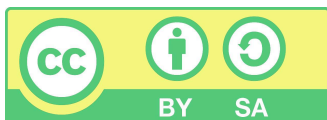




**Open
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Best Practices for Open Healthware Device Quality



OSHWA

Abstract

Open Healthware (OH) projects - open-source medical devices designed for distributed manufacturing - require robust quality practices to ensure reliability and reproducibility. As OH experiences broader adoption, there is an increasing mandate to set and maintain levels of quality that aggressively minimize the risks to the health and well-being of the patients who interact with these devices as well as their healthcare practitioners and providers. Central to minimizing these risks are defining and driving adoption of Quality Assurance (QA) & Quality Control (QC) practices that maximize the quality and consistency of OH and provide all stakeholders in the supply chain with trust and confidence in these devices. This guide outlines recommended practices inspired from interactions with stakeholders in the Open Healthware community. These practices for QA and QC that are tailored to the unique challenges of open-source ecosystems. By defining roles, responsibilities, and workflows across makers, manufacturers, and users, this guide provides a framework for improving replicability and performance in Open Healthware development and deployment.

Who This Guide Is For & How To Use It

This guide was designed for reproducers and manufacturers of Open Healthware. This guide also has beneficial material for users and designers of Open Healthware as it relates to device quality practices. The goal of this guide is to suggest practices that can be utilized by reproducers, designers, and users of Open Healthware to achieve the highest quality reproduction of an Open Healthware project. This guide is meant to be educational and assumes a base level understanding of manufacturing processes and techniques. For best use of this guide, we recommend taking the information provided here as a starting point and doing further research on the topics covered in this guide, as necessary.

Introduction

Medical devices must be used correctly and perform as intended or they can cause risks to patients and providers. Open-source medical devices, also known as Open Healthware, have the additional complexity of potentially being recreated in vastly different conditions from which they were designed. Therefore, when replicating open healthware, it is critical to verify device functionality. The two main mechanisms for this verification are Quality Assurance (QA) and Quality Control (QC).

Quality Assurance, in the context of Open Healthware, refers to the structured processes, documentation practices, and community governance mechanisms that enable devices to be consistently designed and fabricated across distributed contributors and environments. Quality Control encompasses the inspection, testing, and validation activities conducted on individual device instances to ensure compliance with defined performance and functional requirements. The overall QA and QC workflow for Open Healthware projects is illustrated in Figure 1.

4 | Best Practices for Open Healthware Device Quality

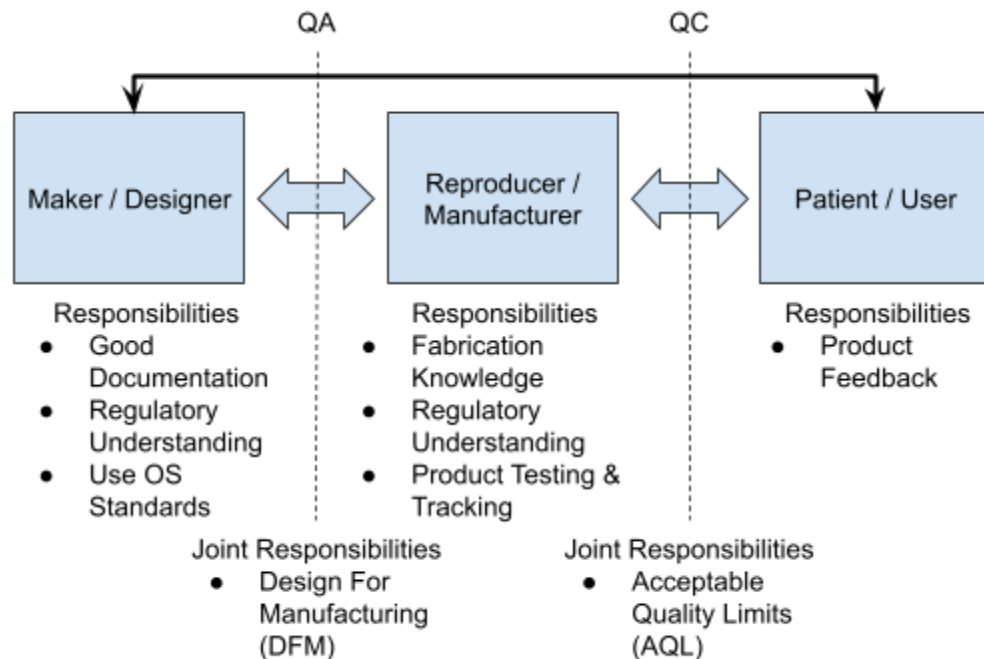


Figure 1: Open-source (OS) workflow for quality assurance (QA) and quality control (QC). The diagram outlines the major stakeholders in this workflow, Makers/Designers, Reproducers/Manufacturers, and Patients/Users. The blue block arrows designate a direct connection between two groups, while the solid black arrow shows an indirect connection between groups. Direct connection refers to interactions between two groups of stakeholders where the stakeholders make contact with each other (ex: email, face-to-face meeting, etc.). Indirect connection refers to interactions where one group of stakeholder's decisions affect another but do not occur through direct contact (ex: word of mouth reviews). The individual responsibilities of these stakeholders within the scheme of the OS workflow is highlighted as well. The Joint responsibilities shown highlight where multiple stakeholders must work collaboratively to achieve a goal. For QA, the Maker/Designer and Reproducer/Manufacturer groups must work together to successfully complete Design For Manufacturing (DFM). For QC, Reproducer/Manufacturer and Patient/User groups must work together to define Acceptable Quality Limits (AQL).

The main parties in this workflow are makers/designers, reproducers/manufacturers, and users/patients.

- *Maker/Designer*: A self-identified term often used in the open hardware industry to define the role of someone at one or more steps of the process of creating open hardware.
- *Reproducer/Manufacturer*: A self-identified term often used in the open hardware industry to define someone who is reproducing someone else's design.
- *User/Patient*: Someone who utilizes an Open Healthware project.

Buyers and distributors of Open Healthware products are also an important additional part of the Open Healthware ecosystem. In this workflow, they are considered as a part of the user/patient group but it may be useful to think of them as a separate stakeholder depending on the use case.

Within this framework, manufacturers are assumed to interact bidirectionally with both designers and users, whereas direct interaction between makers and users may not occur. However, makers and users have an indirect relationship that provides benefits to both groups. Information, such as intended use case or repair instructions, provided by makers can be incredibly helpful to users. Conversely, user feedback is a very useful tool to help iterate during the maker's design process. This guide examines the direct interactions in the proposed framework.

QA is conceptualized as a **proactive process** primarily occurring between makers and manufacturers, emphasizing the development of robust and reproducible design practices prior to fabrication. Conversely, QC is understood as a **retroactive process** occurring between manufacturers and users, focusing on the evaluation of device performance after production. QA ensures that devices can be reliably reproduced across diverse contexts, while QC ensures that individual device instances perform effectively. When combined, strong QA and QC practices result in the creation of high quality devices. This guide presents recommended practices for implementing QA and QC in Open Healthware projects, with the goal of supporting the development and dissemination of trustworthy and accessible medical devices. These practices are inspired by feedback from multiple members within the Open Healthware community. These practices also support the belief that enacting high caliber quality practices can create devices that empower makers to create superb quality practices that produce devices equivalent or superior to proprietary options, drastically mitigate experiences of harm from dubious constructed projects, and enable users to have consistent positive experiences during adoption and utilization of OH projects.

QA Recommended Practices

Quality Assurance within Open Healthware is most effective when supported by continuous, bidirectional communication between reproducers/manufacturers and makers/designers. As a proactive process, QA should be integrated early in the design phase to account for downstream manufacturing and usage considerations. Early incorporation of QA principles enhances reproducibility and reduces the likelihood of design-related errors during fabrication.

Reproducer/Manufacturer

Manufacturers of OH play a critical role in QA implementation. A primary responsibility of these stakeholders is the assessment of fabrication capabilities, including the availability of tools, materials, and technical expertise required to reproduce a given design. For instance, discrepancies between specified manufacturing methods (e.g., injection molding) and available fabrication techniques (e.g., 3D printing) must be identified and addressed to ensure feasible production.

Manufacturer feedback to the maker is of critical importance. Manufacturers should provide makers with lived experience data from the reproduction of their product. Examples of good data to provide are failure and investigation data, end user feedback or customer complaints, amounts of units created, and shipping locations. Tracking data is particularly invaluable to many makers and can help bridge the gap between intended impact and actual production. Design for Manufacturing (DFM) is particularly important in addressing gaps between design intent and production capability. DFM refers to the practice of designing products such that they can be efficiently and consistently produced using available materials, tools, and processes. Within Open Healthware, DFM should be approached as a collaborative process between makers and manufacturers, especially when adapting designs for different production contexts or scaling requirements.

Manufacturers should also evaluate regulatory requirements within their local context, which may differ from those of the original design environment. We recognize that full compliance with formal standards, such as those developed by International Organization for Standardization (ISO), can be difficult to achieve due to resource constraints. In situations where manufacturers cannot replicate standards exactly, we recommend making reasonable efforts to align with established best practices by

extracting and applying the key themes of the standard and documenting any deviations.

Due to the decentralized nature of open-source development, manufacturers may not always have direct access to original designers. In such cases, it is essential to rely on available documentation and, where necessary, reconstruct missing design information to ensure accurate reproduction.

Makers/Designers

For makers/designers, comprehensive documentation is foundational to effective QA. Well-documented projects enable consistent replication across distributed environments and are therefore central to the success of Open Healthware initiatives. Essential documentation should include, but is not limited to, a bill of materials (BOM), risk analyses, testing and validation data, and records of key design decisions and their underlying rationale. The use of quality management system (QMS) tools can facilitate documentation, version control, and traceability.

In addition, makers should maintain awareness of the regulatory requirements relevant to the intended context of use. Regulatory frameworks may vary significantly across jurisdictions; for example, medical devices in the United States are regulated by the U.S. Food and Drug Administration, whereas other regions may have limited or no formal regulatory oversight. Designers can therefore consider these differences and incorporate regulatory considerations into the design process where applicable. Adherence to open-source-oriented standards is also recommended, including certifications and documentation frameworks such as those provided by the Open Source Hardware Association (OSHWA).

Finally, makers should keep an active line of communication open for their projects. Creating an OH project can be a time intensive, labor of love that leaves people with a myriad of feelings from pride to relief that the project is done. While many makers can take the “throw it over the wall” approach where project maintenance stops after it is released, we recommend that makers provide up to date contact information so that manufacturers can ask questions and refine their DFM processes. We acknowledge that this is extra work however, we believe staying updated and contactable is the best way for OH projects to have the highest impact.

QC Recommended Practices

Quality Control in Open Healthware is a collaborative process between manufacturers and users. As a retroactive process, QC focuses on evaluating the performance and reliability of individual device instances after fabrication.

Reproducer/Manufacturer

Manufacturers are responsible for establishing and executing systematic QC procedures. A key component of this process involves utilizing testing data provided by makers to define measurable performance benchmarks and inspection criteria. These benchmarks can then be translated into quality checkpoints to ensure that each device meets the intended specifications. A widely used tool in QC that turns data into a checkpoint is the implementation of Acceptable Quality Limits (AQL). AQL refers to the maximum number of defects that can be tolerated within a production batch during sampling-based inspection. Defects are typically categorized into critical, major, and minor classifications, each associated with predefined acceptance thresholds. During QC, a random sample is drawn from a production batch, and the observed defects are compared against these thresholds to determine whether the batch should be accepted or rejected.

The determination of AQL thresholds should be a collaborative process between manufacturers and users, with manufacturers establishing tolerance levels informed by user feedback and risk considerations. This approach ensures that quality expectations are aligned with real-world performance requirements. Furthermore, AQL is particularly valuable in accommodating variations in production scale, as it provides a structured method for maintaining quality consistency across both small- and large-scale manufacturing contexts.

User/Patient

Users play an important role in QC by providing feedback on device performance under real-world conditions. This includes reporting functional outcomes, identifying failures, and communicating safety concerns. Such feedback is critical for enabling iterative improvements and informing future production decisions.

How Open Healthware Certification can help you with QA & QC

The Open Healthware certification can play a significant role in supporting effective Quality Assurance (QA) and Quality Control (QC) practices within open-source medical device ecosystems. As part of the certification process, projects are required to provide comprehensive documentation, including a bill of materials (BOM), testing and validation data, risk analyses, and other relevant design considerations. These materials form a critical foundation for both QA and QC processes by enabling reproducibility and facilitating performance verification. Additionally, certification requires the inclusion of contact information and project tracking through use of OSHWA's certification mark. These practices hereby promote communication between stakeholders, allowing the transfer of important information like number of manufactured projects and device recalls.

Furthermore, OSHWA maintains publicly accessible directories of approved projects. These repositories serve as valuable resources for identifying validated Open Healthware designs and for examining the application of QA and QC practices across diverse regulatory and resource contexts. By providing access to a global network of projects and contributors, such directories facilitate collaboration and knowledge exchange among makers, manufacturers, and users.

Collectively, Open Healthware certification frameworks contribute to the standardization and dissemination of best practices thereby strengthening the overall reliability of open-source medical devices. With this information OH certification users can gather tangible data that can be used for fundraising, regulatory submissions, and more.