

Standards & Quality Management



Purpose

Field Ready has put together documents called “Technical Papers” summarizing a variety of issues and topics that relate to our work. These serve as white papers that clarify our approach, form the basis of policy, explain challenging subjects and provide thought leadership to our sector.

Specific Purpose of this Technical Paper

The purpose of Technical Brief #3 is to outline Field Ready’s approach and detail its response methods involving standards and quality management.

Thank you to Christopher Schmitt, Brynmor John, Joanne von Alroth and Eric James for their input on this paper.

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1. Overview

There are often low expectations for anything made “locally.” Poor quality and a lack of standards are the main culprit. This results in overlooked capacity, ignored abilities and lost opportunities. With the right approach, however, high standards and quality can be achieved anywhere.

The ability to provide quality in locally made items is particularly important to Field Ready. We believe in “making useful things for people in challenging places,” following standards and ensuring quality. This is set forth by established manufacturing and production techniques from some of the most advanced systems-driven industries.

Field Ready assists disaster-affected people by addressing emergent needs through comprehensive market-risk analysis, strategic planning and development tools and using local resources when available including personnel, raw materials and manufacturing and production facilities. In this Technical Brief, a case study is provided and many more exist in the field as we continue to assist people worldwide.

2. What is quality management?

Quality is a subjective term that can mean different things to different people. It often ends up being “you know it when you see it,” so the perceived value of something impacts quality. At a basic level, quality can be thought of as the degree to which an object, process or service satisfies a specified set of attributes or requirements.¹ Quality involves characteristics such as design, materials, the application of know-how and craftsmanship. Age, location, usefulness, reliability and the way people interact with objects (known as “human factors”) also influence quality. Where something is made often plays a role in the perception of quality as well.

There is a perception that “local” means low quality. In part, this stems from the technologies available in locations themselves and, on occasion, the undermining of craftsmanship. That belief can also be wrapped up in the relationship between cost and value. While different needs arise in different contexts, for our purposes here quality is about being fit for purpose and meeting market expectations of “right time, right place.” This can be addressed with quality management.

Quality management is a formalized system that documents processes, procedures and responsibilities for achieving quality policies and objectives. Such a system coordinates and directs an organization’s activities to meet customer and regulatory requirements while improving its effectiveness and efficiency on a continuous basis.

As shown in the diagram (above), quality assurance (QA) is a subset of quality management and is not the same thing as quality control (QC). These are separate concepts and deserve further discussion. Field Ready has



¹ See, e.g., <https://hbr.org/1983/07/quality-is-more-than-making-a-good-product>

policies and procedures, and undertakes action, in all these areas to ensure that what we do reaches an appropriate level of quality and provides value to end-users.

According to the American Society of Quality,² QA and QC are different in several ways. Quality assurance can be defined as "part of *quality management* focused on providing confidence that *quality requirements* will be fulfilled." The confidence provided by quality assurance is twofold — internally to management and externally to customers, government agencies, regulators, certifiers and third parties. Another definition of QA is "all the planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfill requirements for quality."

In contrast, QC can be defined as "part of *quality management* focused on fulfilling *quality requirements*." While quality assurance relates to how a process is performed or how a product is made, quality control is more the inspection aspect of quality management. An alternate definition is "the operational techniques and activities used to fulfill requirements for quality." The differences between QA and QC are expanded on in the table below.

Quality Assurance	Quality Control
Makes sure that we are doing the right things, in the right way	Makes sure the results of what we've done are what we expected
Focused on end-user/customer	Focused on meeting required standards
A preventive process – how things are made or delivered	A corrective process focused on output – work-in-progress and finished goods
Done by improving production processes	Done through monitoring and inspection (checking and sampling)
Targeted at the whole organization	Targeted at production activities
Tools: quality metrics, reviews, audits, team work	Tools: inspection, testing, reporting
Medium to long-term process; not implemented quickly	Short-term; can be implemented rapidly
Quality is built into life-cycle of the process and extends to the product/solution	Quality is achieved by testing and weeding out defects

Field Ready provides a quality product which itself is the result of skillful craftsmanship with the best resources available and attention to detail. Field Ready goes further than this by not just providing outputs ("products") but also by adding local, continued-production capabilities; a structure that emphasizes training and partnering with local manufacturers who will provide quality and follow-up (service).

In these ways, Field Ready follows traditional best practices including specialization, standardized regulation, measurement, care in reaching standards and statistical analysis. Field Ready also takes into consideration non-linear approaches, adaptive pluralism and the consideration of complexity such as versatility, adaptive pluralist, eclecticism, facilitation, alertness, surprises, relevance, triangulation and successive approximation. We accomplish this through our continuous management programs and work toward providing real value through "field readiness" (see Annex 1)³ and other qualities that are needed in challenging situations.

² See their website here: <https://asq.org/quality-resources/quality-assurance-vs-control>

³ For more information, please also see: <https://wikifactory.com/+FieldReady/stories/field-ready-readiness-levels>

3. How does Field Ready decide what to make?

Many proprietary systems and technological solutions involve remedies that demand a search for problems before their application. Even the “needs based” approach commonly followed across the aid sector seeks to identify gaps in supply chain and works to fill them – but ignores valuable factors including actual user need, locally resourced supply capacity of primary and ancillary materials for production and the ability of local infrastructures to accommodate new market entrants in the process. Instead, Field Ready’s approach starts with people and works forward from there. Our assessment methodology incorporates four lines of inquiry undertaken in parallel following a number of questions such as:

Situation: What is the problem? What is the condition of hospitals, schools, houses, markets, camps, etc.? What was the situation before (baseline)? How many people are affected? Are there threats and access issues (e.g., security, logistics, environment, etc.)? How will this situation evolve/change over time; (e.g., forced displacement, outbreaks or insecurity) and what will the situation be six and 12 months from now, and then in five years?

Needs: What are the immediate needs? What are the medium- and long-term needs? How are different people affected? Look at each sector: health, WASH, food, shelter/NFIs, protection, livelihoods, education, etc. to gain a complete understanding. More specifically: what is broken or missing? What could be safer? What will make people’s lives better? If you had a magic wand, what’s the one thing that you would change?

Capacities: What skills and talents do people have (think about different levels, age and other groupings)? What are the needs for capacity-building and training? How do people communicate and obtain goods? What material resources are available (e.g., in markets, in schools and spaces, as debris, etc.)? What workspaces, tools and equipment are available (and what are their costs)?

Opportunities: What are others doing: government, business, universities, labs/maker-spaces, UN, NGOs, donors? What are the gaps? How can partnerships be formed?

Following technical review of the findings of these assessments, we:

1. Consult existing designs and solutions
2. If none exist, co-create new alternatives
3. Create prototypes for end-user feedback
4. Trial the solutions

Depending on the complexity and context to determine which items will be used, the above steps progress through the technology readiness levels (TRLs), available in Annex 2.

4. How does Field Ready manage quality?

Field Ready’s approach to quality management is an integral part of our product-development process (from identified need to finished solution). We rely on user feedback for development approval at a

number of key stages in our process. We implement the use of Lean Manufacturing⁴ tools from other sectors, such as the aviation and medical industries, as well as developing our own ways of working. This guides our daily work and provides a practical way in which to develop and produce cost effective, quality items in difficult places using the most efficient production model available according to emergent conditions.

When appropriate, we select open-source designs that meet recognized industry standards (e.g., CE markings) before completing our own QC testing and documentation. We also regularly consult and work to international standards when developing our branded products (e.g. testing our designs to the BS EN standard). When appropriate we closely follow World Health Organization guidelines and local and regional government regulations.

We develop all products using iterative human-centered design. This ensures that the user is included throughout the process; therefore, regular user-testing is essential. User inclusion involves feedback of the professionals working in their specific area of expertise (e.g. medical professionals) with our products and continuously improving all aspects of the production, supply and use chain. When appropriate, we ensure we have formal accreditation for research and manufacturing from the related necessary professional body.

Field Ready's Quality Management is a well thought-out system adopted from the best approaches in a variety of sectors and specifically tailored to the contexts in which we work. Field Ready's Quality Management consists of five parts:

1. Super talented people

We start with great people and then we empower them to make decisions that will have impact. This is not to be understated. They have training, tacit knowledge⁵ and skills that are the products of top universities, industry-leading companies and other personal/professional experience. They hold the necessary knowledge of how to produce quality solutions that make a difference in people's lives and scale those that are needed in bigger sets matching the solution to the identified need. Our people have a special combination of experience and tacit knowledge that are not available at other organizations.

2. Solid foundations

The foundations for our quality-management system begin with us taking time to understand the political geography and emotional philosophy⁶ of the region we intend to work. Our staff consists of people from multiple disciplines and background; most are from affected countries themselves. The ways in which we work are well documented, from our internal processes (discussed further below) and external training, to offerings like our Technical Briefs and book, *Managing Humanitarian Innovation: The Cutting Edge of Aid* (Practical Action, 2018).⁷ Our quality-management system is built on a number of available and proven models, methods and tools. Our specific Product Development Process was developed from a combination of sources including:

⁴ For more information, see: <https://www.sciencedirect.com/topics/engineering/lean-manufacturing>

⁵ See https://en.wikipedia.org/wiki/Tacit_knowledge

⁶ See, e.g., <https://plato.stanford.edu/entries/emotion/#~:text=The%20view%20that%20emotions%20are,in%20the%20philosophy%20of%20emotions.>

⁷ Available here: <https://www.fieldready.org/book>

- Existing Field Ready tools (e.g. Field Days, need assessments, prioritizing tool, 3DP triage tool)
- Human-centred design process, such as that used by IDEO and Philips
- Adaption of risk-assessment tools used in industry (similar to those used by the National Health Service and British Medical Journal)
- Adaption of quality-control procedures also used in industry (such as the First Article Inspection SAE Aviation Standard)

3. Focused process

For each specific hardware solution, Field Ready follows a rigorous product development process (PDP). This starts with the identification of environmental needs along with local assets, capabilities and market opportunities. During this process, our team discovers the problems that people face and consequently identify the rationale for a new product production to solve those problems. We do not guess - wherever possible we quantify the need using justified metrics, not just the perception of need.

The process requires our teams to produce a detailed technical specification with a bulleted list of design features. It includes both Primary and Secondary features. Primary features are essential to address the item in need. Secondary features are non-essential but still important considerations in meeting end-user considerations. Test plans are developed and our teams often use tools such as Design Failure Mode and Effects Analysis (DFMEA),⁸ Taguchi method⁹ and Order of build (DFA). Through this our teams get input from users in the intended environment. It is important to get input from the widest demographic possible. We ask the users to perform different functional tasks, collect data such as time taken to complete the task, number of mistakes and user satisfaction.

4. Managed risk

Field Ready treats risk very seriously. Our risk-assessments rankings are detailed in our parts catalog. This measures severity and likelihood of the risk involved for the maker and end-user of the item. The mitigation and control measures are documented by Field Ready in separate risk assessments for each item it makes.

- A number of questions are answered in order to assess risk in making any identified item. What are the hazards involved? We consider all hazards that exist, regardless of severity, likelihood or existing controls. For example, anything that is used in the preparation or transport of food or drink carries a hazardous substances risk, as it could ultimately be ingested and be toxic or cause infection.
- What are the vulnerabilities? How the hazard might have an outcome if there is an accident or negligent use, and what the result might be. Examples include but are not limited to burns, cuts, falls, product malfunction or anything that might cause harm, including death.
- What is the severity and likelihood? We consider the impact and frequency the hazard might have on the user and likelihood it could take place.
- What are the control and mitigation measures? What can be done to lessen or prevent the hazard? Controls that eliminate hazards are preferable to measures that create barrier, such as

⁸ For more information, see: https://en.wikipedia.org/wiki/Failure_mode_and_effects_analysis

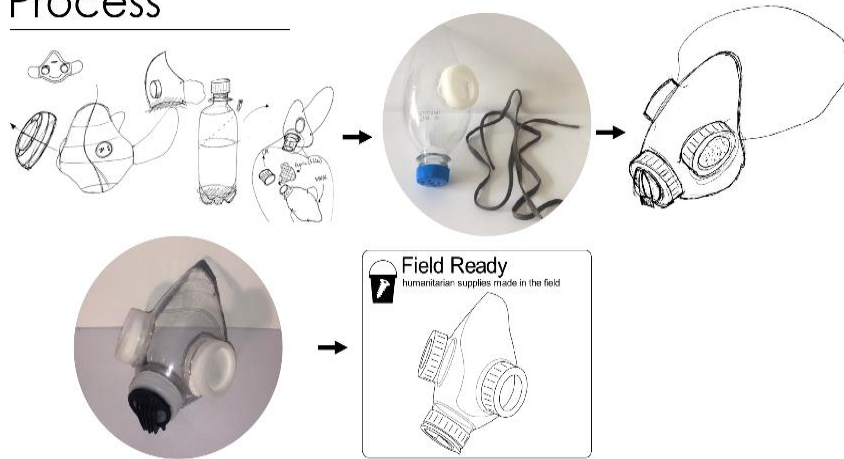
⁹ More is available here: https://en.wikipedia.org/wiki/Taguchi_methods

safety guards or personal protection equipment or administrative controls such as lengthy user instructions.

- Additional considerations: Is there anything else that should be considered particularly from the end-users' perspective, such as risks that emerge through wear and tear or any other unintended consequences? Does the risk of not providing the item outweigh any other risks?

In practical terms, this means careful attention to detail and ensuring the process just outlined is followed. This involves regular management and technical calls, online systems (including MS 365 and the other tools outlined here) and inspections whenever appropriate.

Process



If a product needs to be durable, for example, we are likely to perform drop tests stressing material and design weaknesses. The ultimate test however is end-user feedback. Because we undertake this throughout the process (e.g., using lean methods, not “water fall”), we increase the likelihood the objects we make are actually used.

5. Sharing and Improvement

Once a solution has made it to distribution, Field Ready’s highest level of readiness, it is shared online following the Open Know-How Manifest, and it might go through additional certification by the Open Source Hardware Association (OSHW).¹⁰ Our process is fully documented in our portfolio, which is, maintained using Airtable;¹¹ when this is finalized, the product is listed in the Field Ready Parts Catalog.¹²

Ultimately, we stress learning and a continual development. We appreciate the Japanese concept of *kaizen* which when done correctly, humanizes the workplace, eliminates overly hard work (*muri*) teaches people how to perform experiments on their work using scientific method and then how to learn to spot and eliminate waste in making useful things for people in challenging places.

¹⁰ See: <https://www.oshwa.org/>

¹¹ The service we use is available here: <https://airtable.com/>

¹² Field Ready’s Parts Catalog is available here: <https://www.fieldready.org/>

5. Case Study: Rescue Airbag

Buildings collapse as a result of both earthquakes and violent conflict (by artillery shelling and aerial bombardment). Victims can survive the initial event and then live for days trapped in the wreckage. Specialist equipment is needed to lift the tons of rubble and save people lives.

Field Ready's project began when our team conducted a number of focus group interviews with search-and-rescue workers in Syria. The process produced a list of search-and-rescue products that were not readily available in the field. Through a process that involved using a prioritizing matrix tool, we identified a great need for heavy-lifting rescue airbags.



Once the need had been identified the design brief was drawn up. This was a declaration of the work to be undertaken. In this case the design brief stated simply, “to design an inflatable bag that is capable of safely lifting a heavy load thus allowing the rescue of trapped individual.”

The next stage was to conduct market and technical research. This process involved analysis of international standards, existing solutions already on the market, local requirements, capabilities and any limiting factors.

This research was essential in producing a detailed product design specification (PDS). A PDS is a bulleted list of design features. It includes both Primary and Secondary features. Primary features are essential to address the area of need. Secondary features are non-essential but still important considerations for end-users.

Once this document was established, it acted as the mantle that enveloped all the subsequent stages in the design iteration. The PDS thus acted as the control for the total design activity, because it placed the

boundaries on the subsequent designs. The conceptual design was carried out within the envelope of the PDS constraints, and this applied to all subsequent stages through the end-stage design iteration. The PDS enabled the engineering team to set up the rescue airbag on the Field Ready Portfolio. This is a cloud-based platform – a spreadsheet/database hybrid available to everyone in the Field Ready organization. Setting up the rescue airbag on the Portfolio involved creating initial project data, including a unique Field Ready part number, version control, the location and start date. This data is important for collaborative working; iterative design and quality assurance ensure contributors are working on the items' most current iteration.

The next stage is an iterative process; engineers focused on user needs by involving rescue workers and implementing a process called human-centered design (HCD). Our team used it to produce a comprehensive range of concept sketches, sketch models and CAD models in an attempt to meet the parameters of the PDS.

Based on the input from the rescue workers and internal design reviews we were able to evaluate these concepts against the brief and product design specification. This process identified the concepts that held the most potential for successful production implementation. The next challenge was to build and test prototypes of each of these concepts. The prototypes were produced so that they fully described all aspects of the proposed solution and were as production-representative as possible.

The team tested each prototype using the BS/EN standard. This involved the construction of a number of test rigs as stipulated in the standard. The team developed and improved the prototypes using tools such as the Field Ready Risk Assessment and other tools mentioned above (e.g., DFMEA and DFA).

Once the team produced a prototype that had passed the BS/EN standard and had been fully risk-assessed they were able to perform end-user field testing. The end-user testing captured vital input from rescue workers in the intended environment. It was important to get input as well as observe them performing different tasks. The team collected data that included time taken to complete the task, number of mistakes and user satisfaction. We were also able to assess the effectiveness of the documentation produced, such as the user manual. This process highlighted a number of areas of weakness that were addressed in the following prototype iterations and supporting documentation.

With all the areas of weakness addressed (based on the BS/EN standard and user testing), the design and documentation were finalized and uploaded to the Field Ready Portfolio. This allowed Field Ready's Nepal team to use the documentation to make the airbag. To boost its quality, they improved the documentation and production process.

The first production run began when design and documentation had been finalized. We ensured quality by referencing the well-defined PDS, Engineering Drawing Pack and BOM. Quality control procedures were based on the BS/EN standard performance tests and the Field Ready; First Article Inspection document.

After distribution, our engineering team contacted the rescue workers for feedback to ensure the airbags were performing as intended. This highlighted a few weaknesses in the user manual. The team amended the manual and captured it in our lessons-learned document.

This product development process allowed the airbag to be implemented by a subsequent Field Ready team in Nepal. To date, more than 300 airbags have been successfully manufactured and distributed globally.





Essential: The item is needed in a humanitarian, recovery, reconstruction and/or development context. Indeed, it should serve a vital purpose as a prototype, unique fix, replacement part or mass-produced item. There will be adverse consequences if the item is not made and distributed.



Checked for quality and safety: The item will be closely examined for its quality and safety. The intention is normally to meet all reasonable standards, however, there is a recognition that this might not be possible in certain contexts. In cases where known standards (e.g., as set by the U.S. FDA or other regulatory bodies) are not met, a risk assessment will be carried out and acknowledged. To the extent possible, it should be environmentally sustainable.



Easy to use: It should be exactly fit for purpose. The item should be intuitively designed following human-centered principles. The design features will make the item useable with as little instruction or training as possible. In most cases, the item should not be labor saving (i.e., it should be labor intensive); instead it should engage local people to use their skills, knowledge and physical effort. Whenever possible, it should be repairable using local means.



Robust: The item will be optimized to function in a field context. Typically, this will include design features that add to its toughness (e.g., reinforced friction points). These features will depend on its intended use but can also include strength, shock resistance, an ability to survive conditions such as moisture and dust, and levels of wear and tear that are beyond what is experienced in more developed areas.



Replicable: The item must be able to be replicated in other contexts from its original design and use. Widespread use is a specific intention. There should be no intellectual property issues hindering its use, and alternatives should be openly recognized. It should also be affordable. The designs and instructions to re-make the item will be available publicly (openly) and passed on through training. These instructions should be made in a way that can be communicated amongst different cultures and levels of education.

Annex 2: Technology Readiness Levels

When determining if an innovation is “ready,” there can be many interpretations. For example, there can be a chasm between making the first prototype and the intended users using a final product. Therefore, having a common way to measure the status of a technology under development can be helpful. This is especially true when there are potential safety concerns, or certain standards need to be met. It is also true when there is a need for dialogue between a diverse group of people with different specialties and there are different types of technology under consideration.

The U.S. government developed such a tool in the 1970s that has since served as a model adopted by a number of organizations worldwide. The Technology Readiness Level (TRL) scale and its variants are based on different levels, most often ranging from one (the initial idea) to nine (the innovation is in use). What appears below is a consolidation of various scales put together for the purposes here:

Level 1: This is the lowest level of readiness where the basic idea is observed and recognized by moving a step past scientific research toward applied research and development (R&D).

Level 2: Validating the potential application is when invention starts. At this stage, studies are limited and without proof or detailed analysis so the invention is speculative.

Level 3: At this level, the proof-of-concept is shown through active R&D. Detailed analytical studies and laboratory studies are done, usually on separate elements of the technology.

Level 4: The rudimentary hardware components are put together to establish that they will work together in a laboratory setting. This is when the first “fidelity” prototype might be available.

Level 5: The basic components are validated in a simulated environment. At this level, the technology will reach a “high-fidelity” stage with laboratory integration of components.

Level 6: This level is a significant step above the previous level of readiness, which validates the entire system in a simulated operational environment.

Level 7: At this level, the prototype is demonstrated in an operational environment in or near where it will normally be used. This can be considered a “field trial” or software “alpha test.”

Level 8: This level sees the prototype completed and qualified through test and demonstration that ensures user acceptance (in software, a “beta test”). The technology has been proven to work in its final form and under expected conditions.

Level 9: The prototype is proven through successful operations. This means it is available “on the shelf” and/or in the “hands” of intended users. With other factors in place, it might be ready to scale.

Annex 3: Field Ready’s Product Development Process



FIELD READY

NEW PRODUCT DEVELOPMENT PROCESS

(Please note that this is a guide & simplification therefore it is subject to change)

