The Global Open Source Quality Assurance System (GOSQAS): Does it fulfill the requirements of a customer complaint system for the production and distribution of regulated medical devices made in the United States?

What is post market surveillance and why is it important?

Post-market surveillance is a component of the medical device manufacturer or distributor's quality system designed to monitor the safety of any device after release. For the purpose of this report, the term “complaints” or “complaint files” will be used when discussing regulatory requirements instead of the broader “post-market surveillance”.

Grassroots organizations are among the first to answer any call to action where the health and safety of our fellow humans is in jeopardy. Makers, nonprofit organizations, and individuals demonstrated unmatched speed and adaptability during the COVID-19 global emergency when over 48 million units of medical devices were produced and distributed in the US while traditional manufacturing and supply chains were unable to respond adequately [1].

The speed of the response was blunted by a lack of existing regulatory clarity and availability of open source, easy-to-utilize tools and procedures. Many makers quickly encountered regulatory challenges that were unexpected and difficult to navigate [3].

During this global crisis, the FDA in the US enacted emergency use authorizations (EUA) for many of the medical devices manufactured by makers and distributed by NGO organizations. The COVID-19 public health emergency (PHE) declared under section 319 of the Public Health Service (PHS) Act expired on May 11, 2023, which began a transition away from the existing EUAs in place. Makers that continue to manufacture medical devices will increasingly need to adhere to regulatory requirements in order to serve communities in need [2].

Makers manufacture medical devices ultimately to assist other people in need. An important component of offering assistance is evaluating the risk inherent in this endeavor. The responsibility of the maker does not end when the medical device leaves the door; continual monitoring of safety and effectiveness is crucial. Under FDA and ISO regulations, all manufacturers of medical devices must maintain a complaint file [6][7]

The manufacturer is responsible for gathering, evaluating, and reacting to feedback related to the medical device in a timely manner. The end user is responsible for providing relevant feedback to the manufacturer [6][7]. Complaint files, as outlined in 21 CFR 820.198 for FDA and ISO 13485.2016 8.2 for ISO, are an exhaustive record of all complaints received and the details of the resolution of each complaint. These records are maintained for the entire life of each medical device. Each complaint must be evaluated by the manufacturer in order to determine if any further action is required. Further actions include investigations, corrective actions and reportable events which each have their own regulations and responses[10]. Complaint files are almost always reviewed in the event of an audit which makes using a system that can capture clear, detailed information by both the manufacturer and end user extremely important.

A maker as a manufacturer of medical devices may take many forms, ranging from state-of-the-art manufacturing facilities and diverse staff to a converted makerspace under a bridge [4]. Having a standardized, easy-to-implement feedback and complaint tracking system lowers the barrier to implementing such a system. End users of products produced by makers are often in low-resource settings and are almost always limited in time and attention to anything aside from the care being provided [8]. Providing an easy-to-use feedback system that works regardless of manufacturer ensures critical feedback will be given as challenges are encountered.

Quality systems in the United States

ISO

ISO 13485:2016 is a voluntary quality management standard specifically for those involved in medical device design, production and distribution that is used in addition to local regulations. This standard is based on the more broadly applicable ISO 9001 standard. ISO 13485:2016 was designed to conform to both FDA and MDR regulations (European Medical Device Regulations); however, some differences remain. The advantage of obtaining an ISO 13485:2016 is that it is rapidly becoming a global standard of medical device quality management.

Certification ensures organizations are continually evaluating the risks to the end user by continuous monitoring of processes and devices. ISO increasingly facilitates importation into regions without developed regulatory bodies, such as Uganda, where ISO standards have been adopted while their regulatory system is developed [5].

Disadvantages of pursuing an ISO certification include price and depending on third-party certification organizations. FDA registration is still required even after ISO certification has been completed.

ISO Certification annual cost USD
Over $5000, depending on organization

FDA (US CFR)

FDA Title 21 Parts 800-1299 is a set of mandatory USA federal regulation that applies to all facilities manufacturing or distributing medical devices, even if the device is exported for use in another country. Some class I medical devices may be exempt from portions of part title 21, but the majority are not. The advantages of adhering to FDA regulations include freely available documentation and having a lower cost compared to ISO. Parts relevant to small scale manufacturers include:
Part 820, details the required quality system for manufacturers and distributors of medical devices and includes the requirements for complaint files. Parts 7, 810 and 806, detail product recalls, corrections and removals for medical devices.

Product recalls are a predominantly voluntary action a manufacturer or distributor takes in the event a defect with a medical device or label has the potential to adversely impact end users and are carried out under part 7 [11]. In rare cases of negligence the FDA may initiate a mandatory recall under part 810. In most cases a recall, correction or removal of any medical device initiated because of a risk to health must be reported to the FDA. Collecting, tracking and maintaining information related to distributed products greatly improves the ability to report and respond to recalls, corrections and removals.

FDA Registration annual cost USD
$6493[12]

GOSQAS Case Study

In order to determine the suitability of the GOSQAS Asset Provenance Tracker, a test simulating common forms of end-user feedback was performed. This test should be considered an early demonstration and may not fulfill all regulatory requirements for any given medical device. Consulting with a regulatory specialist is recommended before implementing this system for on-market devices.

Scope

This test intends to assess the utility of the GOSQAS Asset Provenance Tracker in capturing and responding to end user feedback for a fictional FDA Class I medical device classified under Title 21 CFR 878.5900. Eight complaints and two end user feedback instances were performed for the protocol [fig1.]. Each instance was written to demonstrate a different type of feedback that is typical for a medical device. Creation and modification of records were performed on a Windows PC and an Android mobile device to simulate real-world conditions.

Fig 1.

- TP1.1 Southern Reach Makerspace. Tourniquet PN123 SN321 (View Provenance)
- TP1.2 Southern Reach Makerspace. Tourniquet PN123 SN321, SN322, SN323, SN324 (View Provenance)
- TP1.3 Southern Reach Makerspace. Tourniquet PN123 SN325 (View Provenance)
- TP1.4 Southern Reach Makerspace. Tourniquet PN123 SN326 (View Provenance)
- TP1.5 Southern Reach Makerspace. Tourniquet PN123 SN327 (View Provenance)
- TP1.6 Southern Reach Makerspace. Tourniquet PN123 SN328 (View Provenance)
- TP1.7 Southern Reach Makerspace. Tourniquet PN123 SN329 (View Provenance)
- TP1.8 Southern Reach Makerspace. Tourniquet PN123 SN330 (View Provenance)
- TP1.9 Southern Reach Makerspace. Tourniquet PN123 SN331 (View Provenance)
- TP1.10 Southern Reach Makerspace. Tourniquet PN123 SN332 (View Provenance)

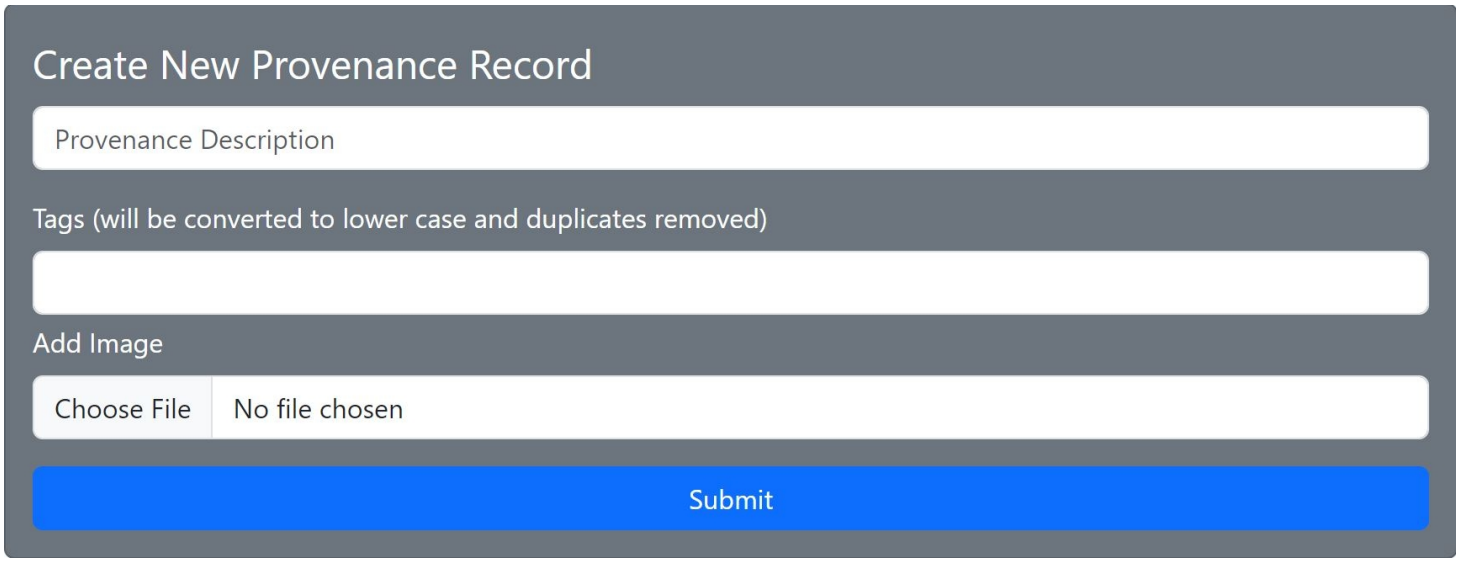
Limitations

This test is not extensive and is only meant to evaluate the early feasibility of this platform. GOSQAS software is currently in development, and features that may add additional functionality related to this test were not available at the time the test was performed.

Test Results

Overall, the system appears to fulfill the basic requirements of the complaint capture and review portion of ISO and FDA regulations. The design of the tracker is lightweight and lacks many of the features normally found in asset tracking system software, such as dedicated and enforced fields. Input into the tracking system is limited to two strings of characters, one free text, one comma separated for tags, and one for file attachments [fig2]. This lightweight design has several possible advantages. The system is accessible via any internet-capable device and does not require special software or login credentials. Input of information and viewing of records is straightforward as long as the correct identifying information was entered when the record was created.

Fig 2.

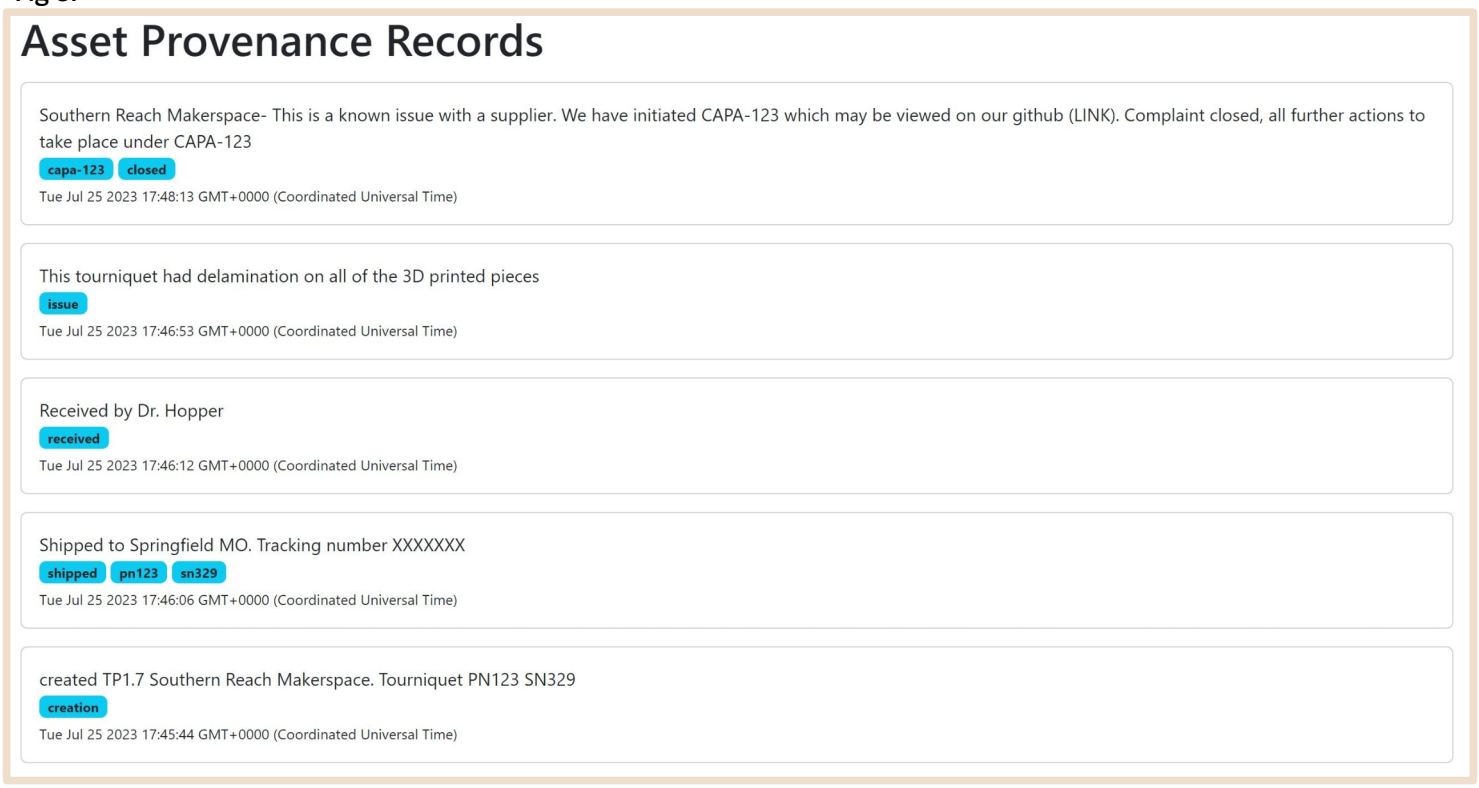


GOSQAS Case Study

Test Results

Individual entries cannot be deleted by the user, and all entries are time and date stamped. The entire record is easily viewable, which aids in following a complaint workflow and providing evidence in an audit [fig3]. The format and content of the free text and tags must be uniform in order to be able to analyze trends and ensure records are easily accessible. Organizations could minimize this impact by implementing thorough procedures for a standard format of the free text. API integration for large amounts of records would be advantageous and reduce human error. The ability to link records to one another would be beneficial in the event of a recall and adverse events. A relationship could be established by the manufacturer using the record ID, but this introduces risk of error. Indicating and changing the status of the complaint was achieved using the tag system; However this method was difficult and prone to error. An important function of a complaint system is the ability to track complaint status to determine if proper action has been taken.

Fig 3.



Conclusion – Current Limitations

In the current implementation GOSQAS asset provenance tracker has several potential limitations. As a platform in development some of these limitations will likely be resolved as the broader community experiments with novel solutions. These limitations are related to the scope of this report and are a starting point for further investigation rather than a comprehensive list.

Electronic Records

Electronic records and signatures related to customer complaints are defined under CFR Title 21 Part 11 for FDA and to a lesser extent ISO13485:2016 section 4.2.5. In the current form GOSQAS asset provenance tracker may not conform with FDA regulations due primarily to the inability to tie individual entries to makers within the manufacturer Further investigation into how this software could be used in a larger quality system should be conducted.

Product Recalls

GOSQAS is actively developing the ability to link records using a system called “linkage by containment” which would allow individual records to be associated with a parent record, such as a batch. This would allow for a recall to be issued to all individual products where records were generated, assisting greatly in product recalls, corrections and removals. Until this is implemented an additional record should be maintained by the manufacturer to ensure all products are tracked individually and on a batch basis in the event of a recall.

Complaint Status

FDA CFR Title 21 part 820.198 and ISO13485:2016 section 8.2.2 requires all complaints be reviewed, responded to and escalated if required in a timely manner. The ability to categorize individual records into separate queues is extremely important when tracking multiple complaints and retrieving records in an audit.

The current software has limited abilities to associate records to actions such as investigations and corrective actions but lacks the ability to change queues and the status of a records due to the inability to change individual entries where the tags are entered. Free text tags are susceptible to human error and great care should be taken when adding tags that could effect multiple records. Novel solutions using the existing system may be possible but the addition of changeable queues would greatly improve the utility of this system when used as a complaint management system.

Records Export

The current software does not have the ability to export records. Manual exporting or records is possible but impractical once the complaint files begin to accumulate. Analyzing trends and evaluating the population of released products is an important aspect of maintaining a complaint system as outlined in ISO13485:2016 section 8.4 and FDA CFR Title 21 part 820.250. In order to statistically analyze and produce reports related to specific complaint types a mechanism to export individual and batch records is important.

Conclusion

Summary

GOSQAS asset provenance tracker in the current form is a novel, lightweight solution for medical device manufacturers to use as the basis of a complaint file system. Because this system was designed with a wide scope of uses in mind, it is not as specialized for the unique challenges of medical device regulations as commercial solutions. However, being an open source solution that is more accessible to end users in low-resource settings, this may be better suited for makers and NGOs where cost and lack of infrastructure are challenges.

Robust procedures and training within the quality management system of an organization utilizing this tracker could overcome the limitations that are currently present. More work and testing needs to be done in order to evaluate the utility of this system. A formal validation of the system would help identify deficiencies and allow for easier adoption by organizations preparing for FDA registration or ISO certification

A diverse and large set of early adopters would accelerate the development of this platform by providing feedback and evaluating regulatory suitability. As makers and non-traditional manufacturers continue to expand in order to meet unexpected challenges, we will increasingly need to rely on open source and easy-to-implement quality tools. At the end of the day, people in need are the reason we respond to calls to action, and their safety is in our hands. We should invest in building strong, open source systems to ensure our devices are of the highest possible quality for them.

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