1.0 PURPOSE

To establish the process for creating and managing distributors, who sell, install, and support Tricefy to their respective markets. This procedure establishes the controls over such procedures to ensure conformity to applicable regulatory requirements for outsourced processes.

2.0 RESPONSIBILITIES

- **Regional Sale Managers** are responsible for distributors within their respective markets
  - These responsibilities include approval, annual review, complaint handling, and feedback collection
- The **Trice Academy Manager** is responsible for initial and ongoing training and communication
- **Top Management** is responsible for monitoring distributors during Management Review
- **Quality** is responsible for reviewing modified contracts and ensuring compliance with all applicable regulations

3.0 REFERENCES

- Quality System Regulation, 21 CFR Part 820
- EU 2017/745 Medical Device Regulation (MDR)
- QM1 Quality System Manual
- SOP3 Training
- SOP4 Management Responsibilities
- SOP9 Vendor Management
- 2017 Trust Services Criteria (TSC) Section CC1.4
- ISO 13485:2016
- SOP11 New Markets
- SOP21 Sales & Installation
- SOP23 Complaints & Support
- SOP38 Customer Feedback
- Distributor (Quality) Agreement
- ISO 27002 Section 7.1

4.0 DEFINITIONS

Economic Operator: A manufacturer, authorized representative, or a distributor, according to the EU Medical Device Regulation. See Section 11 at this end of this document for handling EU distributors.

5.0 ACCEPTANCE / APPROVAL

5.1. Sales Manager confirms distributors are in an approved market by checking the Approved Countries List (CNTRY-01)

5.1.1. If Trice Imaging hasn´t realized the product in that country, refer to SOP11 New Markets

5.2. Sales Manager reviews the following criteria to ensure the distributor has the ability and qualifications to supply product per requirements set forth by Trice Imaging:

5.2.1. Qualifications of personnel:

a) Technical knowledge and ability to understand and troubleshoot product

b) Industry knowledge and ability to suggest and improve customer workflows

c) Experience in selling and supporting medical devices

5.2.2. Qualifications of company:

a) Legally allowed to sell medical devices in the region

b) Adequate resources to deliver first-line support, sales, installation

c) Experience selling similar products

d) Has appropriate customer base that would be interested in product

5.3. Sales Manager completes the Vendor/Supplier Approval Form per SOP9 (Risk Level=3)

5.3.1. A copy of this form is located in SOP22 within the QMS

5.3.2. Completed forms are stored within the Distributor's folder in SOP22

5.3.2.1 Confirm that the form contains the number for distributor support

5.3.3. Distributor is added to the Distributor Tab of the Approved Vendor Log within SOP9

6.0 DISTRIBUTOR CONTRACTS

6.1. Distributor contracts are reviewed by Quality before entering a new market (to ensure contracts meet regulatory requirements), when new standards/regulations/laws are released, or when standards/regulations/laws are updated

6.2. All distributor contracts must use the distributor contract template

6.2.1. EU distributor contracts must use the contract specified for the EU and contain the Authorized Representative's name and email address

6.3. Modifications to contract templates are reviewed and approved by Quality

6.4. All distributor contracts must be stored in the Distributor's folder in SOP22 within the QMS

7.0 TRAINING

Distributors are trained per SOP3 (Training) and initial training is documented on the Distributor Training Form (DIST-01)

DIST-01, in SOP3, provides a generic training plan, although Sales Managers/Academy Manager may modify the plan to account for integration and special use cases. Trice Imaging will train new distributors on-site or via video call.

7.1. **Additional Training:** Distributors are re-trained at least twice a year and a remote call is offered to all distributors prior to the release of new functionality

7.1.1. Training records are maintained by the Academy Manager

7.1.2. Training records are stored in the Distributor's folder in SOP22 within the QMS

8.0 FEEDBACK & COMPLAINTS

8.1 Complaints:

8.1.1 Distributors not located in the EU report all complaints to support@triceimaging.com, which will automatically open a ticket. These tickets are tagged "DISTRIBUTOR" per SOP23 Complaints.

If the distributor shares the complaint to the Sales Manager, the Sales Manager opens the ticket in Zendesk, and tags "DISTRIBUTOR", while including the name of the distributor in the ticket.

Complaints are then handled by SOP23 Complaints and Support.

8.1.2 EU Distributors: See Section 12.2 for handling of EU distributor complaints

8.2 Feedback: Distributors report all feedback by emailing feedback@triceimaging.com. Quality and Product review this inbox for feedback per SOP38 Feedback.

9.0 INSTALLATION

Training for distributors includes installation and verification of installation. Acceptance criteria are the completion of the onboarding steps and assuring studies are appearing on the Study List.

10.0 ANNUAL REVIEW

Distributors are annually reviewed using the Supplier/Vendor Review Form REVIEW-01 in SOP9. A copy of this form is also in SOP22. Reviews are discussed during Management Review.

10.1 Acceptance criteria to determine if the distributor has met expectations and requirements:

- Is their Support team functional??
  - Are product complaints being reported within the given timeframe?
- Are their customers using the system successfully?
  - This can be determined using the onboarding report
- Are they reaching their anticipated sales goals?
- Are EU distributors meeting their MDR obligations?

If the distributor has ISO or other certifications, confirm the certificates located within their file are up-to-date and request renewed versions, as needed.

10.2 Completed review forms are stored in the Distributor's folder in SOP22 within the QMS

11.0 COMMUNICATION

11.1. Distributors are notified of all releases by subscribing to the Status Page. This will inform them of any bug fixes, backend improvements, or product enhancements. This page will also notify them of any service outages or performance disruptions, as well as provide notification when issue is resolved.

11.1.1. Trice Academy Manager is responsible for determining when changes to the product require additional communication and/or training.

11.2. Trice Academy Manager sends an annual newsletter to all distributors to keep them updated on new features, enhancements, and any additional information that they need regarding the new developments

11.3. Any changes to Trice Imaging's processes involving sales, support, or installation that may affect the operation of a distributor is communicated and trained accordingly

11.4. Any changes to the Distributor's processes involving sales, support, or installation that may affect their operation, is communicated to their Sales Manager prior to the changes going into effect

12.0 EU Distributors / MDR

12.1. MDR refers to distributors as "economic operators" and per the regulation, they are obligated participate in post-market surveillance activities (complaints, feedback, and field safety corrections)

12.1.1. Refer to the EU Distributor Manual for information, procedures, and instructional material regarding EU distributors and their obligations

a) This manual is provided to all EU distributors

b) Manual contains contact information, UDI, MDR definitions, procedures for labeling, translations, and post-market surveillance activities

c) Failure to comply with this manual may result in termination of the contract

12.1.2. EU distributors receive additional training to cover the contents of the manual

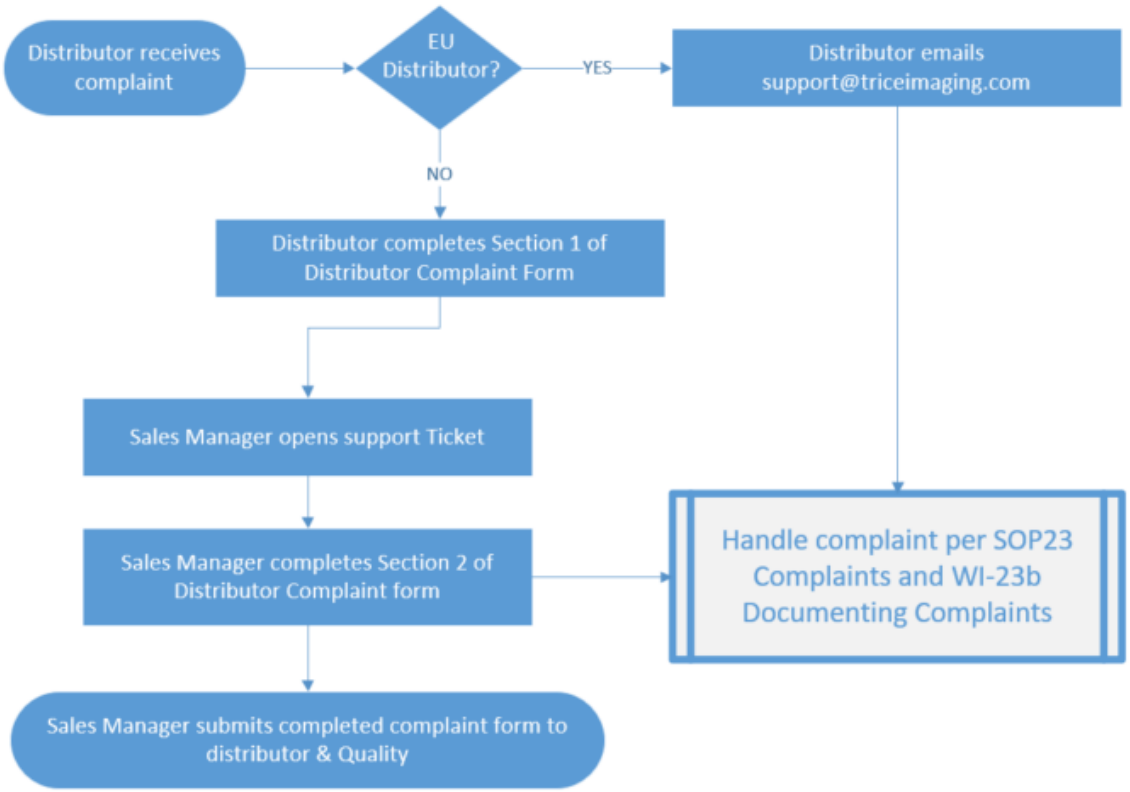
12.1.3. Training material and the manual are available on the Trice Academy

12.2 Complaints: EU Distributors

12.2.1 Distributors are required to keep registrar of complaints

12.2.2 Distributors use PCF-DIST Distributor Complaint Form to report and track complaints

12.2.3 Procedure:



1. To initiate a complaint, Distributors complete Section 1 of the form and submit the form to their sales manager
2. The Sales Manager opens the support ticket and tags “DISTRIBUTOR” and “COMPLAINT”

3. The complaint is handled by Support per SOP23 Support and Complaints
4. The Sales Manager completes Section 2 of the PCF-DIST Complaint Form
5. The Sales Manager sends the completed form to the distributor (for their records) and Quality (for Trice Imaging's records)

13.0 Procedure Workflow