

A digital Quality Infrastructure for testing and calibration laboratories: from theory to practice

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Abstract – The digital Quality Infrastructure (QI) offers significant potential to enhance the technical excellence and efficiency of laboratory operations. By leveraging tools and processes of a digital QI, laboratories, their customers, authorities, and other stakeholders can enhance efficiency, foster trust, and generate added value. This paper introduces the digital QI toolset and ecosystem as developed in the German initiative QI-Digital, and explores concrete scenarios for their implementation in laboratories. Successful rollout not only requires technical development but also intense stakeholder engagement. Consequently, this paper shares insights and outcomes from a structured stakeholder dialogue with the laboratory community, and outlines the establishment of the 'digital LabHub' as a pivotal step to drive digital transformation and facilitate the widespread adoption of digital QI within laboratories and their broader ecosystem.

I. INTRODUCTION

The digital transformation of laboratories encompasses a wide range of topics and fields of action such as seamlessly connected labs, data-driven services, and AI-supported analyses. They redefine laboratory services elevating them to a driver of efficiency and product innovation. Gains in productivity and enhanced technical excellence free up resources to foster innovation throughout the entire value chain. Also tools and processes of a digital Quality Infrastructure (QI) promise to empower laboratories, their clients, regulatory bodies, and other stakeholders to collaboratively boost efficiency, build trust, and generate added value. In the German initiative QI-Digital such digital QI solutions are being developed, putting particular focus to their transfer and application in laboratories and their community through stakeholder dialogues and targeted measures [1, 2, 3].

This paper presents a concise overview of the toolbox of a digital QI and describes a vision for their use in laboratories' testing and calibration workflows. We then report insights from a structured dialogue with the laboratory community on requirements and obstacles with regard to the implementation of a digital QI [1, 2]. As one outcome from this process, we conclude by introducing the community-building initiative 'digital LabHub' that aims

at supporting the roll-out of a digital QI and digital transformation in laboratories in general.

II. BACKGROUND: DIGITAL QI FOR THE DIGITAL LABORATORY BUSINESS OF TOMORROW

Tools and processes of a digitally enhanced QI can unlock significant potential for everyday laboratory operations. This section briefly presents the tools and digital ecosystem as developed by the initiative QI-Digital. Their use is being illustrated in a vision for two basic everyday processes in calibration and testing laboratories.

A. QI-Digital Toolbox and digital ecosystem for QI

The toolbox of a digital QI aims to offer advanced, machine-readable versions of documents that are integral to routine laboratory processes, which are traditionally utilized in paper or PDF formats. This encompasses machine-readable versions of standards (SMART Standards [4]) and **quality documents**, integrated into digitally connected processes. Quality documents include the **Digital Calibration Certificate** (DCC) [5], the **Digital Certificate of Conformity** (D-CoC) [6], **Digital Reference Material Document** (DRMD) [7] and their media break free integration into everyday laboratory and production processes [8]. While currently schemas are being developed for these documents in separate projects (though informed by each other), an overarching, modular **DX Schema** from which many quality documents (incl. e.g. Digital Test Reports (DTR)) can be derived promises further simplification and ease of use [9,10,11]. The **digital accreditation symbol** as developed by the German accreditation body DAkkS, applied to any such digital quality document gives proof that it was issued by an accredited body within its designated scope. With this, reports, certificates, or any other quality documents become fully machine-readable and secure tamper-proof **eAttestations**.

To realize their full potential, these tools must work seamlessly with each other, which requires i.e. harmonized semantics and terminologies. Moreover, smooth data and information exchange between different players in the value chain, including customers and authorities, necessitates integration into higher-level data ecosystems. A broad **digital ecosystem for QI** can be leveraged by

existing standardized platforms and technologies for sovereign and secure data management and transfer. This includes the **Asset Administration Shell (AAS)** [14,15] for QI-related applications (such as quality documents) and solutions for the sovereign data exchange via industrial **international data spaces** [13]. This toolbox embedded into a comprehensive digital ecosystem will not only contribute to more efficient and secure conformity assessment services, documentation and provision of proof of conformity. It also enhances end-to-end traceability and can constitute an enabler for a successful implementation of the **Digital Product Passport (DPP)**.

B. Characteristics of the digital QI in calibration and testing laboratories

Currently, interactions between laboratories, their customers, and regulatory authorities often involve telephone calls, individually written emails, printed documents, and documents sent by post or fax, which are then filed by all parties. Manual data handling to transfer information from documents into systems at various stages of the process costs unnecessary resources that could be devoted to **higher-value tasks**. Creating digitally interoperable workflows among stakeholders will replace this patchwork with seamless, end-to-end interactions.

The vision for a digital QI in laboratories can be encapsulated in six key terms: automated, transparent, secure, integrated, networked, and competent. Leveraging digital tools to automate processes, the speed of testing and calibration procedures can be significantly increased. Many steps could be performed without human intervention, boosting capacity and laboratory throughput while minimizing errors from manual handling [1,2]. Also, end-to-end traceability of e.g. calibration orders—paired with automatic status alerts—gives everyone complete transparency: each job can be monitored in real time, and customers immediately see whether their instrument is queued, being calibrated, or ready with results.

In the following we describe two examples for processes that make use of the digital QI tools and ecosystem as is currently being developed, illustrating the benefits they offer.

The future process for calibration

1. Calibrating sensors and measuring instruments is among the most time- and cost-intensive routine tasks for many companies. The process often relies on manual ordering steps, media discontinuities, and repeated data entry—tying up valuable resources and limiting transparency. Digital QI tools such as the Digital Calibration Request (DCR), SMART standards, and the DCC can automate this workflow end-to-end and integrate it seamlessly into existing ERP, production, and quality-management systems. The following scenario illustrates what a fully digital calibration chain could look like—from automated

reminders of upcoming calibrations and machine-readable ordering, to verified feedback of results and their immediate use in production. A company receives an automatic notification in its ERP system indicating that the calibration interval for a sensor in a production facility is nearing its end. In response, they begin reallocating production capacities and removing the sensor.

2. A Digital Calibration Request (DCR) is automatically created in a standardized format applicable across all industries. It includes essential information about the sensor to be calibrated, such as its type/model, serial/identification number, and other relevant data. Additionally, it specifies the calibration details, including the standard to be used, measuring range, tolerances for measurement deviations and uncertainties, and any special features.
3. The company places an order directly from their ERP system through an interface to their calibration partner's order platform, providing all necessary data via the DCR. They receive a tracking number to monitor the sensor throughout the calibration process.
4. The sensor to be calibrated is either removed and sent to the accredited calibration laboratory or accessed remotely by the laboratory. The laboratory assigns it to the appropriate order using the DCR and the sensor's serial number. The current calibration standard for the sensor type and use is loaded in machine-readable form (SMART standard) via an interface to the standard-setting organization and fed into the calibration laboratory's devices. The calibration process is largely automated, allowing the customer to track progress and plan accordingly.
5. Upon successful completion of the calibration, the accredited laboratory automatically generates the DCC, which includes detailed data on the sensor, the calibration performed, a direct reference to the SMART standard used, and the measurement deviations determined. The certificate is cryptographically signed with a digital accreditation symbol, making it an eAttestation.
6. The customer is automatically notified when the calibration is complete. They can access the DCC through a portal with a mailbox function, an interface, or by providing it via a federated data space, where they can also view previous calibrations.
7. The sensor is returned to the customer (if it was calibrated in the laboratory) and reinstalled in the production system. The DCC, as an eAttestation, is digitally validated to ensure authenticity and integrity, confirming the validity of the accreditation, the authenticity of the laboratory, and the integrity of the data. The production systems then automatically adjust the sensor's measured values based on the calibration and re-evaluate the measurement uncertainty. With previous calibration results available in machine-

readable form, long-term drift can be corrected effectively and automatically. If the uncertainty increases unexpectedly, an automatic alarm is triggered, prompting recalibration or other measures. Using the collected calibration data, the laboratory and customer can plan which sensor needs calibration next and when, allowing the customer to schedule their production accordingly.

The future process for testing requests

The second scenario shows how an accredited testing laboratory can provide its customers with a fully digital, end-to-end service—from sample submission to globally verifiable results—within a connected data ecosystem. Digital QI tools and ecosystem together with AI, can streamline every step of the analytical testing workflow, from AI-guided ordering and automated data capture to machine-readable, tamper-proof certificates, eliminating manual hand-offs and increasing transparency and shortening turnaround times for both laboratories and their customers.

1. The customer accesses the web portal of the (accredited) laboratory where AI assists them in selecting the appropriate analysis service and placing the order directly through the shop system. Alternatively, the customer could find a suitable service provider via data space marketplaces. An automatic test plan is generated and provided to the customer, along with a tracking code to label their samples.
2. The customer submits the samples to the laboratory and can track the progress of their order using the tracking code.
3. The laboratory processes the order, from sample preparation and analysis to result validation, with all data stored digitally in a standardized system. Results are automatically recorded, and AI helps validate them before final review by a laboratory specialist.
4. Once the results are ready, the laboratory creates a machine-readable test report (DTR, compatible with ISO 17025). The DTR includes detailed information for interpreting the results in a human-readable format and standardized administrative and result data in a machine-readable format. It is sealed with a digital accreditation symbol, making it tamper-proof and verifiable worldwide. Additional certificates of conformity are automatically generated using the laboratory data if needed.
5. The DTR and other documents are made available to the customer through the laboratory's web portal*, an interface, or a federated data space. The customer can use the machine-readable certificates in their own systems or provide them to regulatory authorities as proof of conformity.

*The web portal must currently be equipped with a mailbox function, as ISO/IEC 17025 requires the report to be *issued*. The DAkkS interprets that the laboratory must *send* the report to the

customer. Accordingly, a portal solution is only possible if there is a mailbox function as a "digital mailbox".

While many industry stakeholders already engage in the development of and integration in data spaces (see Manufacturing-X, Catena-X, etc.) they also hold huge potential for laboratories as part of larger value chains and ecosystems. Integration in data spaces not only enables the sovereign and trustworthy provision of data (results, certificates, ...) and the offering of services via data space marketplaces. Data spaces can connect all actors involved in the process chain (laboratories, customers, authorities, ...) and promote new usage paths for data, services and new business models, fostering innovation and the reduction of bureaucratic burden in regulatory compliance and information obligations [13].

To put these workflow scenarios for testing and calibration laboratories that make use of a digitised QI, embedded into a digital ecosystem, into action, concrete laboratory requirements and potential obstacles need to be understood. To this end, we invited the laboratory community to a structured dialogue [1, 2]. Section III illustrates the process and outcomes.

III. LABORATORIES AND THE WAY TO DIGITAL QI: STAKEHOLDER DIALOGUE

The laboratory sector is highly diverse—with diverse fields of action, different sizes, private and public—yet every laboratory remains a cornerstone of QI, with services along industrial value chains and for the public-good (such as health and consumer protection). This makes them pivotal in the practical implementation of a digital QI. Proactively involving them and their direct ecosystem (customers, suppliers, authorities, etc.) is thus vital for the successful adoption of digital QI tools and processes.

But how can the laboratory world be successfully and sustainably digitalised? What does this mean in concrete terms? Where are the obstacles and hurdles on the way to digital laboratory work? And what does it take for the industry to transform its workflows, tools and processes and take the next steps towards end-to-end digitalised processes and new business models?

Workshops: Background

To answer these questions and to support the involvement of laboratories into the development of the digital QI, a structured stakeholder engagement process was initiated by BAM, supported by the German accreditation body DAkkS and the German Association of Independent Laboratories (VUP). The multi-event dialogue format 'Digital Quality Infrastructure in Testing and Calibration Laboratories – From Trend to Daily Business' had 102 participants from 55 organizations representing various sectors (Table 1). The majority were from private sector laboratories, including both independent and industry-owned labs, followed by public laboratories, state authorities, measurement/laboratory equipment manufacturers, IT service providers, software

providers, and associations. This diverse representation allowed for a multi-perspective approach [1,2].

Table 1. Participants in the QI-Digital stakeholder dialogue according to their type of organization [1,2]

Organization	Percentage
Private laboratories	60 %
IT service and software providers	9 %
Associations	3,6 %
Public laboratories	5,5 %
State authorities	1,8 %
QI-Digital and partner	5,5 %
Measurement/laboratory equipment manufacturers	7,3 %
Others	7,3 %

The workshops offered presentations on digital QI solutions as well as guided discussions and working sessions, aimed at better understanding the **requirements** from the perspective of the laboratories and their extended ecosystem regarding the tools and processes of a digital QI. Furthermore, the identification of **hurdles** for implementing accordant solutions and the deduction of **recommendations** and concrete measures for supporting the digital transformation of laboratories were central goals of the dialogue.

Key Insights from the Workshops: Challenges, Barriers, and Recommendations

The workshop revealed that laboratories are aware of potentials that come with digital transformation. Two stand out specifically:

- higher efficiency through accelerated processes and reduction of error sources, and
- greater attractiveness for skilled workforce through automated data handling and documentation that allow focus on more demanding tasks.

This would set free financial, time and personnel resources to engage in the further development and optimization of existing processes and services as well as the development of new business models.

The needs and requirements with regard to a digital QI for laboratories and digital transformation at large that were identified in the practical workshops are quite diverse and complex. However, **four key areas** have emerged as the focal points for the most pressing challenges: "regulation," "tools/IT architecture," "networks/knowledge," and "business development." [1,2].

Key area 1: Networks and Knowledge

Participants emphasized that a lack of structured, accessible knowledge is a major barrier to digital transformation. Many laboratories—particularly small and medium-sized ones—struggle to keep pace with

technological developments due to limited awareness of available tools and their practical benefits. Moreover, the QI ecosystem is characterized by siloed structures and insufficient peer exchange. Thus, workshop participants emphasized the need for a stronger knowledge base and networks for exchange to enable an effective dissemination of digital expertise.

To address these issues, several priorities were recommended:

- A central, low-threshold information hub offering technical updates, best practices, and training resources;
- Modular training programs tailored to different user groups, from lab technicians, quality managers, to decision-makers;
- Peer-to-peer exchange platforms and regional forums to foster collaboration and mutual learning.
- “best practice showcases” to highlight successful digital implementations and their economic impact.

Participants stressed the importance of fostering a culture of collaboration and mutual support across the QI ecosystem. This includes breaking down silos between laboratories, regulators, and technology providers, and encouraging interdisciplinary dialogue on challenges and solutions. These measures are seen as essential to building a culture of digital competence and shared innovation across the QI.

Key Area 2: Tools and IT Architecture

The participants highlighted the challenge of fragmented digital solutions and a widespread reliance on proprietary, non-interoperable systems that hinder scalability and integration. Many laboratories report having to use custom-built solutions that are difficult to maintain or connect with external systems and existing workflows. Moreover, many digital tools are criticized not being designed with end-users in mind, making them not user-friendly, particularly for non-IT specialists.

Key requirements for future digital tools include:

- Interoperability through open, standardized interfaces;
- Modular, open-source architectures that allow for customization and integration into existing workflows;
- Intuitive usability to ensure broad adoption across varying levels of digital maturity;
- Co-development formats in which laboratories and developers collaborate on tool design and refinement;
- Transparent publication of APIs, documentation, and source code to support integration and customization.

Such approaches are expected to promote interoperability, reduce redundancy, and ensure that digital tools align with real-world laboratory needs.

Key Area 3: Regulation

The regulatory framework was identified as a critical enabler—or barrier—of digital transformation. However,

this field of action revealed a quite broad scope of challenges, that encompass technical aspects, rules, norms and standards. Laboratories reported that existing norms and procedures are often not compatible with digital processes, and there is no unified semantic framework for data exchange. They would wish for biding standards for procedures and digital implementation. Also, a standardized regulatory framework and less bureaucracy were called for. Moreover, regulatory bodies themselves are not yet fully digitized, which limits the acceptance of digital certificates and processes.

Participants specifically highlighted the need for:

- Internationally harmonized, digital-ready standards and terminologies;
- Mandatory open interfaces to facilitate seamless data exchange;
- A stronger commitment by regulatory institutions to digitize their own processes;
- Interdisciplinary working groups to align regulatory updates with practical needs.

Key Area 4: Business Development

While the potential of digitalization is acknowledged, many laboratories—especially SMEs—lack the resources and strategic foresight to develop new digital business models. There is also a lack of concrete evidence on the return on investment (ROI) and other benefits of digital transformation, which hampers broader adoption. This was highlighted especially with regard to the still lacking customer demand for digital QI tools like DCC. Missing best practices and blueprints of success stories as well as missing support for innovation are further challenges.

To stimulate innovation, participants proposed:

- Dedicated “Business Camps” and “Innovation Labs” to co-create new services and models;
- ROI case studies and best-practice blueprints to inspire and guide implementation;
- Stronger collaboration between laboratories, customers, and technology providers to explore data-driven opportunities such as predictive maintenance and quality analytics.

These actions could help turning digital QI solutions into a driver of innovation and value creation.

Cross-Cutting Perspectives

In addition to the four strategic areas, three cross-cutting perspectives emerged as particularly influential in shaping the path toward a digital QI:

1. Central role of customer requirements

Laboratories emphasized that customer expectations are a key driver of digital transformation. Laboratories report that customers increasingly wish for digital shop systems, continuous traceability of processes and their progress, as well as smooth data exchange. However, demand for aspects of a digital QI such as machine-readable certificates are yet very limited. Communication is often still paper based and highly individual (e.g. excel, PDF, own databases). Often customer requirements are routed in

strict regulatory requirements making their consideration pivotal for a successful digital transformation. Participants stressed the importance of engaging customers early and continuously to align digital offerings with their needs and demonstrate added value.

2. Responsibilities of the laboratory community

Laboratories feel the growing pressure to digitally transform and innovate to stay competitive. The workshops underscored the need for laboratories to take proactive ownership of the digital transition. This includes prioritizing digitalization at the leadership level, investing in staff training, avoiding isolated technical solutions, and fostering inter-laboratory collaboration. A shared commitment to open standards and interoperability was seen as essential.

3. Experience with tools of a digital QI

Awareness of digital QI tools—such as the Digital Calibration Certificate (DCC) and the Digital Accreditation Symbol— as well as the digital ecosystem for QI remains limited. While participants recognized their potential when being presented at the workshop, they called for clearer guidance, better integration support, and regulatory acceptance to facilitate practical implementation.

The workshops demonstrated that the digital transformation of QI is not only a technical challenge but also a cultural and organizational one. Strategic partnerships, harmonized standards, and targeted support measures are essential to accelerate progress and ensure that laboratories can fully realize the benefits of digitalization.

What stood out overall was the need to learn (from each other) and keep an oversight on the technical solutions, their easy implementation and accordant value creation. To this end, two main measures for immediate support were deducted: Building strong partner networks and establishing a central information hub. Thus, based on the insights and recommendations from this dialogue process, the project team of BAM, DAKKS and VUP continued to establish the so-called “digital LabHub” as a first measure. The next section introduces the idea and first steps.

IV. LABORATORIES AND THE WAY TO DIGITAL QI: DIGITAL LABHUB

Stakeholder engagement and information access proved crucial alongside developing digital solutions. Hence, BAM, DAKKS, and VUP have proposed the implementation of the ‘digital LabHub’ as a one-stop shop for knowledge, training, and collaboration on digital QI – and digital transformation of laboratories at large. The basis of the digital LabHub is a community of dedicated actors from all areas of the laboratory ecosystem that join forces to contribute know-how, networks and solutions. The group jointly creates a web platform offering curated information from the topic area, how-to guides, best practices, courses, funding information, events, and a

toolbox of software kits and guidelines.

In a Kick-off Workshop in April 2025 various stakeholders came together to create transparency and identify synergies between everyone's activities, projects and initiatives centred around Lab4.0, FutureLab, SmartLab etc. The gathered information are now being aggregated and analysed to then map the different contributions and their applicability along laboratory processes and ecosystems. While communication with laboratories is now being enforced e.g. through talks and presentations, co-operation with other potential partners, particularly at an international level (e.g. with Eurolab) with a focus on knowledge transfer and interoperability is a key objective.

V. CONCLUSION AND OUTLOOK

The shift to digital QI marks a major advancement for laboratories, offering enhanced efficiency, precision, and reliability in their operations. As a key component of QI, laboratories stand to gain from digitalization but must also actively participate in its development and receive support to integrate it into their daily practices.

This paper gave an overview about the digital tools available through the initiative QI-Digital, and provided a vision of their use in laboratories and their ecosystem. Since the availability of digital solutions for laboratories alone does not guarantee a successful digital transformation, the paper stressed the need for a close stakeholder engagement. The insights and conclusions from our dialogue with the laboratory community should not only aid the QI-Digital initiative in better understanding the requirements and accordingly align the development of technical solutions. We also aim to encourage other key stakeholders in the QI ecosystem, including associations, research institutions, and companies, to utilize these findings and recommendations.

The collaborative approach taken in the subsequent digital LabHub initiative has received enormous positive feedback so far. This joint effort of key players of laboratory digitalization will work to break down silos, leverage synergies, and create intersections between various relevant initiatives and efforts aimed at accelerating digital transformation of the laboratory ecosystem.

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