QUESTIONS	
	Yes / No / N/A
	Yes / No / N/A
	Yes / No / N/A
	Yes / No / N/A

End of Section C.

SUPPLIER APPROVAL QUESTIONNAIRE

We appreciate you taking the time to complete this questionnaire. Your responses assist us in upholding the quality of our products and the safety of our patients.

Supplier please ensure you attach required documentation before returning back to the Pharmaxis requestor.

Questions have been appropriately completed by the supplier.

Sign and Date Pharmaxis Requestor:.....

SUPPLIER APPROVAL QUESTIONNAIRE

SECTION D) TO BE COMPLETED BY THE COMPUTERISED SYSTEM SUPPLIER REPRESENTATIVE

This section of the questionnaire is only to be sent to computerised system providers.

QUESTIONNAIRE – COMPUTERISED SYSTEMS	Circle Applicable Answer
Software Development	
Does your company have a written policy/procedure for the Software Development Life Cycle (SDLC) methodology (i.e. Project Initiation → Project Planning → Requirements Gathering → System Design → System Development → System Testing → System Release) followed within your company? If yes, provide details on governing Procedure/ Document:	**Yes / No / N/A**
Software Quality Policies, Standards, and Procedures	
Is the development & testing of systems performed & documented at multiple layers (e.g. module/ code review/integration /IQ/OQ). Is there a source code listing? If yes, provide details	**Yes / No / N/A** **Yes / No / N/A**
Does your company have written procedures for the system testing strategy at each level of development (such as unit/module testing (UT), system testing (ST), integration testing (IT), stress/ performance testing and user acceptance testing (UAT)? Related document/ procedure:	**Yes / No / N/A**
Does your company have a written procedure for executing tests (such as defining acceptance criteria/expected results, retaining raw data, recording test results, handling and resolving test failures (variances), and reviewing test results)? Related document/ procedure:	**Yes / No / N/A**
Does your company have a written procedure for verifying the traceability between requirements/design specification and executed tests? If yes, please attach documented evidence that traceability verification was performed for the system/ product, under consideration.	**Yes / No / N/A**

SUPPLIER APPROVAL QUESTIONNAIRE

QUESTIONNAIRE – COMPUTERISED SYSTEMS	Circle Applicable Answer
Personnel/ Supplier / Subcontractor Qualifications and Performance	
Is your company's staff qualified & trained appropriately to develop/configure/customize the application software/computer system? Is the staff trained on regulatory requirement such as 21 CFR Part 11/Annexure 11 Provide details as an attachment.	**Yes / No / N/A**
Has the application been tested for compliance to regulatory requirements such as 21 CFR Part 11 / Annexure 11 ?	**Yes / No / N/A**
Is any of the software used to provide the service to Pharmaxis purchased from a third party. If yes, has it been subjected to regulatory compliance checks such as 21 CFR Part 11?	**Yes / No / N/A**
Software Code Control / Security & Maintenance Practices	
Is access to your company's system development environment or Data/Infrastructure center (in case of cloud based systems) restricted? Related procedure/ document: _____	**Yes / No / N/A**
Does your company have a written procedure for backup and recovery (including secure storage and onsite and offsite handling of media) of software code/ system data (in case of cloud based systems)? Related procedure/ document: _____	**Yes / No / N/A**
Has your company performed disaster recovery testing of software code or system data/ network infrastructure (in case of cloud based systems)?	**Yes / No / N/A**
Does the system provide for archival and retrieval of records? Related procedure/ document: _____	**Yes / No / N/A**
In case of cloud products/services, has the aspects such as network infrastructure physical/ logical security framework and data security measures have been tested and documented?	**Yes / No / N/A**

SECTION D) CONTINUED

QUESTIONNAIRE– COMPUTERISED SYSTEMS	Circle Applicable Answer
Software Release / Customer Support Practices	
Does your company have a reporting system for communicating to customer's upgrades/patches and/or new releases to the system? Related procedure/ document:	**Yes / No / N/A**
Does your company have written procedure for bug fixes and patch management? Can you describe how customers are alerted:	**Yes / No / N/A**
Documentation Support	
Does your company have documented evidence that the system has been tested for the base or out-of-box functionality? If yes, please attach a Test Summary Report/ Qualification Certificate for the system.	**Yes / No / N/A**
Supplier Specific Questions	
	Yes / No / N/A
	Yes / No / N/A
	Yes / No / N/A

End of Section D.

SUPPLIER APPROVAL QUESTIONNAIRE

We appreciate you taking the time to complete this questionnaire. Your responses assist us in upholding the quality of our products and the safety of our patients.

Supplier please ensure you attach required documentation before returning back to the Pharmaxis requestor.

Questions have been appropriately completed by the supplier.

Sign and Date Pharmaxis Requestor:.....

Sign and Date Pharmaxis Computer Systems Engineer:.....

End of document.