

Quality and Management Processes

Date: 2022 – Sept - 20

Auditor(s): Ankush Sharma

Products or services

Quality and Management Processes

Applicable Q.A. Standard:

ISO 9001, IATF 16949:16949, ISO 13485:2016, AS 9100D, 21 CFR 820

Other: N/A

Audit object: Quality and Management Processes

Section 1

Verification of Corrective Actions Effectiveness for CARs issued as a result of the previous Audit.

CAR #	Issue date	Non-conformance summary	CAR status	Closure Date
N/A	N/A	N/A	N/A	N/A

Section 2

Employees met during the audit.

Name	Title	Sector
Jack McDonald	President	Management
Pierre Cameron	VP Partner Relations	Management
Abdessamad Ismaili	Director Operations	Operations

Quality document references

Document	Rev. No.	Issue date
QM300 Quality Manual IATF 16949:2016	2	2022 Feb 21
QM100 Quality Manual AS9100D	4	2022 Feb 21
QM 200 Quality Manual ISO 13485:2016	5	2022 Feb 21
QP001/QP001A Quality Policy / Quality Objectives	8/6	2022 January 14
B006 Precikam Organization Chart	10	2022 September 12
B007 Precikam Global Process	3	2020 February 12
QP009 Monitoring and Measuring of Processes and Product & Analysis of Data	13	2020 December 01
QP019 Control of Records	16	2022 Aug 23
QP010 Documents Control	15	2022 June 30
Various forms, customer scorecards	N/A	N/A
IATF 16946:2016	N/A	N/A
AS9100D	N/A	N/A
ISO 13485:2016	N/A	N/A
ISO 9001:2015	N/A	N/A

Sources of Evidence

Quality and Management Processes

Type and Number of Records reviewed

KPI Overall customer satisfaction rating, 90 % min. Customer satisfaction data not available at the moment of audit. Survey to be started in November 2022. Reduction of number of complaints vs precedent year, 25 % min. For Q1,Q2 reduction of number of complaints 27 % YTD – target met; Real sales vs Target, 98% min. Real for Q1,Q2 – 120 %. Target met; Cost of customer returns, 1.5% max. Real for Q1,Q2 – 0.473%. Target met. Employee Handbook available on ADP, QP001/QP001A Quality Policy / Quality Objectives. Communicated to all staff. Posted on production floor. All hands meeting minutes for all production shifts. Reviewed Contingency plan CP100 Rev. 03 Customer specific requirements for automotive customers. Matrix with link between CSR and Precikam process. Customer scorecards: ██████ 100 % (Jul-Dec 2021); ██████ – 86/105 Good (Apr-Jun 2022); ██████ – 4.5/5 (Jan – Mar 2022). ██████ 98% (100% Quality, 96% OTD – 2022-Jul-11). ██████ 97% (2022 Aug.) ██████ 100% (Jan-Jun 2022) Management Review Meeting notes for Q1 and Q2. KPI matrix reviewed. For three processes KPIs not met. CAR C2022-18; C2022-19; C2022-20 were issued for not meeting target. Internal audit schedule for 2022. All audits completed as planned. Reviewed Corrective actions log.

Section 3

Audit Summary Results

Strong Points

Very good general understanding of the process. Top management demonstrates strong commitment to quality. Significant investments in infrastructure and equipment. Very good communication throughout the organization. Using of ERP for different aspects of company management. Significant reduction of number of complaints and improvement of customer satisfaction rating.

List of Opportunities for improvement that must be reviewed and implemented at the first possibility.

Opportunities for Improvement

List of corrective actions issued for the quality system nonconformances.

C.A.R. No.	Réf. Norme / Standard ref.	Non-conformance Summary
N/A	N/A	N/A

We require that you enter in the corrective action report the actions taken, as needed, and to please return it to us before N/A with all relevant documents if applicable to the undersigned.

Recommendations / Recommendations:

Training of additional operators for medical printing to respond to increased production volumes.

Conclusion: Quality and Management processes deemed effective.

Auditee Acknowledgement of Audit Report

Nom / Name	Titre / Title	Report sent date
Jack McDonald	President	2022-Sept-21
Susan Raywood	Executive VP	2022-Sept-21
Pierre Cameron	VP Partner Relations	2022-Sept-21

Ankush Sharma Auditor, Precikam.