QI DIGITAL

February 2023

# THE DIGITAL QUALITY INFRASTRUCTURE – A GUARANTOR FOR INNOVATION AND SUSTAINABILITY


www.qi-digital.de

Metrology, standardisation, conformity assessment, accreditation and market surveillance are the five pillars of quality and quality assurance for which Germany enjoys a high level of recognition worldwide thanks to its established top institutions and leading research facilities. Together, these five pillars form the **Quality Infrastructure** (QI).

Production and trade are taking place in increasingly complex **value creation networks**. At the same time, **digital and green transformation** are making exponential progress. The associated **technological innovations** are highly dependent on ensuring and efficiently verifying the quality, safety and sustainability of goods, services and processes. A modern and efficient QI system is essential for this.

This was also recently confirmed by the **United Nations Industrial Development Organisation** (UNIDO) in an overview of the **sustainability of national quality infrastructures** in 137 countries.[1] The German QI takes first place worldwide. Maintaining and expanding QI contributes to many of the seventeen UN Sustainable Development Goals (SDGs), such as combating poverty and hunger, but also promoting health, industry, innovation, infrastructure and the sustainability of consumption and production.

In light of the **challenges and opportunities** presented by digital technologies and the digital transformation, it is of central importance that QI is also continuously further developed. This is the only way it can meet the new requirements and continue to fulfil its essential functions. **Digital QI enables innovation, provides trust and ensures security** – also in the digital future.

[1] UNIDO, QI4SD – Quality Infrastructure for Sustainable Development Index
https://hub.unido.org/sites/default/files/publications/Quality%20Infrastructure%20for%20Sustainable%20Development%20Index_REPORT_online.pdf, accessed on 6 October 2023.



## What is QI–Digital?

QI–Digital stands for a digitalised quality infrastructure (QI) with digital tools, processes and data spaces. It will make it possible to improve **quality management processes** in companies and facilitate the integrated, smooth provision of quality information across the entire value chain – for customers, companies, authorities and other QI stakeholders. Digital QI solutions offer sustainable potential for **increased efficiency and additional value creation.**

In digitalised QI, requirements will in future be automatically checked as machine-understandable standards (SMART standards), results reports will be provided digitally and transferred along **value chains** and **product lifecycles** without media disruption. Digital data formats and infrastructures enable the **optimisation of data flow and data access.**

The tools and processes of QI are complex and interlinked – their transformation to digital requires a collaborative, coordinated approach by QI organisations and institutions. Five key players in German QI have therefore joined forces in the QI–Digital initiative, supported by the **Federal Ministry of Economics and Climate Action (BMWK)**, to jointly develop these solutions for digital QI:

- the Federal Institute for Materials Research and Testing (BAM),
- the German Accreditation Body (DAkkS),
- the German Institute for Standardisation (DIN),
- the German Commission for Electrical, Electronic & Information Technologies (DKE)
- and the Physikalisch-Technische Bundesanstalt (PTB).

The research and development projects of the QI–Digital initiative combine practical use cases with scientific groundwork. In this way, they create the basis for the joint development of tools and procedures for digital QI as concrete **solutions for market & society.**

The QI system as a whole is being rethought and the digitisation processes are being driven forward jointly and across institutions. The central concern is the transfer of the developed solutions into application in order to ensure the sustainability of the project results. To this end, a QI–Digital innovation ecosystem will be established in which a sustainable QI will be created together with a **network from industry, society, research and xpolitics.**

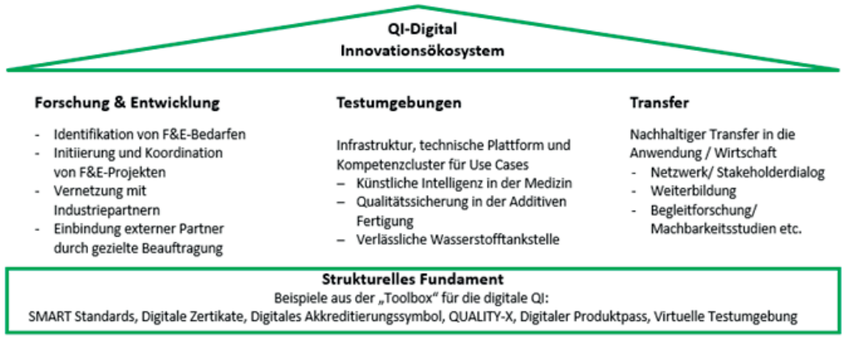


*Figure 1: The QI digital ecosystem*

The QI digital working groups deal with the digitalisation of central QI tools („**toolbox**"). Interoperable digital QI elements are being developed for selected process chains as part of an integration architecture and their potential demonstrated. In addition to harmonised terminologies, standardised data formats and standardised interfaces, the focus is on the further development of **quantifiable quality criteria**. The solutions developed will **enable digital QI to be used globally**.

The tools from the „toolbox" are being used and optimised in three pilot projects to develop digital solutions: „AI in medicine", „Reliable hydrogen filling station" and „Additive manufacturing".



## The structural foundation of digital QI („toolbox")

The structural foundation of digital QI („toolbox") A digital quality infrastructure requires digital tools and processes. To this end, the QI-Digital initiative is jointly developing concrete, data-sovereign and secure digital solutions. These enable reliable digital verification chains that can be used by all stakeholders.

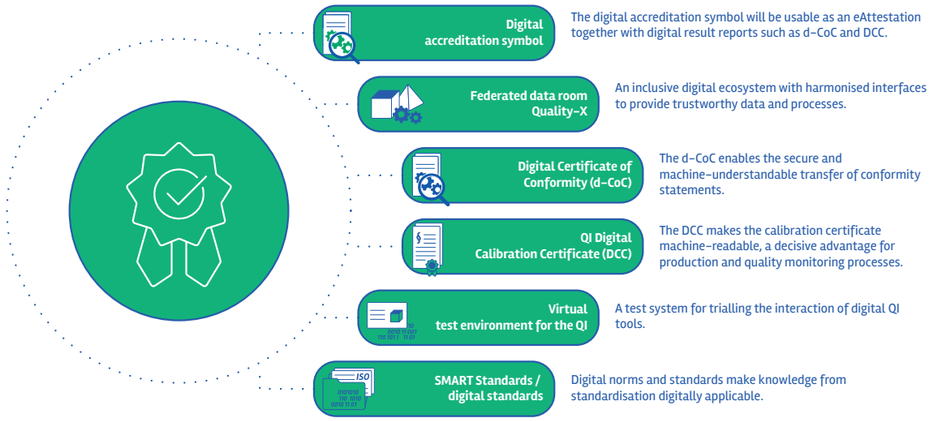


*Figure 2: Examples of tools from the QI Digital „toolbox".*

### SMART STANDARDS

In a digital world, **s**tandards for **m**achines must be **a**pplicable, **r**eadable and **t**ransferable, i.e. **SMART**. These SMART standards are the key to being able to apply the knowledge from the standard digitally. The advantages of „smart standards" are that they save time during implementation, create trust between the players in the digital exchange and enable simple identification of all requirements for products and services.

The **Digital Standards Initiative (IDiS)**, which was founded by DIN and DKE, provides support in the design and realisation of digital norms & standards (SMART standards). The work carried out there is linked to QI-Digital by, for example, developing SMART standards in pilot projects of the initiative which are implemented and trialled, depending on their level of maturity.

In the future, these standards can be used in a media-interruption-free digital value chain, interpreted independently by machines in a next step and finally carry out self-learning and self-optimising analyses with AI support. This will turn standards into a digital actor in their own right. The first standards converted into SMART standards will be published in 2024.

## DIGITAL CERTIFICATES

**Machine-readable data and reports** are an important element of digitalised systems. In recent years, PTB has therefore worked closely with industry and international partners to develop a scheme for **Digital Calibration Certificates** (DCC) that is suitable for worldwide use. Coordination processes that are of great importance for the harmonisation and establishment of DCCs are currently underway within the framework of national and international committees and initiatives.

A digital certificate of conformity (d-CoC M) is initially being developed for conformity assessment in the area of legal metrology in accordance with European directives and national regulations. The specifications for the general part of the d-CoC, which have been harmonised at European level, were recently published by the Coordination Group of European Notified Bodies in Legal Metrology. In addition to the development of a data structure, tools for creating, editing and viewing the certificate information are at the centre of the development work.

## THE DIGITAL ACCREDITATION SYMBOL

The German Accreditation Body (DAkkS) is responsible for the accreditation of conformity assessment bodies in Germany. It is the only national institution authorised to issue an accreditation symbol to accredited bodies, which is linked to or represents a national emblem. The DAkkS has developed a **digital accreditation symbol** for a digitalised QI.

For this, the accreditation body must guarantee its **integrity and authenticity**. This could be guaranteed by **cryptographic procedures** to protect the accreditation symbol under the responsibility of **a qualified trust service.**

Using a **public key infrastructure** (PKI), the DAkkS enables accredited conformity assessment bodies to issue digital and machine-readable conformity confirmations (**eAttestation** = digital conformity confirmation + digital accreditation symbol). This infrastructure is used to establish a universal system of secure digital identities of accredited bodies, which can be uniquely **verified worldwide in real time**.

This application has now been finalised and will be made available to all accredited bodies upon request from **Q2/2024**. In close cooperation with other QI-Digital partners, the integration of **the digital accreditation symbol** into **Digital Calibration Certificates** (DCC) was successfully implemented as part of the "**Reliable Hydrogen Fuelling Station**" pilot project by BAM and PTB. An important step towards greater trust in the digital space.



## THE CONCEPT FOR FEDERATED DATA SPACES: QUALITY-X

The true potential of digital instruments can only be realised if they are seamlessly integrated into a **coherent digital QI ecosystem**. Harmonised and interoperable national QI systems are a prerequisite for promoting international cooperation, creating mutual trust and facilitating **national and international trade**. A data ecosystem based on established digital standards (**SMART standards**) for companies, public administrations and QI stakeholders promotes **digital transformation and innovation** in these sometimes highly regulated areas.

The „Quality-X" project addresses concepts and solutions for the previously lacking integration of QI elements in data spaces and initiates concrete work. This is a decisive prerequisite for the implementation of a digital QI ecosystem in **the International Dataspaces (IDS)** and related German and European projects. Quality-X is orientated towards existing lighthouse projects that are also based on the **GAIA-X** integration architecture and provides infrastructure elements and data spaces **for secure data exchange.**

The prototypical implementation of basic processes along the Quality-X concept is made possible by the integration of IDS-compliant **Eclipse Data Space Components** (EDC connectors) and the node infrastructure set up in the **European Metrology Cloud** project.

## THE VIRTUAL QI TEST ENVIRONMENT

To evaluate and demonstrate components of a digital QI, an **open platform** is being developed on which existing software elements can be linked. This platform will be used as a **virtual testing ground** for digital process chains.

By 2024, a DCC document service for the **exchange of calibration data with digital product passports** and within **interlaboratory comparisons** as well as an initial **AI utilisation concept** for autonomous data interoperation will be made ready for use as part of the **Digital Intercomparison Project**. Building on this, a **GAIA-X-capable data room adapter** is being developed and the integration of the international reference database for the SI units of measurement is being implemented. The first components of the test environment have already been made publicly available as open source on **GitHub**.

# PILOT PROJECTS

The QI-Digital initiative is developing solutions in **three specific pilot projects** using the above-mentioned tools ("toolbox") to address the core areas of digitalisation relating to the quality infrastructure. The **AI in Medicine pilot project** is developing quantifiable quality statements on the topic of artificial intelligence. Other topics include the **evaluation and certification of AI training data** of real origin as well as the generation of synthetic AI training data.

The quality assurance **pilot project for additive manufacturing** is an example of modern machine production (Industry 4.0). The **Reliable Hydrogen Filling Station** pilot project is a prototype for **digitally supported quality assurance of complex technical systems**, which are of fundamental importance for further progress on the path to **green transformation and decarbonisation**. These three application-orientated projects are significantly accelerating research, development and innovation work on digital QI.

## ARTIFICIAL INTELLIGENCE IN MEDICINE

The use of AI in medicine promotes, among other things, more efficient diagnostics and therapy planning tailored to individual patient needs as part of personalised medicine. Due to the special protection needs of patients, such AI systems require careful monitoring by the quality infrastructure over the entire life cycle of the system.

At the centre of the Artificial Intelligence in Medicine pilot project is work on the basic principles for the objective evaluation of artificial intelligence (AI) based on three quantifiable criteria: Explainability, robustness and uncertainty. This is of particular importance in the healthcare sector with its special requirements. Another focus is on quantifying the quality of AI test and training data using new methods and tools.

In addition, procedures for generating synthetic reference data are being created and reference data sets for use cases in intensive care medicine and dosimetry are being developed. These research results are transferred to metrological services.



## DIGITAL QI FOR TECHNICAL SYSTEMS: PILOT PROJECT RELIABLE HYDROGEN FILLING STATION

By introducing digital QI tools and procedures, **quality assurance processes** for technical systems can be optimised. This increases **reliability, safety, resource efficiency and cost-effectiveness** in operation. Using the example of a **hydrogen refuelling station**, solutions for modern quality assurance are being developed, tested and demonstrated in BAM's real laboratory. Innovative approaches for **new monitoring and testing methods**, state-of-the-art sensor technologies and **advanced digital models** are used. The aim is to implement modern QI tools – including machine-readable standards, digital calibration certificates, test reports and certificates as well as a digital data infrastructure (Quality-X) – in a practical way and test them under real conditions.

The work focusses on three levels:

- The **digital mapping** of the overall system using a prototype process control and sensor system
- Modern **sensors and sensor networks** for digital QI
- Solutions for the continuous monitoring of the component integrity of pressure vessels using modern **structural health monitoring** (SHM) methods and AI with the aim of flexible testing and calibration periods depending on the actual load and condition

In cooperation with **South Korean partners**, a safety management system for hydrogen safety is also being tested. In addition, the project is driving forward the **digital documentation of quality-relevant information** using the example of a **digital life cycle file** for pressure vessels that covers the **entire life cycle**. In addition to the technical aspects, the pilot project is also addressing the need to adapt standardisation and regulation.

Further work concerns the prototypes of the Digital Certificate of Conformity (d-CoC) for certain components. **Hydrogen refuelling stations** are a particularly suitable pilot application for this, as they fall under several legal regulations. Interfaces to Quality-X will make the digital QI information from the pilot project accessible at various user levels.

## A DIGITAL QI FOR MODERN PRODUCTION: DATA-BASED QUALITY ASSURANCE IN ADDITIVE MANUFACTURING

**Additive manufacturing** is representative of modern production processes in Industry 4.0, for which solutions for modern, digital QI need to be developed. The "Additive Manufacturing" pilot project forms the framework for developing methods for the reliable, digitally supported quality assurance of additively manufactured components using exemplary production process chains. The focus is on the digital mapping of the physical material flow in the production process as the basis for the use of digital QI tools.

To test and further develop new, digital quality assurance procedures and the prototypical implementation of SMART standards, digital test reports and other elements of digital QI, BAM has set up a **real laboratory** that corresponds to **industrial conditions**. In this real laboratory, users can work together with BAM scientists on components, process conditions and new quality assurance procedures.

The real laboratory is audited according to AM quality assurance standards (e.g. ISO/ASTM 52920), whereby **promising digitalisation potentials in quality assurance and certification** are specifically identified and implemented. As part of quality assurance, PTB is involved in the development and implementation of comparative measurements of sample components using various methods such as computed tomography (CT) in order to determine criteria for quality control, as well as the optimisation of sample components and test specimens.

## ACCOMPANYING ACTIVITIES AND TRANSFER

The central concern of the initiative is the transfer of the developed solutions into application and thus the **sustainability** of the project results. This requires the involvement of broad interest groups in the activities and solution development as well as a **continuous stakeholder dialogue** on requirements, applications and ideas.

### DIGITAL PRODUCT PASSPORT (DPP)

The core of the new **Ecodesign for Sustainable Products Regulation** (ESPR) proposed by the EU Commission in March 2022 is the introduction of the **Digital Product Passport** (DPP), which contains essential information about the product across its life cycle and thus makes an important contribution to the **circular economy**. The first concrete use case is the **battery passport**. The efficient design and implementation of digital product passports is significantly promoted by digital QI tools.

The digital solutions developed as part of the QI-Digital initiative will help to enable simple integrations and establish **seamless digital verification chains**. The initiative maintains close contact with central DPP projects, for example at national level with the Battery Pass project. The initiative is also involved in the **European CIRPASS project**, which brings together leading organisations to develop the European vision of a Digital Product Passport (DPP) across multiple value chains. CIRPASS is intended to prepare the ground for the **gradual testing and introduction** of DPPs, with an initial focus on the electronics, batteries and textiles sectors.

### INDUSTRY 4.0 – COMPATIBILITY

QI-Digital is organising the projects in such a way that the interfaces between industry and QI are developed in parallel and interoperably. For example, solutions for the **Industrial Internet of Things** (IIoT) are currently being developed as part of the **Industry 4.0 platform**. With the **asset administration shell** (AAS), the industry is increasingly realising automated production processes on the basis of "digital twins", i.e. the data representation of physical and virtual "things" or processes. The tools developed as part of QI-Digital are designed in such a way that they can be integrated into the existing AAS architecture in order to actively simplify processes and save costs for the economy.



### STANDARDISATION ACTIVITIES

Standards and standardisation are an important **technology transfer channel**. The members of the QI-Digital initiative are therefore actively involved in relevant **standardisation activities**. This also includes involvement in the creation of German **standardisation roadmaps**, e.g. for AI (completed) and hydrogen (ongoing), as well as their implementation in **national and international committees**. The expert group on data-based quality assurance in additive manufacturing played a leading role in the development of a draft standard, which will be submitted at ISO level following further discussion.

DIN and DKE founded a joint **DPP committee** in summer 2023, in which the QI-Digital initiative is also represented. It is thus actively involved at the interface between the manufacturer's application and the necessary mapping of evidence for placing on the market, in particular with regard to **conformity certificates** from third parties.

### NETWORKS

Knowing the requirements and practices of users and stakeholders from industry and administration is the basis for developing market-orientated solutions. The QI-Digital initiative therefore relies on a strong and active network of interested stakeholders. The annual **QI-Digital Forum** is the central platform that enables stakeholders from the field of QI and the interfaces to politics, business and society to inform themselves about the state of digitalisation, exchange ideas and network. We are also involved in exchanges with specialist organisations and associations.

**Conformity assessment** is a key pillar of our QI. In order to gain an even better understanding of the expectations, needs and experiences with regard to digital QI tools and procedures from the perspective of testing and calibration laboratories, we are establishing "practical workshops for laboratories". Co-creative workshops enable targeted exchange and dialogue in order to further develop the work and offerings of the QI-Digital initiative in a practical way.

The global acceptance of the solutions developed as part of QI-Digital is important for their success. For international networking, QI-Digital is therefore in close dialogue with the BMWK and BMZ **Global Project Quality Infrastructure** (GPQI) initiative, for example. A working group of the advisory board also deals specifically with the topic of internationalisation and develops corresponding priorities and strategies.

## ACCOMPANYING RESEARCH

The QI-Digital initiative sees itself not only as a developer of technical solutions for a digital quality infrastructure. Rather, essential framework conditions must also be created for a successful transformation. In addition, the initiative is an ambassador for a better perception of QI and its services as well as their design. To this end, various studies are being conducted as accompanying research as part of QI-Digital.

- **Suitability of the legal framework for digitalised QI:** hurdles and solutions (including use of real-world laboratories for regulation and innovation)
- **Economic importance of QI:** Quantitative assessment of the contribution of QI to the German economy and society
- **QI 2035 trend study:** Development of future scenarios for QI against the backdrop of digitalisation and other influencing factors
- **Status of digitalisation in conformity assessment:** Empirical study in Germany and 15 other countries

## Collaboration:

Important foundations have been laid. However, the successful further development of the digital quality infrastructure is inconceivable without the participation and commitment of politics, business and society, i.e. all relevant QI stakeholders.

### *Be part of it!*

Share your questions, requirements and ideas with us. Try our solutions and let's further develop the digital QI together.

Contact: **info(at)qi-digital.de**



## *ORGANISATION AND STRUCTURES*

The joint work in the QI-Digital initiative is managed by cross-institutional bodies: A **steering committee** consisting of the heads of the participating institutions, a **coordination team** as the operational body of the initiative, and an **office** for administrative and organisational support.

These structures ensure the connection with **politics, business, science and society** as well as the **networking with other important projects, platforms and standardisation activities**. The technical and strategic advice on market integration, global orientation and application-orientated activities provided by the initiative's **advisory board** with members from business, research, politics, society and authorities supports these objectives. The **Federal Ministry of Economics and Climate Action** (BMWK) and the **Federal Ministry of Labour and Social Affairs** (BMAS) are represented on the advisory board as permanent guests. The advisory board focuses in particular on the topics of strategy and internationalisation, use cases and tools, as well as the regulatory framework.

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The QI-Digital initiative is supported by BAM, DakkS, DIN, DKE and PTB.

Supported by:

Bundesministerium für Wirtschaft und Klimaschutz

BAM Bundesanstalt für Materialforschung und -prüfung

DAkkS Deutsche Akkreditierungsstelle

DIN

DKE

PTB

Status: 02 / 2024