QI DIGITAL

October 2023

QUALITY–X: A FEDERATED DIGITAL ECOSYSTEM FOR THE FUTURE QUALITY INFRASTRUCTURE

www.qi-digital.de

QUALITY–X: A FEDERATED DIGITAL ECOSYSTEM FOR THE FUTURE QUALITY INFRASTRUCTURE

Production and trade within increasingly complex value networks, the ongoing digital and green transformation, and technological innovation rely heavily on the assurance and efficient proof of the quality, safety, and environmental sustainability of goods, services, and processes. Indispensable for this is a modern and powerful quality infrastructure (QI).

A QI with digital tools and procedures can enhance quality management processes in enterprises and facilitate an integrated, smooth provision of quality information across value chains – including customers, authorities, and other stakeholders of the QI. Digital QI solutions provide opportunities for efficiency gains and additional value creation.

QUALITY INFRASTRUCTURE (QI)

The QI constitutes a well-established system that comprises all necessary organizations, both public and private, as well as the requisite policies, relevant legal and regulatory frameworks, and practices needed to support and enhance the quality, safety and environmental soundness of goods, services and processes. It builds on metrology, standardization, conformity assessment, accreditation, and market surveillance. (UNIDO, 2021)

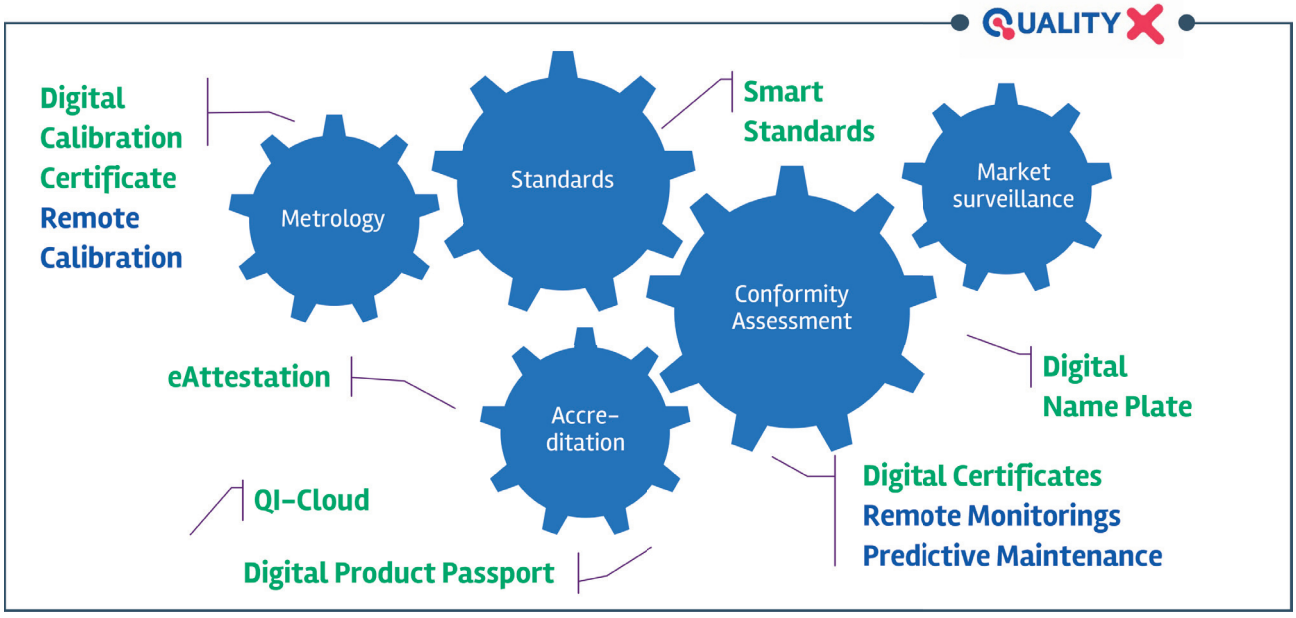

Fig. 1: Vision of a digital quality infrastructure

Harmonized and interoperable national QI systems are essential for fostering cooperation, promoting mutual trust, and facilitating trade. The true potential of the QI is realized when its elements and actors are seamlessly integrated into a cohesive digital QI ecosystem. Recent developments towards industrial international data spaces enable such an ecosystem but require the integration of QI principles. Recognizing the lack of such a platform, Quality-X aims at setting the stage for the implementation of a QI ecosystem in international data spaces (IDS), GAIA-X and related German and European projects dedicated to secure data sharing. Quality-X is not about the construction of a platform; it is the creation of an inclusive QI ecosystem with harmonized interfaces. Instead of imposing rigid data structures, it prioritizes interoperability. Through the utilization of Decentralized Identifiers (DIDs), Verifiable Credentials, and Identity Hubs, Quality-X seeks seamless interactions across diverse service provider systems.

This white paper outlines the prevailing challenges associated with the digitalization of the QI. The document serves as a starting point for discussions, initiating collaboration, and gathering feedback from stakeholders and interested groups within Germany and Europe. We here introduce the vision of Quality-X and discuss the general prerequisites for integrating QI processes within data spaces. Further on, we introduce existing testbeds, which will serve as an experimental proving ground for exploring various use cases related to the implementation of the vision of a QI-Digital.

QI-DIGITAL INITIATIVE

A consortium comprising the five central QI players in Germany steers the initiative "QI-Digital" to foster the digital transformation of QI. Through real-world pilot projects digital tools and digitized processes for a more efficient and future-proof QI are being developed and tested.

These tools include machine-readable standards and certificates, electronic seals, and accreditation statements as well as cloud-native interfaces to services.

QI-Digital.de

Towards an Integrated Quality Infrastructure System

At the core of Quality-X lies the ambition to make trust universally accessible to a wide range of stakeholders – from governmental and private organizations, small and medium enterprises, to users that require high-quality and safe products. This goal can be achieved by establishing a QI ecosystem that comprises interfaces, digital assets, and services accessible to providers and users throughout the entire product lifecycle. The initial use cases considered for Quality-X will represent diverse scenarios, including QI applications for modern production facilities, technical establishments, and accredited laboratories. For each use case we investigate the roles, operations, and requirements necessary for implementation within a data space framework.

QI-Digital encompasses several initiatives aimed at transforming legacy QI documents and workflows into their digital counterparts and developing new digital solutions. Quality-X aims at formulating the backbone of an appropriate digital ecosystem to leverage the full poten-

tial of these innovations. Based on the general principles and technologies of IDS's federated services, Quality-X streamlines and harmonizes the entire validation process while maintaining compatibility with legacy systems.

IDS offer various basic services, which serve as building blocks for Quality-X: semantic hubs, identification providers, clearing house, and vocabulary provider are among the essential components facilitating data interoperability, integration, and accessibility. Based on seamless integration and communication within and between data spaces, our aim is to break down silos and ensure that QI assets can interact and integrate seamlessly. Moreover, Quality-X envisions the establishment of a harmonized and unified digital QI. By leveraging a federated concept framework, we aim to bridge the gap between private and public markets. This not only facilitates more straightforward collaboration but also paves the way for innovations. Central to this vision is the use of decentralized identity systems and verifiable credentials, ensuring the authenticity and integrity of all participants at each stage of the process.

DESCRIPTION OF IDS SERVICES

A **semantic hub** provides fundamental meaning to data and their relationships, relying on semantic models.

An **identification provider** is a service that enables authentication within the IDS.

In IDS, a **clearing house** acts as an intermediary between data owners and consumers.

A **vocabulary provider** is a service that provides domain-specific terminologies.

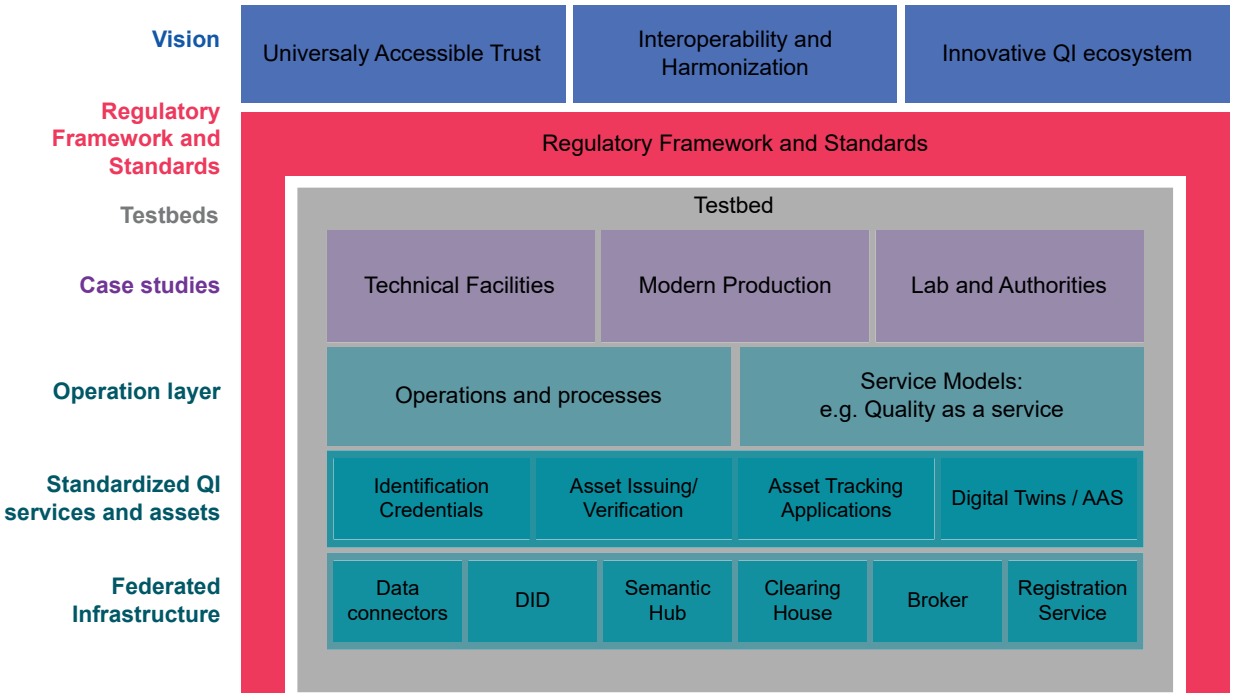

Fig. 2: The general architecture of the Quality-X project is structured across distinct layers: from overarching vision and strategic direction to regulatory frameworks and, finally, dedicated testbeds to bring all elements to life.

Quality–X as a Modern and Trustworthy Digital Framework

The Quality–X framework should seamlessly integrate various components, actors, and assets to create a unified, efficient, and transparent environment. Therefore, the Quality–X concept builds upon the existing fundamental elements of IDS:

Functional agreements in a digital QI must contain specifications of services such as calibration, conformity assessment, or accreditation. Each service should have a well–defined definition of processes and roles associated with it, often outlined in regulations or defined by standards. Consequently, functional agreements need to reference their regulatory basis in a traceable manner.

Technical agreements in a digital QI contain definitions of interfaces, data formats, and semantics to ensure interoperability between different organizations within the QI, as well as for the interoperability of QI statements and services with other infrastructures. Frequently, international standards and regulatory documents specify corresponding requirements for these technical agreements.

Operational agreements for digital QI processes must ensure that their origin and outcome are documented in an unambiguous and trustworthy way. Typically, access to data and information relies on well–defined roles, such as market surveillance officers or accreditation auditors, and these roles should be clearly defined in operational agreements.

Legal agreements on data exchange for digital QI processes in data spaces can often be derived from existing legal agreements based on roles and responsibilities in the QI. Transitioning from traditional QI legal agreements to digital QI processes in data spaces presents challenges. The digital landscape amplifies concerns around data privacy, interoperability, jurisdictional variances, and intellectual property rights. Additionally, the redefinition of roles, enforceability of digital contracts, and complexities in liabilities and dispute resolution require attention.

Commercial assumptions in a digital QI are of relevance for all QI services provided by private organizations. For instance, product testing, conformity assessment and calibration services are often provided by companies. The corresponding assumptions for their integration in a data space must take into account the need for

authentication and accreditation of such service providers. A calibration service in regulated areas, for example, can only be provided by a company that has a corresponding accreditation.

Liaisons agreements are an important factor for digital QI processes because services and certificates are typically part of international agreements, treaties and regulations in trade and commerce.

SOLUTION FOR TRUSTWORTHY CERTIFICATES

Counterfeit certificates for products pose a significant economic and safety concern. Quality-X aims to provide trustworthy, reliable, and tracible information to companies and their partners along the value chain, also serving authorities, certification bodies, testing laboratories, and accreditation bodies.

By employing decentralized identity systems and verifiable credentials, Quality-X efficiently ensures the authenticity of a digital certificate, the issuing body, and its accreditation status.

Quality-X aims to weave a digital QI framework into existing initiatives to leverage developed functionality and gain acceptance among industrial stakeholders. For this purpose, GAIA-X on the infrastructure level and International Data Spaces (IDS) on the data level represent initiatives to automate data sharing following European values across organization boundaries. These principles underpin the general concept of Quality-X.

Quality-X implementations make use of building blocks from existing initiatives, for instance, from Catena-X, which represents the most advanced GAIA-X implementation. These initiatives share some general processes with the QI. For example, conformity assessment bodies (CAB) authorized by Catena-X certify software, services, and processes to be compliant with the Catena-X requirements. The trustworthy integration of digital QI-related assets, e.g., digital certificates, smart standards, or system of units, with third-party validation has not yet been communicated.

Manufacturing-X is a recent lighthouse project utilizing the GAIA-X/IDS stack, launched in Spring 2023. It implements cross-industry data spaces of Industrie 4.0, focusing on improving production processes and supply chains. While the project discusses data sharing between organizations, aspects of conformity assessment methods have not yet been implemented and are outlined as future tasks.

The Asset Administration Shell (AAS) serves as the backbone of the German Industrie 4.0 initiative and is an integral part of Quality-X. Various sub-models follow a defined scheme that allows them to hold multiple instructions, files or references, such as construction plans, certificates, or manuals, for specific assets. For instance, a new initiative under the project “Interopera” is developing a sub-model for the interface to digital calibration certificates (DCCs).

QUALITY-X EXAMPLE: DIGITAL CALIBRATION CERTIFICATE (DCC)

A conformity assessment body validates device operations based on a calibrated reference using a Digital Calibration Certificate (DCC), which is electronically signed and integrates the DAkkS eAttestation symbol. The DCC metadata is registered with a service, maintaining the calibration information over the device's lifecycle. This enables real-time tracking of a product's manufacturing stages and machine settings, offering a customized, machine-readable response to the recipient.

Moreover, at the Hannover Fair 2023, DIN/DKE showed an implementation of smart standards interfaces based on AAS.

The integration of QI into data spaces holds the potential to introduce novel services and transform existing services and roles, including:

- **Broker services** could act as a directory service, facilitating participants discovering each other and ensuring secure data exchange.
- **Identity providers** could play a crucial role in validating and verifying the identities of participants, ensuring trustworthiness and mutual recognition.
- A **clearing house** could act as a logging service, serving as a tamper-proof bookkeeping service for recording data sharing interactions.
- **Connectors** could enable secure data exchange between participants, ensuring data sovereignty and protection.

The requirements for QI processes in data spaces must address the exchange of sensitive information among a restricted community regarding regulated products and services within legally guided processes to guarantee confidence in the safety and quality of products and to protect the customers and users. These requirements are largely governed by European directives within the New Approach (COM2016/C272), which sets up a quality infrastructure for products, such as 2014/31/EU and 2014/32/EU, and regulations, such as 765/2008 and Decision 768/2008/EC.

Several digital solutions, commonly referred to as digital assets, are currently under development within or in consultancy with the quality infrastructure:

- **Smart Standards** which enable machine-readable access to standardization, ensuring dynamic adaptability and digital integration of standards.

- **Digital Calibration Certificate (DCC),** providing machine-actionable digital access to measurement quality information of measuring instruments and tools.
- **Digital Certificate of Conformance (D-CoC)** offering machine-readable access to information regarding product validation in compliance with regulations and standards.
- **QI Cloud**, serving as prototype of a federated secure infrastructure for the digitalization of processes within the QI.
- **Digital Product Passport (DPP)**, which serves as a digital representation of products, providing details about their lifecycle, components, and conformity status.

Quality-X aims to integrate these developments with IDS to create an efficient and versatile digital ecosystem for quality infrastructure. While IDS is employed within the framework of GAIA-X, Quality-X is designed to be inclusive of various technologies and strives for global interoperability with other systems. In this context, digital assets such as DCC and Smart Standards, as mentioned above, will become interoperable for use in diverse systems.

Quality-X Testbeds: An Experimental Ground for Collaboration

While Quality-X builds upon the fundamental principles and architectures of IDS, reference implementations and testbeds are necessary for the development of QI-specific assets and processes. The complexities and nuances inherent in individual sectors demand tailored solutions. While generic architectures provide a foundational basis, they often overlook the intricacies of specific sectors. Sector-specific testbeds, tailored for QI, ensure that solutions are not only theoretically sound but also practically viable, efficient, and effective. Moreover, testbeds enable QI stakeholders to develop, redefine and test their processes and to issue, distribute, track, and verify digital assets, ranging from digital product passports to smart standards and digital certificates, within a realistic environment.

As a starting point, we consider two approaches for the provision of experimental and demonstration grounds to initiate collaborations and develop reference implementations. One testbed builds upon the PTB initiative of a **"European Metrology Cloud"** and the "QI Cloud" initiated in 2017. The other testbed implements and directly adapts existing IDS components, integrating principles and processes from Quality-X, as further outlined in this white paper.

For the QI-Cloud, the same general principles as

for the IDS were underpinning the development from the beginning: data sovereignty, secured processes, distributed data sources, and a data service infrastructure. The current implementation of the QI Cloud employs a secured node architecture that encapsulates independent services within isolated virtual elements. This approach had the advantage of a simplified development based on common data schemes, highly efficient process interconnections and streamlined testing and validation.

For the **Quality-X testbed**, BAM and PTB are currently working on a novel reference implementation. This implementation provides a federated system of potentially distributed elements orchestrated in accordance with the same principles as IDS. This approach offers the flexibility to pilot innovative approaches for evaluating Quality-X concepts independently of existing IDS component implementations.

Quality-X Case Studies for Illustration

As the QI-Digital project develops guidelines for the integration of QI processes into existing software systems, concrete case studies serve as real-world scenarios for prototype implementations that showcase the application and benefits of Quality-X by an integration into data space architectures.

CASE STUDY "QUALITY-X FOR TECHNICAL FACILITIES"

Complex technical systems now offer more comprehensive status data thanks to affordable and multifaceted sensors that are connected through standardized protocols. Within QI-Digital, BAM is establishing a hydrogen refueling station (HRS) testbed to investigate trustworthy and safe operational parameters. These parameters serve as the basis for recommendations that will eventually be translated into not yet existing standards. Thereby, various aspects are covered with novel QI approaches, including targeting storage for structural health monitoring, sensors for predictive maintenance, and system view as a digital twin approach of an entire HRS instance.

Digital assets, such as a Digital Conformity Certificate (D-CoC) or Digital Product Passport (DPP), document measurements or evaluations of physical components, production processes, or service procedures. In this context, novel challenges arise, including the digital transformation of trusted publications, the **secure and tamper-proof maintenance** of asset lifecycle metadata as well as real-time validation and verification within a federated framework.

Further, Quality–X explores new functionalities that emerge as traditional certifications transition into trustworthy, queryable digital assets, each with its own lifecycle.

CASE STUDY "QUALITY–X FOR MODERN PRODUCTION"

While mass production processes are mostly well–defined and equipped with quality measurements at many stages, individual part creation via layer–based Additive Manufacturing (AM) faces challenges related to conformity assessment methods and **data management** during the build process. Within QI–Digital, BAM is establishing an AM living laboratory, which serves as a platform for conducting research for safe and quality–assured printing processes using various methods and metal alloys. Given the limited reproducibility of AM processes, data management becomes crucial in the quest to develop reliable parameters for printing processes that can subsequently be translated into standards. In addition, efficient data aggregation and reduction options must be identified to balance data economy and stakeholder interests. Finally, data lifecycle definitions must account for storage requirements, quality of service aspects, and access constraints.

Quality–X interfaces order–related material and process data, instance–related machine certification containing built–in sub–components, applied smart standards, in–situ and ex–situ evaluation data. Providers may be distributed across different organizations, making trustworthy data sharing mandatory to address concerns related to both safeguarding trade secrets and ensuring transparency regarding product safety.

CASE STUDY "QUALITY–X FOR REGULATED PROCESSES"

For quality management purposes and due to regulatory requirements in certain areas, regular re–calibration or re–verification of products becomes necessary. As a concrete example, PTB considers the use case of requesting and performing the regular re–verification of a measuring instrument under the European Measuring Instrument Directive (MID) and the corresponding German laws. The objective is to efficiently implement the process of issuing re–verification requests for a series of measuring instruments, leveraging the distributed QI Cloud infrastructure and its further development into a federated Quality–X framework.

Information and data about the processes in this case study are stored in a fully distributed manner using the existing "Metrology Cloud Nodes". A central digital representation of the product summarizes this information, while keeping the original data at its respective sources. With this approach, innovative concepts such as interconnection of audit information and other novel concepts will be investigated. The existing framework uses encapsulated modules that will be further developed into an architecture following the Quality–X concepts.

Summary and Outlook

The Quality-X initiative represents a significant step toward establishing a comprehensive digital quality infrastructure. The outlined goals underscore the QI-Digital initiative's commitment to holistic transformation. Central to Quality-X is its framework, which serves as the scaffolding upon which the initiative is built. The testbeds, tangible manifestations of Quality-X's practical approach, offer a controlled environment for rigorous testing, validation, and iterative refinements. Diverse use cases and digital assets further highlight the versatility and adaptability of the initiative, ensuring it remains responsive to industry-specific challenges.

The success of Quality-X hinges on collective participation. We extend an earnest invitation to stakeholders across the QI spectrum: Engage, contribute, and be a part of this pioneering journey. Your insights, experiences, and collaboration are invaluable in ensuring that Quality-X will develop the necessary components and services to truly realize its vision and potential.

QI DIGITAL

Contact

QI-Digital Office
c/o Physikalisch-Technische Bundesanstalt (PTB)
Bundesallee 100
38116 Braunschweig

info@qi-digital.de
www.qi-digital.de

QI-Digital is an initiative by BAM, DAkkS, DIN, DKE, and PTB.

Supported by:

Bundesministerium für Wirtschaft und Klimaschutz

October 2023