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DOCUMENT APPROVAL

Author's Signature:

Your signature indicates that this document has been prepared in accordance with company standards or guidelines and adequately reflects the tasks and deliverables necessary.

Signature	.....	**Date**	18-Jun-14
Print Name	James Drury		
Title	Production Engineer		

Reviewer's Signature:

Your signature indicates that, you have reviewed this document and that it accurately and completely reflects the tasks and deliverables necessary.

Signature	.....	**Date**	18-Jun-14
Print Name	Ian Haigh		
Title	Engineering manager		

Quality Assurance/Compliance Approver's Signature:

Your signature indicates that this document complies with company standards or guidelines; and that the documentation and information contained herein complies with applicable regulatory, corporate, divisional/departmental requirements, and current Good Manufacturing Practices.

Signature	.....	**Date**	18 June 14
Print Name	Gary Crawley		
Title	Quality Manager		

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1.0 PURPOSE

1.1. The purpose of the document is to define the SOP (Standard Operating Procedures) to be followed by ADVANEX EUROPE Ltd, in order to ensure that all changes to products and manufacturing processes are appropriately controlled, approved and reviewed.

2.0 SCOPE

2.1. For the purpose of this SOP a "change" is regarded as a modification to a product, process or material. Maintenance and "like for like" replacements are not considered changes in this context.

2.2. This document provides a generic procedure to be followed where no customer(s) specific requirements have been provided. If customer(s) specific requirements are provided they will take precedence over this document.

2.3. This document applies to all changes to the management system and the processes defined within it.

2.4. Life cycle phase, as defined in GAMP 5.

2.4.1. **Concept Stage -** The Concept Stage covers the project through its initial stages until the design work begins, this stage is outside this change control procedure. The concept phase is closed once an initial project proposal has been approved and issued.

2.4.2. **Project Stage** - The Project Stage covers the development of the project through the planning, specification, configuration, verification and release up to the completion of the Process Qualification document. Once each level of qualification has been completed and signed off, any change that affects the current qualification level of the project will be required to go through full change control as detailed from step 5.2. The documents detail in steps 2.4.2.1 to 2.4.2.4 are subject to the change control procedure though out the entire Project Stage.

2.4.2.1. URS.

2.4.2.2. Customer drawing / Product specification.

2.4.2.3. Works Order / PQI.

2.4.2.4. Validation Plan.

2.4.3. **Operation Stage** - The Operation Stage covers the project once the Process Qualification document has been completed and signed off, through the production phase and whilst is being run under a normal production environment until the withdrawal of the product and Retirement Stage then begins. All documents, processes and material that may affect the resultant components, or the production process of, are required to go through the full change control procedure detailed below.

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2.4.4. **Retirement Stage** - The Retirement Stage covers system withdrawal, decommissioning, disposal or relocation, and migration of any required data. Once a project is in the retirement stage, then no change control is required unless specified by the customer as per line 2.2.

3.0 TERMS, DEFINITIONS & ABBREVIATIONS

3.1. GAMP 5 - Good Automated Manufacturing Practice revision 5 - A set of guidelines for manufacturers and users of automated systems.

3.2. Procedures - Agreed methods of working. Can be defined in formalised documented instructions or through training.

3.3. Planned change - A non-essential but desired change, designed to bring improvement to a process.

3.4. Forced change - An essential change to correct an undesirable situation or enable continuity.

3.5. PPAP - Production Part Approval Process - An automotive industry standard procedure for the supply of approved components.

3.6. Process - Method of manufacture of a company product including routing operations, workflow sequence, systems, equipment, Standard Operating Procedures, work instructions etc.

3.7. Product - Any item manufactured or procured by Advanex for sale to external customers and Advanex group members.

3.8. Document - Information and its supporting medium. The medium can be paper, film or electronic data.

4.0 ASSOCIATED DOCUMENTS

4.1. Change Request Form (CRF) (Document Number AEU00216).

4.2. Change Control Procedure for Pharmaceutical Customers (AEU00226).

4.3. External Change Request Form (Document Number AEU00108).

4.4. Change Request Form Register. Located on the Advanex network in the folder; F:\ENGINEERING\Admin\Engineering Changes

5.0 PROCEDURE

5.1. **Responsibility.**

5.1.1. It is the responsibility of all personnel to ensure that all processes are undertaken in accordance with current procedures until such time as these processes are officially updated and the new procedure becomes the current procedure.

5.2. **Change Control Procedure.**

5.2.1. **Submitting Change Request Form.**

5.2.1.1. Persons wishing to propose a change to a product or process will provide a description of the change in section '1' and will also identify themselves by writing

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their name in the "REQUESTED BY" section at the bottom of a change request form, (Document Number AEU00216), this form is then to be submitted via their immediate supervisor, where appropriate.

5.2.1.2. The form is to be submitted to the Engineering Department for review.

5.2.1.3. The Head of Engineering or appointed nominee will list the change request on a register and allocate a unique reference number.

5.2.1.4. An electronic copy of the change request form, (Document Number AEU00216), will then be stored on the Advanex network in a dedicated folder title with the unique reference number, any further supporting documentation may be stored in this folder as the change progresses.

5.2.2. **Initial Review Meeting.**

5.2.2.1. The Head of Engineering or appointed nominee will call a meeting with the proposer and all stakeholders.

5.2.2.2. This meeting is to assess the viability, impact upon Advanex systems, stock, and any potential customer impact of the proposed change.

5.2.2.3. If the change is deemed viable, then the stakeholders and their required actions will be identified along with any time frame required.

5.2.2.4. Agree a method of implementation for the change, this method is to be detailed in section '2' of the change request form, (Document Number AEU00216) already started for the change request.

5.2.3. **External Customer Approval.**

5.2.3.1. **Pharmaceutical Changes.** If the change is deemed to be pharmaceutical then SOP AEU00226 will be started to gain approval, were appropriate from the customer(s) for the change.

5.2.3.2. **Automotive Changes.** If the change is deemed to be automotive then once the change has been completed the PPAP procedure will be triggered.

5.2.3.3. **External Approval Required.** The change may be for components that do not fall into either the pharmaceutical or automotive sectors but still require external approval before implementation, the QA department will advise.

5.2.3.4. If any external approval is required, then until written approval has been received from the affected customer(s), all products will be supplied as per the existing processes and materials and will conform to customer(s) agreed or supplied specifications, unless any product is requested or required as samples in writing. These samples will be clearly identified and sent separately from any production batches.

5.2.4. **Progress Change.**

5.2.4.1. Once all required approval has been gained, then the completion of section '3' of the change request form, (Document Number AEU00216) will start, this will respond to the method of implementation detailed in section '2' of the change request form.

5.2.5. **Approval.**

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5.2.5.1. Once all items identified in section'2' have been closed as evidenced by the date of completion column, then the QA (Quality Assurance) department will ensure the effectiveness of the change and that all required verification activities have been completed along with sufficient documentation before approval is granted.

5.2.5.2. The change request register will have its entry for the change request updated to Approved at this time.

5.2.5.3. Once approval has been granted it is the responsibility of the Head of QA and Systems or appointed nominee to ensure that any documentation affected by the change is amended and re-issued.

5.2.5.4. When the required changes have been assessed as being completed then the completed change request form, (Document Number AEU00216) will be signed off by the person who requested the change, the Head of Engineering or appointed nominee and the Head of QA and Systems or appointed nominee.

5.2.5.5. The new procedure then becomes the current procedure the change request register entry will be updated as closed.