Advanex Europe Ltd
Head Office: Southwell Site
Mill Park Way, Southwell
Nottinghamshire, UK. NG25 0ET
☎: 00 44 (0) 1636 815555
℻: 00 44 (0) 1636 817725
Bilborough Site ☎: 00 44 (0) 115 9293931
℻: 00 44 (0) 115 9295773
Video Conference IP:80.176.189.113
www.advanexeurope.co.uk
general@advanexeurope.co.uk

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** 22-SEP-2015
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** 22 Sept 2015
Print Name Steve Harris
Title Head of M&P manufacturing

Signature ..... **Date** 27th Oct 2015
Print Name Rob Newham
Title Operations Manager AEUS

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** 02 Dec 2015
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 the wire forms manufactured on the Pharmaceutical section are done so in a controlled and consistent manner.

2.0 SCOPE

2.1. For the purpose of this procedure manufacturing only includes the forming and in-line heat treatment operations of parts for the HYPERION project.

2.2. All equipment and processes on the Pharmaceutical section have been formally qualified and validated. All personnel working on the Pharmaceutical section are responsible for ensuring that no changes are made to the process without full change control as defined in SOP/PH001 (Document Number AEU00226).

3.0 TERMS, DEFINITIONS & ABBREVIATIONS

3.1. Cpk / Ppk. - Capability indices.

3.2. QA - Quality Assurance.

4.0 HEALTH, SAFETY & ENVIRONMENTAL

4.1. GMP (Good Manufacturing Practice) guidelines apply (Document Number AEU00389).

4.2. Within the factory area safety footwear is mandatory.

4.3. Within the factory area Safety glasses must be worn.

4.4. Material Safety Data Sheets (COSHH).

5.0 ASSOCIATED DOCUMENTS

5.1. Machine Log (Document Number AEU00258): Used to record any unplanned activity on a machine.

5.2. Daily Machine Maintenance Record (Document Number AEU00394): Used to record completion of planned preventive maintenance activity on a machine.

5.3. DIN 560 Coil Change (Document Number AEU00538).

5.4. Label Preparation (Document Number AEU00437).

5.5. Measurement Procedure for Flap Return Spring (Document Number AEU00540).

5.6. Measurement Procedure for Yoke Spring (Document Number AEU00541).

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5.7. HYPERION Packing (Document NumberAEU00578).
5.8. MecWash Procedure (Document Number AEU00466).
5.9. Production Record Sheet: For recording the quantity of parts produced and wire information.
5.10. Correct Usage of Production Bins (Document Number AEU00397).
5.11. Control of Documents (Document Number AEU00002).
5.12. Line Clearance Procedure (Document Number AEU00447).
5.13. De-Burr & Polishing (Document Number AEU00322).
5.14. Weigh Count (Document Number AEU00542).
5.15. Works Order Instructions: Allowing full traceability for the batch.

6.0 PROCEDURE

6.1. **Production Records.**

6.1.1. All records relating to this procedure are subject to the requirements of the procedure Control of Documents (Document Number AEU00002).

6.1.2. The setter must record any unplanned occurrences for the machine on the Machine Log (Document Number AEU00258). This will include machine adjustment, stoppages, tool breakage, wire feed problems etc.

6.1.3. Planned preventive maintenance schedules are described for each machine in the procedure Daily Machine Maintenance Record (Document Number AEU00394), and must be completed to show when maintenance has been carried out.

6.1.4. Production Record sheets must be completed by the machine setter as a record of the quantity of parts produced including the quantity accepted / rejected as well as wire input records.

6.1.5. Records of all inspection activities must be maintained.

6.1.6. All springs must be fully heat-treated before inspection is performed. The results from these checks will be statistically analysed to establish process capability.

6.1.7. A minimum Cpk/Ppk value as defined on the Works Order Instructions must be achieved in order for the process capability to be considered acceptable.

6.1.8. If at any time the process is found not to be in control, the machine setter will ensure that the machine is stopped, that all affected product is segregated, identified and that the Section Leader is informed with any non-conforming components recorded on the Works Order Instructions. The machine will not be re-started until necessary actions have been taken to restore the process.

6.2. **Coil Change.**

6.2.1. If a coil change is required, change in accordance with DIN 560 Coil Change (Document Number AEU00538), ensuring that a note is detailed in MeasurLink when the first samples are checked in step 6.4.1.

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6.3. **Start Up.**

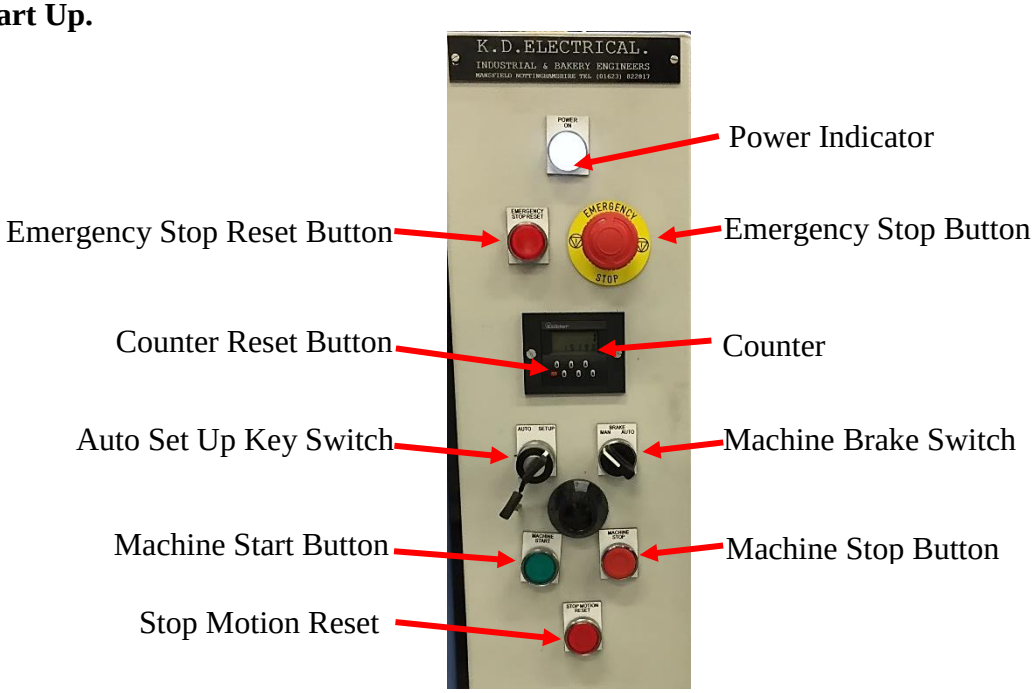

Figure 1: Machine control panel

6.3.1. **Separating Components Made During a Previous Production Run.** The machine setter must ensure that an empty collection bin is positioned at the exit of the heat treatment furnace.

6.3.2. **Final Check Before the Start of Production Run.** The setter must ensure that all required trips and switches are working correctly, reset the counter using the reset button, identified in Figure 1: ensure that all guards and covers are secure and in their correct places.

Figure 2: Example of a Temperature control panel.

6.3.3. **Heat Cycle Control Check.** The Setter must ensure that the heat treatment oven is correctly set as detailed on the Works Order Instructions.

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6.3.4. **Check Lubrication and Retaining Pads.** The Setter must ensure that Lubrication and the Retaining Pads are in good condition and the Lubrication bath is filled with sufficient distillate fluid for the production run. If not rectify in accordance with steps detailed in the procedure DIN 560 Coil Change (Document Number AEU00538).

6.3.5. **Check Safety Features.** The Setter must ensure that all guards and covers are secure and in their correct places.

6.3.6. **Component Control.** At this point the setter will assign a Works Order to identify the product that will be produced.

6.3.7. **Print Labels.** At a time before the competition of the production run and before the any secondary operations commence, the setter will print labels in accordance with the procedure Label Preparation (Document Number AEU00437).

6.4. **Production.**

6.4.1. **Component Inspection.** Upon starting the machine by use of the Machine Start Button, as shown in Figure 1: the setter will complete a recorded first off inspection of one part to ensure conformity of all specified dimensions after heat treatment as detailed in appropriate Measurement Procedure for Flap Return Spring (Document Number AEU00540) or Measurement Procedure for Yoke Spring (Document Number AEU00541).

6.4.2. **SPC Check.** Throughout the production run the Setter will complete and record inspections of all specified critical features at the frequency specified on the Works Order Instructions sheet. All springs must be fully heat-treated before inspection is performed, Using appropriate Measurement Procedure for Flap Return Spring (Document Number AEU00540) or Measurement Procedure for Yoke Spring (Document Number AEU00541) as a reference. The results from these checks will be statistically analysed to establish process capability. A minimum Cpk /Ppk. value as defined on the Works Order Instruction must be achieved in order for the process capability to be considered acceptable.

6.4.3. **Process Control.** If at any time the process is found not to be in control, the machine setter will ensure that the machine is stopped, that all affected product is segregated and identified using the procedure outlined in the procedure Line Clearance Procedure (Document Number AEU00540), with the Section Leader informed. The machine will not be re-started until necessary actions have been taken to improve the process.

6.4.4. **Check Correct Carousel Rotation.** The setter will ensure that the carousel is set to index to the next collection bin at the correct frequency by ensuring the required quantity of components are in each collection bin taken from the carousel.

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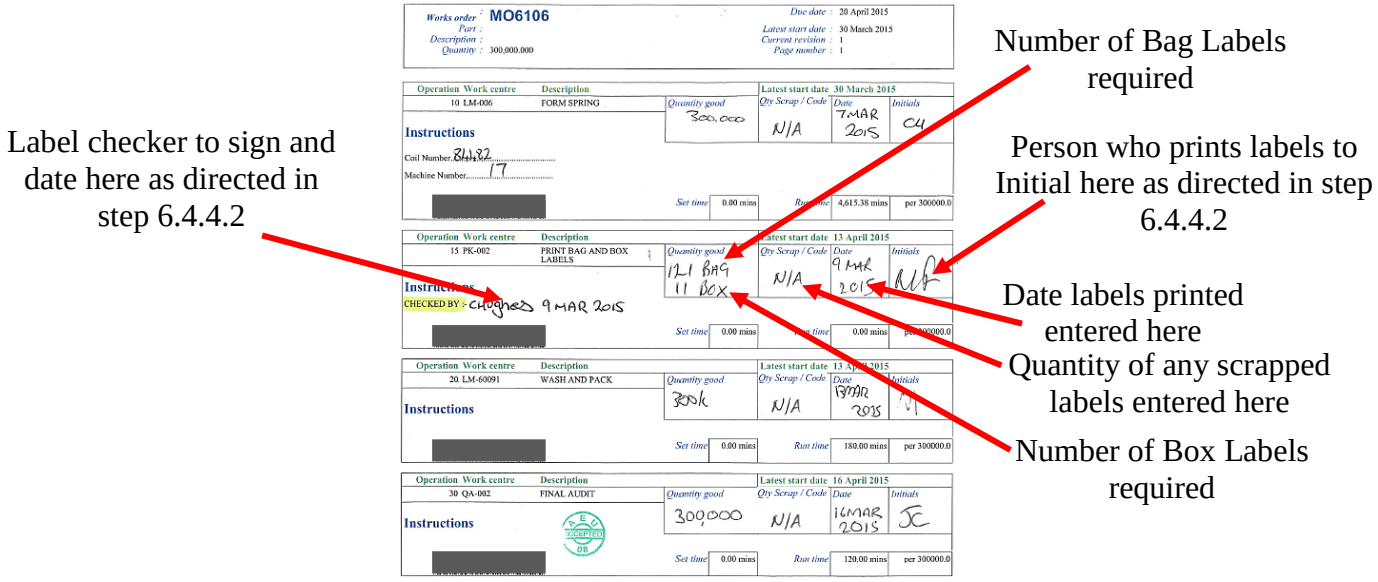

Figure 3: Example of a Works Order Instruction showing the location of information.

6.4.4.1. **Checking Against Work Order Instruction.** The operator is responsible for ensuring that the information on the Works Order Instruction and the label correspond exactly.

6.4.4.2. **Sign Work Order Instruction.** Once satisfied that the labels are correct, the additional labels are attached to the back of the Works Order Instruction, which is then initialled and counter signed by a different setter as evidence of acceptance, as shown in Figure 3: If the operator is not satisfied that the labels are correct, QA are to be informed.

Note: Ensure That The Labels Are Kept With The Components At All Times.

6.4.5. **Component Control.** When either the batch is completed or at appropriate times throughout the shift, the setter will remove all accepted product from the machine. At all times the parts must be identified by the Works Order Instruction number.

6.4.6. **Weigh Count After Heat Treatment.** Weigh counting into required bag quantities is completed as required until the quantity indicated on the Works Order Instruction is achieved, as described in the procedure Weigh Count (Document Number AEU00542).

6.4.7. **Electrical or Oven Failure**. If at any time during production either there is an electrical failure lasting longer than one minute or a fault with the oven maintaining the correct temperature, indicated by the illumination of the ‘Stop Motion Reset’ light as shown in Figure 1: or the ‘STOP RESET’ light as shown in Figure 2: Follow procedure outlined in the procedure Line Clearance Procedure (Document Number AEU00447).

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6.5. **De-Burr.** If the Works Order Instructions indicate that the components require de-burring, process in accordance with the procedure De-Burr & Polishing (Document Number AEU00322). Ensuring that at all times the parts must be identified by the Works Order Instructions number.

6.6. **Aqueous Wash.** If the Works Order Instructions indicate that the components require aqueous washing, this is to be completed once the de-burr operation has finished, process in accordance with the MecWash Procedure (Document Number AEU00466).

6.7. **Pack Components.** Pack components into bags and then boxes as detailed in procedure HYPERION Packing (Document Number AEU00578).

6.8. **Clean Down.**

6.8.1. **End of Forming Process.** At the end of each shift the coiling machine is stopped, either by use of the Machine Stop Button or by the required component count being reached by the counter, as shown in Figure 1:

6.8.2. **Clean Machine.** The face of the machine is cleaned with pressurised air to ensure that it is free of springs from the completed batch.

6.8.3. **Control Components.** All collection bins will be fully emptied of components, weigh counted as per the procedure Weigh Count (Document Number AEU00542), then cleaned with pressurised air.

6.8.4. **Update Log.** The production information is recorded by the machine setter on the Machine Log (Document Number AEU00258).

6.9. **Paperwork.**

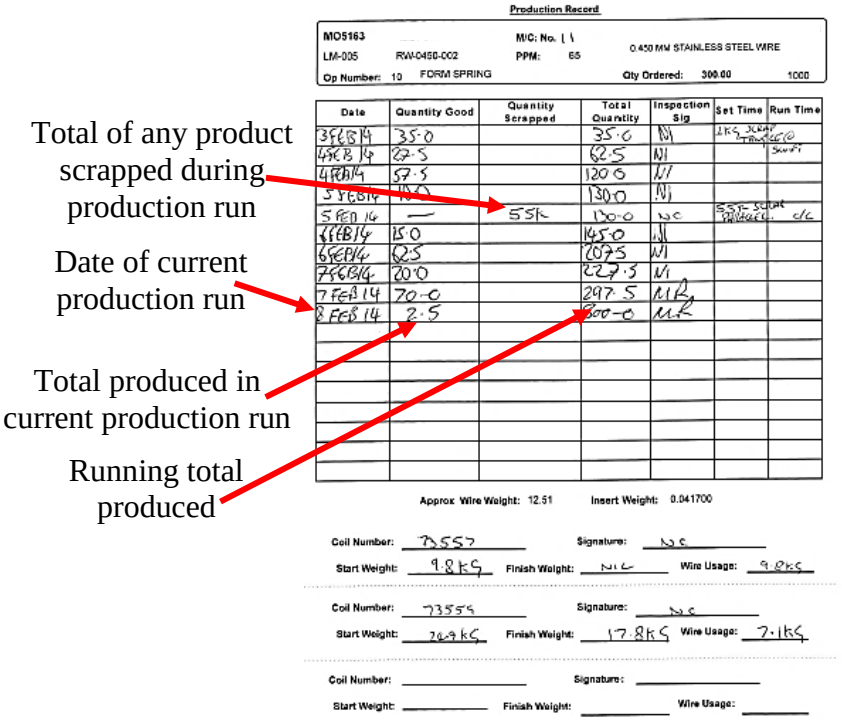

Figure 4: Example of a completed Production Record.

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6.9.1. **Production Record.** At the end of each shift the Production Record is updated with total number of components made / scrapped. Upon completion of number of components specified on the Works Order Instruction in addition to the total number of components made / scrapped information the wire usage is also entered and signed off.

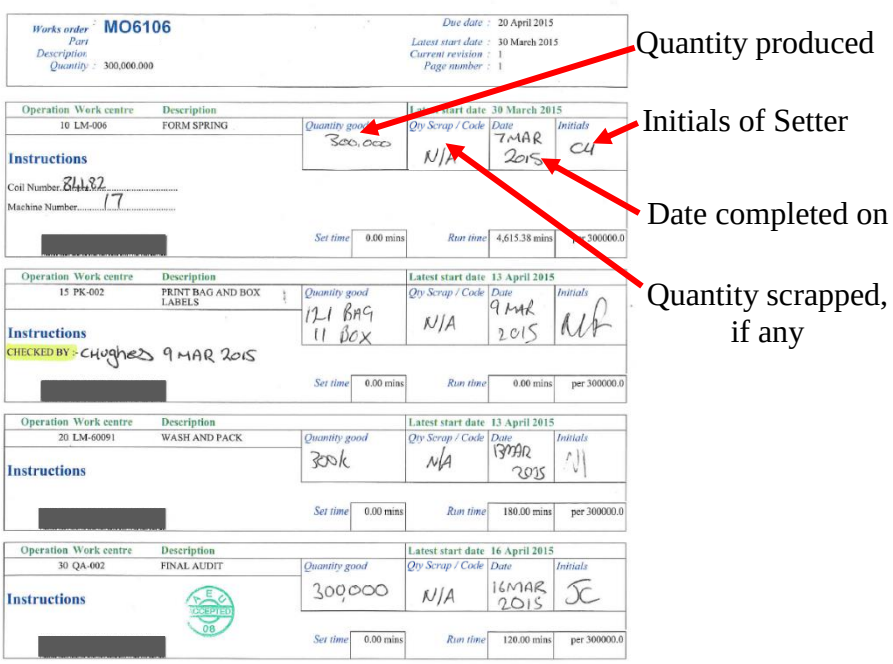

Figure 5: Example of a completed Works Order Instruction.

6.9.2. **Works Order Instruction.** Upon completion of number of components specified on the Works Order Instruction, enter the date completed, the quantity produced, the number of any scrapped off and then sign to indicate compliance with the specification.