OmnexSystems

3025 Boardwalk Suite 290, Ann Arbor, MI 48108

ISO 9001:2015

31 Dec 2021 - 31 Dec 2021

Lead Auditor **User 04**

Observer **User 05**

Client Information	
Company Name	OmnexSystems
Contact Person	User 05
Department/Process	HQ
Address	3025 Boardwalk Suite 290, Ann Arbor, MI 48108
Scope of Audit	>Top management shall demonstrate leadership and commitment with respect to the quality management system by: a) taking accountability for the effectiveness of the quality management system
Date of Audit	31 Dec 2021 - 31 Dec 2021
Location	3025 Boardwalk Suite 290, Ann Arbor, MI 48108
Audit Schedule	QMS Process Audit '21 - '22
Audit Conducted By	Site Internal
Shift	SHIFT A
Auditor	User 03
Report Publisher	User 04
Lead Auditor Signature	NO IMAGES AVAILABLE

Audit Plan

Date	Time	Activity	Person(s) Interviewed

Audit Summary

Objectives of the Audit: The objective for this audit is to evaluate the conformity and effectiveness of Mercury Manufacturing Corporation, Mexico to IATF 16949:2016, ISO 14001 and ISO 45001 BMS, as well as the conformity to Customer Specific Requirements and Mercury Manufacturing Corporation internal documented Quality Management System. This is the system as well manufacturing internal audit.

Scope of the Audit: The scope of the audit includes the requirements of ISO 9001:2015, IATF 16949:2016, , ISO 14001:2015 and ISO 45001:2018 Customer Specific Requirements including but not limited to Ford, FCA US, GM, BMW, VW, and internal documented Quality Management System with application to all processes as per the Process Map attached. The location of the audits is as follows:

Positive Points

Objectives of the Audit: The objective for this audit is to evaluate the conformity and effectiveness of Mercury Manufacturing Corporation, Mexico to IATF 16949:2016, ISO 14001 and ISO 45001 BMS, as well as the conformity to Customer Specific Requirements and Mercury Manufacturing Corporation internal documented Quality Management System. This is the system as well manufacturing internal audit.

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Opportunities for Improvement

Category	Area/Process	Clause
OFI	Continual Improvement Process,Customer Service	ISO 9001:2015 4.4.2

Details:	ISO 9001:2015 4.4.2->To the extent necessary, the organization shall: a) maintain documented information to support the operation of its processes;
Process Standard:	Refer Attachment & Docpro
Attachment:	DT9913-ProcedureandAtribureGRRcsvcsv-201-DT9913-ProcedureandAtribureGRRcsvcsv.csv FillChecklist.pdf

Nonconformances

Area/Process	Clause
Machining,Management Review	ISO 9001:2015 5.1.1
Category:	Minor
Statement of nonconformance:	Commitment with respect to the quality management system by: a) taking accountability for the effectiveness of the quality management system
Requirements:	ISO 9001:2015 5.1.1-Top management shall demonstrate leadership and commitment with respect to the quality management system by: a) taking accountability for the effectiveness of the quality management system; b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization; c) ensuring the integration of the quality management system requirements into the organization's business processes; d) promoting the use of the process approach and risk-based thinking; e) ensuring that the resources needed for the quality management system are available; f) communicating the importance of effective quality management and of conforming to the quality management system requirements; g) ensuring that the quality management system achieves its intended results; h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system; i) promoting improvement; j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.
Objective Evidence:	Top management shall demonstrate leadership and commitment with respect to the quality management system by: a) taking accountability for the effectiveness of the quality management system
Process Standard:	
AttachmentAttachment:	

Corrective Action (NCR) Summary - Issued

CAR#	Standard Clause	Process	Details of Non Conformance	Response Target Date	Date Closed	Date Verified
2021-DEC-SH-ISO-PA-QPA'-'-8-524-OFI-1	ISO 9001:2015 4.4.2	Continual Improvement Process,Customer Service	ISO 9001:2015 4.4.2->To the extent necessary, the organization shall: a) maintain documented information to support the operation of its processes;	01/02/2022		
Root Cause						
Corrective Action (Temporary)						
Corrective Action (permanent)						
Verification Comments						
Validation Comments						
CloseOut Attachment						
2021-DEC-SH-ISO-PA-QPA'-'-8-524-NC-2	ISO 9001:2015 5.1.1	Machining,Management Review	Commitment with respect to the quality management system by: a) taking accountability for the effectiveness of the quality management system	01/12/2022		

Root Cause	
Corrective Action (Temporary)	
Corrective Action (permanent)	
Verification Comments	
Validation Comments	
CloseOut Attachment	

Conclusion

Scope of the Audit: The scope of the audit includes the requirements of ISO 9001:2015, IATF 16949:2016, , ISO 14001:2015 and ISO 45001:2018 Customer Specific Requirements including but not limited to Ford, FCA US, GM, BMW, VW, and internal documented Quality Management System with application to all processes as per the Process Map attached. The location of the audits is as follows:

Name		**Signature**	NO IMAGES AVAILABLE	**Date**	

Classification: Classification : QMS	**Category:** Process Internal | System	**Retention Period:** > Year 2022

Status	NC/OFI	S.No	Checkpoint	Score	Remarks	Attachments
EFC_PCBA_2021						
		2.1.1	2.1.1 Equipment grounding (machine and moving parts) ◯Yes ◯No ◯N/E	N/E		
		2.1.2	2.1.2 Grounding: avoid mixing equipment ground and earth ground ◯Yes ◯No ◯N/E	N/E		
		2.1.3	2.1.3 People grounding ◯Yes ◯No ◯N/E	N/E		
		2.1.4	2.1.4 ESD material grounded ◯Yes ◯No ◯N/E	N/E		
		2.1.5	2.1.5 Worksurfaces/Tracks grounded ◯Yes ◯No ◯N/E	N/E		
		2.2.1	2.2.1 Garments (electric field control) ◯Yes ◯No ◯N/E	N/E		

Status	NC/OFI	S.No	Checkpoint	Score	Remarks	Attachments
		2.2.2	2.2.2 Plastics (electric field control) (machines, process, product, materials) ◯Yes ◯No ◯N/E	N/E		
		2.3.1	2.3.1 Avoid unncessary metals (i.e. metal fixtures hold PCBAs) ◯Yes ◯No ◯N/E	N/E		
		2.3.2	2.3.2 Worksurfaces/Tracks (no metal-to-metal contact with product) ◯Yes ◯No ◯N/E	N/E		
		2.4.1	2.4.1 Ionizer functionality (Balance voltage, Decay times) ◯Yes ◯No ◯N/E	N/E		
		2.4.2	2.4.2 Ionizer effectiveness (Setup, settings, airflow, process time) ◯Yes ◯No ◯N/E	N/E		
		2.4.3	2.4.3 Product (electric field control) (PCBA, components, labels, housings) ◯Yes ◯No ◯N/E	N/E		
		2.4.4	2.4.4 Fixture (electric field control) (Fixture design, materials, grounding, ionizers) ◯Yes ◯No ◯N/E	N/E		
		2.4.5	2.4.5 Machine/Process (electric field control) ◯Yes ◯No ◯N/E	N/E		
		2.4.6	2.4.6 Shipping low charged product (electric field control) ◯Yes ◯No ◯N/E	N/E		
EFC_PCBA_2021						
		1	1.0 Electrostatic Discharge (ESD) Control Procedure and Program Plan ◯Yes ◯No ◯N/E	N/E		
		1.1	1.1 Electric Field Control (EFC) Control Procedure and Program Plan ◯Yes ◯No ◯N/E	N/E		

Status	NC/OFI	S.No	Checkpoint	Score	Remarks	Attachments
		1.2	1.2 Responsibilties & Records Yes No N/E	N/E		
		1.3	1.3 Training program & Records Yes No N/E	N/E		
		1.4	1.4 Site EFC coordinator, expert, or team Yes No N/E	N/E		
		1.5	1.5 EFC qualification procedure (new equipment, process, or product) Yes No N/E	N/E		
		1.6	1.6 EFC compliance verification & records Yes No N/E	N/E		
EFC_PCBA_2021						
		3.1.1	3.1.1 Laser Mark Yes No N/E	N/E		
		3.1.2	3.1.2 Board cleaner Yes No N/E	N/E		
		3.1.3	3.1.3 Solder paste Yes No N/E	N/E		
		3.1.4	3.1.4 SPI, Solder paste inspection Yes No N/E	N/E		
		3.1.5	3.1.5 Pick-n-place Yes No N/E	N/E		
		3.1.6	3.1.6 Oven reflow Yes No N/E	N/E		
		3.1.7	3.1.7 X-Ray Yes No N/E	N/E		
		3.1.8	3.1.8 AOI, solder Yes No N/E	N/E		

Status	NC/OFI	S.No	Checkpoint	Score	Remarks	Attachments
		3.1.9	3.1.9 Manual inspection Yes No N/E	N/E		
		3.1.10	3.1.10 Repair station Yes No N/E	N/E		
EFC_PCBA_2021						
		3.3.1	3.3.1 Component assembly Yes No N/E	N/E		
		3.3.2	3.3.2 Connector install Yes No N/E	N/E		
		3.3.3	3.3.3 Solder reflow Yes No N/E	N/E		
		3.3.4	3.3.4 Heat sink install Yes No N/E	N/E		
		3.3.5	3.3.5 Housing install Yes No N/E	N/E		
		3.3.6	3.3.6 Rework Yes No N/E	N/E		
EFC_PCBA_2021						
		3.2.1	3.2.1 ICT Yes No N/E	N/E		
		3.2.2	3.2.2 ICT Fixture Yes No N/E	N/E		
		3.2.3	3.2.3 ICT GND first Yes No N/E	N/E		
EFC_PCBA_2021						
		3.4.1	3.4.1 Programming Yes No N/E	N/E		
		3.4.2	3.4.2 EOL Functional Yes No N/E	N/E		

Status	NC/OFI	S.No	Checkpoint	Score	Remarks	Attachments
		3.4.3	3.4.3 Burn-in Yes No N/E	N/E		
		3.4.4	3.4.4 Calibration Yes No N/E	N/E		
EFC_PCBA_2021						
		3.5.1	3.5.1 Packaging materials Yes No N/E	N/E		
		3.5.2	3.5.2 Charged product Yes No N/E	N/E		
		3.5.3	3.5.3 Individual slots for product Yes No N/E	N/E		
		3.5.4	3.5.4 No product movement Yes No N/E	N/E		
		3.5.5	3.5.5 No plastic bag on product (preferred) Yes No N/E	N/E		
EFC_PCBA_2021						
		3.6.1	3.6.1 Damaged during shipping Yes No N/E	N/E		
		3.6.2	3.6.2 Charged during shipping Yes No N/E	N/E		
EFC_PCBA_2021						
		4.1.1	4.1.1 ICT Programming Yes No N/E	N/E		
		4.1.2	4.1.2 ICT Functional (powered) Yes No N/E	N/E		
EFC_PCBA_2021						
		4.2.1	4.2.1 Programming: Power up / Power down (spikes or hot switching) Yes No N/E	N/E		

Status	NC/OFI	S.No	Checkpoint	Score	Remarks	Attachments
		4.3.1	4.3.1 EOL Functional: Power up / Power down (spikes or hot switching) ◯Yes ◯No ◯N/E	N/E		
		4.3.2	4.3.2 EOL Functional: Loads and Spikes ◯Yes ◯No ◯N/E	N/E		
		4.4.1	4.4.1 Burn-in: Power up / Power down (spikes or hot switching) ◯Yes ◯No ◯N/E	N/E		
		4.4.2	4.4.2 Burn-in: Loads and Spikes ◯Yes ◯No ◯N/E	N/E		
EFC_PCBA_2021						
		5.1.1	5.1.1 Bench & equipment ◯Yes ◯No ◯N/E	N/E		
		5.1.2	5.1.2 Bench & equipment: Connection sequence: GND first ◯Yes ◯No ◯N/E	N/E		
		5.1.3	5.1.3 Bench & equipment: Loads and Spikes ◯Yes ◯No ◯N/E	N/E		
		5.1.4	5.1.4 Bench & equipment: Power up / Power down (spikes or hot switching) ◯Yes ◯No ◯N/E	N/E		