OmnexSystems

3025 Boardwalk Suite 290, Ann Arbor, MI 48108

ISO 9001:2015

22 Dec 2021 - 23 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	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:
Audit Schedule	QMS Process Audit '21 - '22
Audit Conducted By	Site Internal
Shift	SHIFT B
Auditor	User 02,User 03
Report Publisher	User 03
Signature	
Date	

Audit Plan

Date	Time	Activity	Person(s) Interviewed
User 02			
2021-12-22	08:00 - 08:30	Opening Meeting	
2021-12-22	08:30 - 09:00	Implementation of Product & Process Development	
2021-12-22	09:00 - 09:30	Customer Service	
2021-12-22	09:30 - 10:00	Corporate Responsibility & Sustainability - HQUS02.1	
2021-12-23	16:30 - 17:00	Preperation For Closing Meeting	
2021-12-23	17:00 - 17:30	Closing Meeting	
User 03			
2021-12-22	08:00 - 08:30	Opening Meeting	
2021-12-22	08:30 - 09:00	Implementation of Product & Process Development	
2021-12-22	09:00 - 09:30	Customer Service	
2021-12-22	09:30 - 10:00	Corporate Responsibility & Sustainability - HQUS02.1	
2021-12-23	16:30 - 17:00	Preperation For Closing Meeting	
2021-12-23	17:00 - 17:30	Closing Meeting	
User 04			

Date	Time	Activity	Person(s) Interviewed
2021-12-22	08:00 - 08:30	Opening Meeting	
2021-12-22	08:30 - 09:00	Implementation of Product & Process Development	
2021-12-22	09:00 - 09:30	Customer Service	
2021-12-22	09:30 - 10:00	Corporate Responsibility & Sustainability - HQUS02.1	
2021-12-23	16:30 - 17:00	Preperation For Closing Meeting	
2021-12-23	17:00 - 17:30	Closing Meeting	

Audit Summary

This report summarizes the findings of an internal audit conducted to evaluate the quality management system with application to all automotive processes for Mercury Manufacturing Corporation, it's continued effective implementation and the degree of conformance with the requirements of IATF 16949:2016, ISO 14001 and ISO 45001 the documented system, company objectives, customer requirements and core tools. The processes audited are identified on the audit schedule and audit plans.

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

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Opportunities for Improvement

Category	Area/Process	Clause
OFI	Injection Molding	ISO 9001:2015 10.3
Details:	ISO 9001:2015 10.3->Continual improvement	
Process Standard:		
Attachment:		

Nonconformances

Category:	Area/Process	Clause
Major	Continual Improvement Process,Customer Service	ISO 9001:2015 4.1
Statement of nonconformance:	ISO 9001:2015 4.1->Understanding the organization and its context	
Requirements:	ISO 9001:2015 4.1-The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.The organization shall monitor and review information about these external and internal issues. NOTE 1 Issues can include positive and negative factors or conditions for consideration. NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.	
Objective Evidence:	External and internal issues	
Process Standard:	Process Measure	
Attachment		

Category:	Area/Process	Clause
Minor	Continual Improvement Process,Planning	ISO 9001:2015 6.1.1
Statement of nonconformance:	ISO 9001:2015 6.1.1->Quality management system	
Requirements:	ISO 9001:2015 6.1.1-When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to: a) give assurance that the quality management system can achieve its intended result(s); b) enhance desirable effects; c) prevent, or reduce, undesired effects; d) achieve improvement	
Objective Evidence:	ISO 9001:2015 6.1.1->Quality management system	
Process Standard:	Refer Docpro for reference	
Attachment		

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'-'-1576-NC-1	ISO 9001:2015 4.1	Continual Improvement Process,Customer Service	ISO 9001:2015 4.1->Understanding the organization and its context	01/05/2022		
Root Cause						
Corrective Action (Temporary)						
Corrective Action (permanent)						
Verification Comments						
Validation Comments						
ClosedOut Attachment						
2021-DEC-SH-ISO-PA-QPA'-'-1576-NC-2	ISO 9001:2015 6.1.1	Continual Improvement Process,Planning	ISO 9001:2015 6.1.1->Quality management system	01/15/2022		
Root Cause						
Corrective Action (Temporary)						
Corrective Action (permanent)						
Verification Comments						
Validation Comments						
ClosedOut Attachment						
2021-DEC-SH-ISO-PA-QPA'-'-1576-OFI-3	ISO 9001:2015 10.3	Injection Molding	ISO 9001:2015 10.3->Continual improvement	01/05/2022		
Root Cause						
Corrective Action (Temporary)						

Corrective Action (permanent)	
Verification Comments	
Validation Comments	
ClosedOut Attachment	

Conclusion
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.

Name		Signature		Date	
			NO IMAGES AVAILABLE		

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		
		2.2.2	2.2.2 Plastics (electric field control) (machines, process, product, materials) ◯Yes ◯No ◯N/E	N/E		

Status	NC/OFI	S.No	Checkpoint	Score	Remarks	Attachments
		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		
		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		

Status	NC/OFI	S.No	Checkpoint	Score	Remarks	Attachments
		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		
		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						

Status	NC/OFI	S.No	Checkpoint	Score	Remarks	Attachments
		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		
		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						

Status	NC/OFI	S.No	Checkpoint	Score	Remarks	Attachments
		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		
		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		

Status	NC/OFI	S.No	Checkpoint	Score	Remarks	Attachments
		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		