1. PURPOSE

The purpose of this work instruction is to provide detailed instructions for the implementation our turnkey quality system. The goal is to ensure that the process our consulting team uses for helping clients implement our turnkey quality system is as consistent as possible and no steps are forgotten.

2. SCOPE

This work instruction is specific to the Medical Device Academy team, but anyone may copy the content of this work instruction and adapt it to their quality system implementation needs. If you want a quote for the quality system, please contact Lindsey Walker directly at sales@medicaldeviceacademy.com.

There is also a section that is specific to creating a project is Asana. This is specific to the paid version of Asana that Medical Device Academy uses. If a client is going to share a project with Medical Device Academy in Asana, a free version of Asana should be used instead.

3. REFERENCES AND RELATIONSHIPS

- LST-001 Master Document List

4. RESOURCE NEEDS

Even for a start-up company with one employee, clients should expect to dedicate at least 4-8 hours per week to maintain your quality system **after** it is implemented. The initial implementation requires 100-120 hours to complete the step-by-step implementation tasks.

5. DOCUMENT APPROVAL

Changes to this procedure document and associated forms and templates are to be approved by:

- Rob Packard

6. REVISION HISTORY

Ver	*Date mm/dd/yy*	*DCN*	*What changed?*	*Why did it change?*	*Author*
A	06/30/22	D1	Initial release	Continuous improvement of our turnkey quality system for consistency and customer satisfaction	R. Packard
B	07/15/22	D2	Added POL-001 to section 9.7	Accidently Forgot	R. Packard

7. DEFINITIONS

Term	*Definition*
Turnkey	This does not mean "work-free". We mean that clients receive the quality system procedures that are required by 21 CFR 820, 803, 806, 830, ISO 13485:2016, SOR 98/282, and Regulation (EU) 2017/745. It doesn't mean that clients don't have any work to do.
Free Updates	When we create revisions and updates to our procedures, forms, lists, and templates we will make these available to companies that purchased the earlier version with no additional charges. That does not mean we will make any update a client requests at no charge. Customized procedures will incur hourly consulting fees.

8. ROLES & RESPONSIBILITIES

Roles	*Responsibilities*
Rob Packard	Making sure the customer receives what they ordered, assignment of the project manager, planning revisions to the quality system documentation and training materials, and dispute settlement.
Project Manager – Mary Vater, Sharon Morrow, Bhoomika Joyappa, and Matthew Walker	Starting meetings on-time, providing consulting advice related to the implementation of your quality system, assignment of tasks to the client for completion as "homework", scheduling the next 30-minute meeting with the client, and communicating any alleged deficiencies with the quality system or training materials to Rob Packard via our Master Document List (i.e., the one that is no for distribution).
Client Management Representative	Each client must assign a management representative for their quality system. This should be the person that is responsible for managing the implementation project from the client perspective. This person should be a champion of the quality system and make sure that the rest of the company understands the importance of the quality system and its regulatory impact.

9. STEP-BY-STEP INSTRUCTIONS

Step	*Quality System Implementation Task*
1	Review the quality manual to determine which clauses are applicable and not applicable to your company. You can archive all of the procedures that are not applicable, but you need to provide a justification in the manual. Outsourced processes may require more revision of the appropriate procedure or replacing the procedure with SYS-011 (i.e. Supplier Quality Management). The quality manual also requires that you replace the logo and company name from Medical Device Academy with your company's logo and name.
2	Create your quality plan (TMP-005) for the implementation of the quality system. This will need to be repeated when you make changes to the quality system in the future as well.
3	Schedule a recurring meeting with the consultant assigned to your company. We recommend scheduling 30-minute meetings every week or once every two weeks for the duration of the project. The number of meetings included with the turnkey quality system depends upon which version you purchase, but you can always pay for more consulting time at our hourly rate.
4	Create your own organization chart (FRM-022).
5	Review and modify each procedure, form, list, and template: a) replace the logo and company name from Medical Device Academy to your company b) modifying the titles for job functions that match your organization chart in each procedure (document approval, responsibilities and authorities, and training requirements) c) Updating the metric(s) and/or quality objectives section to reflect the metrics that make sense for your company (read SYS-017 for further explanation) d) Identification of where you will be storing the records from each procedure (electronic or paper); you may choose to replace certain forms, such as our purchase order form to use an existing template you already have from software such as Freshbooks or Quickbooks (we recommend creating a sub-folder for each quality record type that is labeled with the form number e.g., "FRM-001" for your DCN log and DCNs) e) Identify any definitions that need to be included in the procedure and/or make sure that the definitions are included in the Glossary (POL-003). f) Review the referenced documents of external origin to make sure that the standards are up-to-date. There are recognized standards specific to each market, and there are product-specific standards, but you need to add these standards and any applicable guidance documents to your list of documents of external origin (LST-001): a. FDA Recognized Consensus Standards b. List of Recognized Standards for Medical Devices for Canada c. European Normative Standards (we recommend evs.ee)
6	Assign a DCN for review and approval of procedures (individually or as a batch) using LST-002; fill out the DCN form for each DCN (FRM-001).
7	There are 17 training webinars provided with the turnkey quality system, and the webinar training number is the recommended order for reviewing the training webinars. You might choose to modify this based on the applicability of the software and usability procedures. The first procedures we typically recommend companies start to use are the following (numbers correspond to training webinar):

	a) POL-001, Quality Manual b) SYS-001, Document Control - #1 c) SYS-002, Record Control - #1 d) SYS-003, Management Review - #9 e) SYS-004, Training - #1 f) SYS-008, Design Controls - #2 g) SYS-010, Risk Management - #3 h) SYS-044, Software Validation - #13 i) SYS-048, Usability - #14 j) WI-007, Cybersecurity
8	You will need to review and approve 2-3 procedures per week in order to implement your quality system in 4-6 months. If some of the above procedures are not applicable, SYS-011 for Supplier Quality Management and SYS-027 for Purchasing might be the next procedures to consider for implementation.
9	Create job descriptions for each job function and define the training requirements for each person in your company in the job descriptions and/or training matrix (FRM-026).
10	Create a training schedule for all of the employees and document the training on your training records (FRM-002). You will need to include plans for evaluating training effectiveness and competency.
11	Identify all of your suppliers, categorize the suppliers, execute supplier quality agreements where needed (FRM-037), approve the suppliers (FRM-005), and add the suppliers to your approved supplier list (LST-003).
12	Create an audit schedule (LST-007) for internal audits, supplier audits, 3rd party audits, and consider including your management reviews in the same schedule.
13	If you are seeking certification from a 3rd party (e.g. ISO 13485, MDSAP, or CE Marking), you will need to complete an application, get a quote, execute a contract with one certification body, and schedule your Stage 1 and Stage 2 certification audits after the scheduled dates for your first internal audit and management review.
14	Add all of your software, automated equipment, and calibrated devices to your equipment log (LST-006). As new software, automated equipment, and calibrated devices are purchased, these items need to be added to the equipment log at the time of purchase or at the time of receipt at the latest. a) If you plan to use an electronic quality system, you will need to create a risk-based plan for the validation of the quality system software (see SYS-051) and this should be documented in a Master Validation Plan for software. b) Any automated equipment will need a plan for process validation (i.e. IQ, OQ, PQ) in accordance with SYS-014 and any of the applicable sterilization validation procedures. You should consider creating a Master Validation Plan for the automated equipment. You should also include validation of outsourced processes in your Master Validation Plan. c) Any calibrated equipment will need a calibration schedule defined in accordance with SYS-016. The calibration schedule should be based on the manufacturer's recommendations. Annual schedules are typically appropriate, but certain devices such as weigh scales and light meters may require more frequent recalibration (i.e. quarterly or semi-annual). It may also make sense to implement a log for verification of calibration prior to use for items like gauge pins and weigh scales.

15	Most companies wait too long to implement their design control procedure (SY-008), create a design plan (TMP-021), and fail to start building their Design History File (DHF). Create a design plan early and update the plan frequently as your design progresses. Implement your risk management process, software validation (if applicable), and human factors process (SYS-048) in parallel with the design process. These are complex processes that require extensive training. The timing of a pre-submission with the FDA (and/or other regulators) should be shortly after you have created a testing plan for verification and validation and any applicable testing standards should be approved as design inputs in your DHF. Do not wait until you are 100% done with the development of your device to verify your testing plan and regulatory pathway with a regulator.

10. ASANA PROJECT MANAGEMENT

Medical Device Academy has a license for 10 seats of Asana that we use for project management, invoice tracking, for tracking of our sales funnel. We believe this is a superior project management tool and it is easy to use. Asana also offers a free version of the software that we can share with clients. If clients would like to share the project management folder with Medical Device Academy's project manager, the project manager assigned to help them can create a new project in Asana using the free version of the software and share it with the client. The free version includes the following features:

1. Overview
2. List view
3. Board view (similar to Trello)
4. Calendar view
5. Messages
6. Files
7. Ability to use standard templates from Asana

The free version does not include the following features:

1. Timeline view
2. Workflow feature
3. Team dashboard
4. Ability to save custom templates

11. CONFIGURATIONS & VARIANTS OF THE TURNKEY QUALITY SYSTEM

There are five different versions of the turnkey quality system:

1. Al a carte (you buy procedures individually as needed) - 20% discount for purchase of 3 or more procedures (use discount code "Twenty" or request a quote); purchases are via PayPal or Stripe using a credit card, but wire transfers are possible for quotes
2. US Only turnkey quality system - $5,000 (four monthly payments of $1,250), but no consulting time is included
3. US Only turnkey quality system - $6,000 (four monthly payments of $1,500) including 6 hours of consulting time
4. Global turnkey quality system - $6,000 (four monthly payments of $1,500), but no consulting time is included

5. Global turnkey quality system - $7,500 (four monthly payments of $1,875) including 8 hours of consulting time

12. 1ST GROUP OF PROCEDURES & TRAINING

If you purchase one of our turnkey quality systems from the website, you will receive the following after your online payment:

- SYS-001, Document Control - #1
- SYS-002, Record Control - #1
- SYS-003, Management Review - #9
- SYS-004, Training - #1
- SYS-008, Design Controls - #2
- SYS-010, Risk Management - #3
- SYS-044, Software Validation - #13
- SYS-048, Usability - #14
- WI-007, Cybersecurity
- SYS-025, Technical Documentation - Global only
- 21 CFR 820 Training - #7
- ISO 13485:2016 QMS Training Webinar - #15

13. REFUNDS

We do not offer refunds for turnkey quality systems, because it is a digital product that you can copy, and we cannot verify if all copies were destroyed. Therefore, we offer SYS-003 as a free download to help you make your purchasing decision. We also offer to credit you for the purchase of any individual procedures if you decide later to upgrade from individual procedures to a complete quality system or a US-only system to the Global version of the quality system.