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VIRTUAL AUDITS IN MEDTECH

A CALL FOR ACTION

Dr. Klaas Rackebrandt | Dr. Stefan Schlichting | Moritz Pfeiffer

Executive Summary

Virtual or remote audits are currently one of the most relevant topics within the Medical Device Industry, especially in times of the corona pandemic (86,4 % of the companies surveyed confirm this relevance). As a result of a virtual panel discussion held with approximately ~150 participants and an accompanying survey, we developed a common position that reflects the medical technology industry standpoint on this topic has been developed within a panel discussion and an accompanying survey.

68,2 % of the participating companies are already conducting virtual audits. Especially in the areas of QMS system audits, CE surveillance audits and supplier audits, these can be and are regarded as a viable alternative, even after the pandemic. Nevertheless, there is a lack of technical standards (information and communications technology (ICT)) for conducting those audits, which must be specified by the regulatory authorities (opinion of 81 % of the participants). Good preparation and digitally available records/documents are key to successful virtual audits. Based upon the experiences from 70 % of the participants so far, no significant time and cost savings can be expected.

Today, the majority of the participants perceive a lack of guidance (98%) and regulation (59,1 %). This regulatory "white spot" means that the backlog of audits at notified bodies is increasing and important products that can help patients around the globe cannot be placed on the market - especially in the case of initial certification audits under the MDR, under the regime of postponement and travel restrictions.

All of the participants agreed that virtual audits cannot completely replace traditional methods, that non-verbal factors (soft skills) are lost and that flexibility is needed from all sides in order to implement those successfully. Nevertheless, even in times of the corona pandemic there is currently no alternative to onsite audits under the MDR to bring safe medical products to the market.

This is a call for action, so that the remaining time can be used efficiently to foster the adoption of virtual or remote audits, where appropriate, and provide guidance to industry and notified bodies, instructing how these audits can be conducted effectively to ensure their ultimate mission of assuring patient safety.

Heiko Visarius
Owner, VISARTIS Healthcare GmbH

Especially for startups, the recent months have been a challenge. Delays in audits can have a tremendous negative impact for early stage companies who are dependent on reaching milestones and gaining market access. Remote audits are a very valuable alternative allowing for some flexibility in the process.

Statements from the Panel

Many thanks to all the participants in this panel discussion: The panel of experts for discussing this topic and for contributing their thoughts to this white paper, as well as the audience.

Oliver Bisazza
Director Regulations & Industrial Policy, MedTech Europe

COVID-19-related travel restrictions have led to postponement of on-site audits, holding back industry's transition to the IVDR/MDR. MedTech Europe is advocating for virtual audits to be allowed under the Regulations, for all devices in any pandemic context. The alternative is to force 'ready' manufacturers to switch back to the former Directives.

Andreas Purde
Director Active Medical Devices, TÜV Süd

During the corona crisis remote audits are sometimes the only possibility to maintain our surveillance responsibilities a notified body. Based on our experience they work better than we originally thought – in case they are well prepared. Once the crisis is over, some remote audits will remain.

Ulf Hagedorn
Head of IMS Audit Management, Quality & Regulatory Affairs, Dräger

Remote auditing is not the "future of auditing". But it is a legit method that should be balanced with other audit methods. It is an adequate instrument in times of a pandemic - and beyond: Future audits in the medical device industry will systematically include remote techniques to ensure surveillance and compliance.

Daniel Delfosse
Director Regulatory Affairs, Swiss Medtech

The companies need and want to be audited because they are working hard to get MDR ready. They cannot afford to waste any valuable time. It is therefore of paramount importance for manufacturers that guidelines for "Remote Audits" are created and the audit activities resume as soon and as remotely as possible.

Michael Bothe
Co-Head of Certification Body Active Medical Dev., DQS MED

DQS Medizinprodukte GmbH actively supports any Initiative to further adapt the Regulatory framework for Conformity Assessment Procedures in Order to include Remote Audits as a relevant Component. Process Audits, however, dealing with the physical flow of material should explicitly be performed on-site in any case.

Dominik Reterski
VP Corporate Quality, Medtronic

Virtual audits are certainly a good example of work which can be done equally successful remotely. Nevertheless, regulatory constraints are the biggest hurdle, limiting the scope of virtual audits, and discussion on overcoming these barriers should continue, as it will position us better for the future challenges long after Covid pandemic is over.

Status quo on virtual audits

There are already many publications and also as well as normative texts discussing "remote audits". However, in these sources "remote audits" are often not defined. In the following, we provide a short overview.

TERMINOLOGY

There is no standardized definition, whereby ISO 19011:2018[1] speaks of remote audits. All common definitions are listed and classified in Table 1.

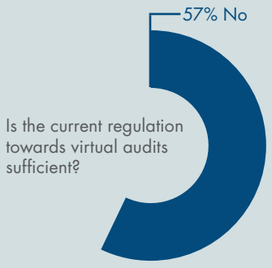
TERMINOLOGY	DEFINITION
Remote Audit	Remote audits refer to the use of ICT to gather information, interview an auditee, etc., when "face-to-face" methods are not possible or desired. Audit performed off-site through the use of information and communication technology.
Virtual Audit	The audit is performed virtually which means that ICT is applied to provide an audit experience as close and flexible as possible compared with on-site audits
Off-site	The audit, or parts of it, is simply completed off-site. This does not define if the audit is conducted remotely via ICT or paper based. The terminology avoids using the term, remote,' as that type of audit is prohibited by regulators for initial certification audits under the MDR. It is possible to split the audit between on-site (< 10 %) and off-site (> 90 %).
Non-on-site	Is the equivalent to using a notified body such as DQS. This covers everything which is not done on-site.

Table 1: Definitions

We recommend using the term "virtual audit", which is in alignment with the recently published paper by Med-TechEurope[2], even though recent publications also speak of Remote Audit. This definition provides flexibility for interpretation but also refers to digitalization technologies such as AR or drones, which can be utilized in order to conduct audits "virtually".

REGULATION

Virtual audits (or as they are called in the standards remote audits) are mentioned in almost all standards or relevant documents e.g. ISO 19011:2018, MDCG 2020-4[3], MDSAP[4], MDD[5], MDR[6] and others. 68,2% of the survey participants already use virtual audits. However, from the point of view of companies, authorities and organisations, regulation is still not sufficient. For example, the MDSAP protocol offers many possibilities for virtual audits, but almost all areas require an on-site part. Especially for MDR initial audits there is a regulatory white spot, that is observed in times of the corona pandemic. In addition to the lack of regulations, 98% of the surveyed participants also find that there is a lack of guidance.



URGENCY

Due to the corona pandemic and its effects such as the associated restrictions for travel, on-site audits, postponement of the MDR, as well as the limited capacity of the notified bodies to carry out MDR audits, there is a need to expand the existing regulations regarding virtual audits and to release guidelines as how to conduct these audits. Both have to be defined by the regulatory authorities. 58 % of the participanting companies think that there will be a high impact on the audit timelines due to the pandemic and under the given regulations.
For the notified bodies, the audit backlog is increasing, which will further complicate the situation for the time after the pandemic. To avoid this impasse, companies will be targeting certification under the directive as soon as possible, which has been replaced by the regulation for good reasons -- to improve patient safety.

"If we not move forward with MDR audits, companies have to go back to MDD instead, which was replaced for good reason by the new regulation"

OLIVER BISAZZA

FUTURE EFFORTS FOR AUDITS

In addition to the described situation resulting from the corona pandemic, the audit requirements will generally change in the future. Due to the MDR requiremeents, there will be a shift towards an increasing number of documentation audits (tech file audits) and an increasing number of audits in general. On the other hand, the landscape of notified bodies is consolidating, which leads to a broad gap in the available capacities. This gap is widened by, among other things, the mismatch between travel time and productivity.

"There is a demand for additional capacity from the perspective of notified bodies. The efforts will double oder triple"

MICHAEL BOTHE

Challenges of virtual audits

Based on the described need for virtual audits as an alternative during and after the corona pandemic, the question arises: What are the challenges for implementation?
From the results of our survey (Fig. 1), two major clusters can be derived (technical requirements and soft facts) besides the regulation itself.

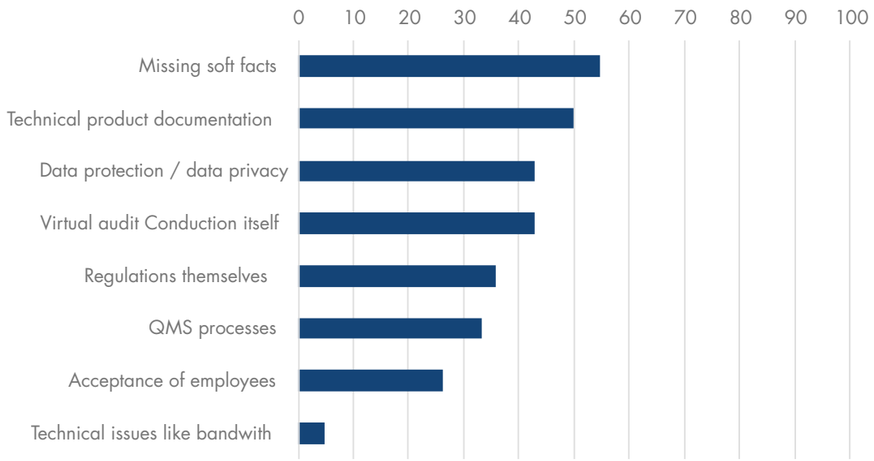


Figure 1: Challenges of virtual audits

TECHNICAL REQUIREMENTS

The technical prerequisites are diverse but can be mastered by modern ICT and the potentials of digitalization. The main requirements arise in the following areas (Table 2):

AREA	CHALLENGES
Infrastructure	Bandwidth, Server, (mobile) Domain Name System (DNS), hosting and networks on both sides
Collaboration	Voice and video with defined quality The company's ability to move around
Data exchange	Secure storage accessible for both sides
Datan availability	Availability of documents in a digital form
Data security and privacy	Data security for every document along the whole process Ensuring employee privacy

Table 2, Collaboration: Using tools, the ability to move around freely within the company and guide the auditor.

"A big challenge is the availability of electronic records, especially for smaller companies"

DOMINIK RETERSKI

54% of the surveyed companies stated that they don't have all of the relevant documents/data available electronically, while the infrastructure is only seen as a problem by 4,8 %.
Since companies often work with several notified bodies and there are no defined ICT standards, different collaboration tools are required.
Nevertheless, 60 % of the participants believe that a sufficient level of data security can be achieved with the common collaboration tools (e.g. Teams, webex…).

"Dräger has four approved collaboration tools at the moment"

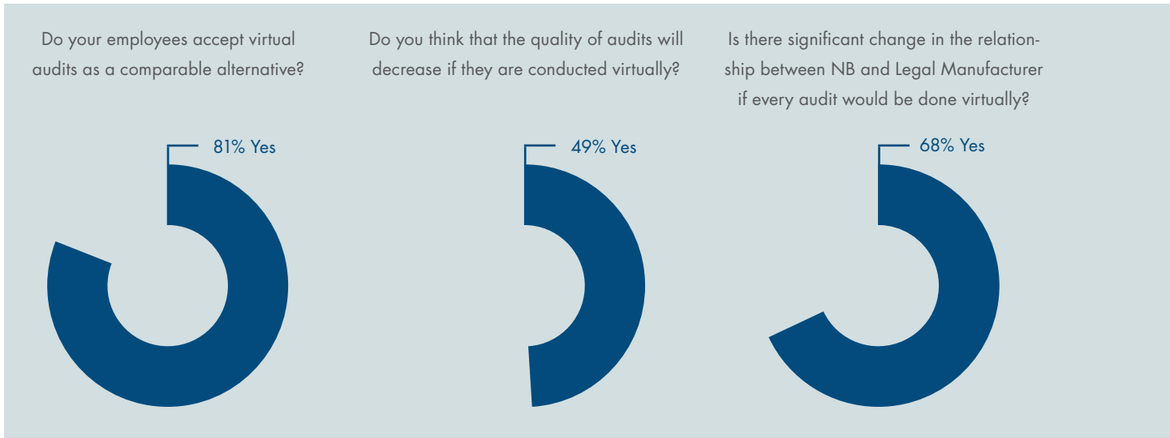
ULF HAGEDORN

SOFT FACTS

Besides the technical requirements, soft facts play a decisive role from the perspective of the panelists and survey participants.

MISSING THE WHOLE PICTURE

For the notified bodies, it is essential for a successful audit to be flexible throughout the audit process and to be able to see in all directions. They are afraid of missing the whole picture during the audit process and the ability to react spontaneously is limited, as the audit is carried out within a meeting room via collaboration tools. For both sides, manufacturers and notified bodies, an audit is always a step towards a trust-based relationship. They anticipate changes in this relationship if audits are only to be conducted virtually.



From an employee's perspective, virtual audits are already well accepted today. There might be a challenge due to demographics, if a significant number of auditors are not accustomed to collaborating digitally. For DQS, this accounts for about 30 % of the auditors. There is a lot of change management needed, which is why Medtronic initialized a program to explain virtual audits and train their employees. But nevertheless, there are concerns that the quality of the audits is decreased if they are done remotely.

Potential solutions to establish virtual audits as a standard

To put it in the words of Dominik Reterski: "Never waste a good crisis. We have to be creative when it comes to the regulations to ensure that global markets can be supplied with life saving medical products."

Based on that quote we will try to define solutions to set a safe, reliable and trust-building basis for virtual audits. The following areas need to be clarified by the reagulators:

BASIC REQUIREMENTS AND COSTS

There are some **basic requirements** which were agreed upon by all of the panelists:

- Plan and accept the shift of efforts from travel to preparation (the efforts are not reduced by virtual audits)
- Prepare your records (on time and before the audit)
- Ensure technical setup (collaboration for multiple parallel sessions), data exchange, and the submission of paper-based documents)
- Validate technical setup upfront
- Ensure availability of the people
- Define roles and responsibilities
- Stick to timelines (incl. account for different time zones)
- Schedule sufficient breaks
- Make sure that (contractual) agreements betwen parties include a statement adressing prohibition of unauthorized recording (voice and video).

The ISO 19011:2018 defines in Annex A.15 and A.16 also basic reguirements or at least points that have to be taken into account[7] e.g.:

- Ensure that the audit team complies with the agreed protocols for the remote audit, respectively, remote access
- If screenshots of documents are to be taken, the permission of the respective partner is required in advance
- Avoid recording of persons without their consent
- If an incident occurs during remote access, the audit team leader assesses the situation together with the audited organization
- Criteria must be defined to determine when a virtual audit should be continued, interrupted or postponed.
- Use floor plans/diagrams of the remote site as a guidance

Due to the shift of activities within virtual audits there is no significant reduction in costs expected. Shifts will only occur in the areas in which the costs are incurred. This was confirmed by the experiences of the panelists and the audience. 69 % of the participants do not see a significant reduction of the costs at this juncture. Nevertheless, the future cost reduction is seen as a potential target by 90,5 % of the participants.

"Preparation is key"
DOMINIK RETERSKI

"There is no significant reduction in costs from our experiences so far"
ULF HAGEDORN

APPLICABLE AREAS

We learned from our panel discussion and the upfront survey that there is a wide range of possible applications for virtual audits (Fig. 2). Thereby the degree of remoteness is favored to be a mix of on-site and off-site from both sides, manufacturers and notified bodies (if possible).

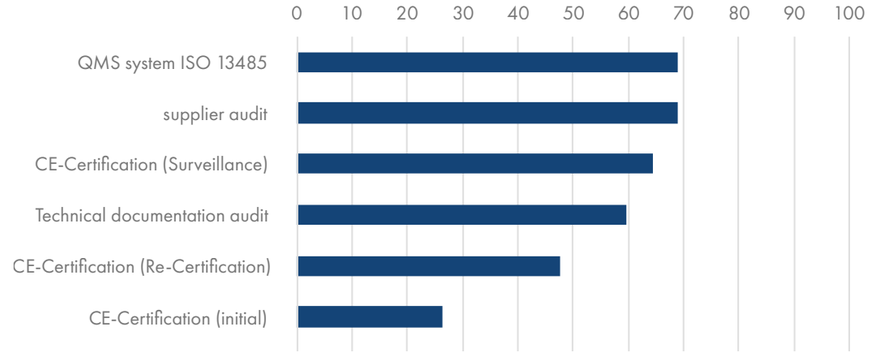


Figure 2: Survey results on applicable areas for virtual audits

Based on the experience of TüV Süd[8], the areas of application for the ISO 13485 are as follows (Table 3):

CHAPTER	NAME	VIRTUAL AUDITS POSSIBLE?
4	Quality Management System	Yes
5	Management responsibility	Yes
6.1	Provision of resources	Yes
6.2	Human resources	Yes
6.3	Infrastructure	No
6.4	Work environment	No
7.1	Planning	Yes
7.2	Customer-related processes	Yes
7.3	Design and Development	Yes
7.4	Purchasing	Yes – Sub-clause 1 & 2 No – Sub-clause 3
7.5	Production and service provision	Yes – Sub-clause 3 No – All sub-clauses (except 3)
7.6	Control of monitoring and measuring devices	No
8.1	General	No
8.2	Monitoring and measurement	Yes
8.3	Control of non-conforming products	Yes – All sub-clauses (except 1) No – Sub-clause 1
8.4	Analysis of data	Yes
8.5	Improvement	Yes

Table 3: Applicable areas for remote audits

As shown in Table 3, a virtual audit is almost completely possible for the QMS under ISO 13485. Even for the Chapters or sub-clauses marked with "no", major part can be carried out virtually / off-site having a stringent argumentation in place.

> **"From our experiences so far a similar effectiveness can be achieved with virtual audits"**
>
> ANDREAS PURDE

> **"90% of audits can be done remotely. The other 10 % are still important though"**
>
> DANIEL DELFOSSE

In a simplified summary, we have derived the following areas (Table 4):

VIRTUAL AUDITS POSSIBLE	VIRTUAL AUDITS NOT POSSIBLE
▪ All surveillance audits ▪ MDR initial audits for existing clients ▪ MDR initial audits in general (in parts only during pandemic times) ▪ Every process except for the physical flow of goods (for new clients)	▪ Unannounced audits ▪ For cause audits

Table 4: Applicable areas for virtual audits (simplified)

> **"Remote audits are not new and should be balanced with other auditing methods"**
>
> ULF HAGEDORN

> **"Everything except the physical flow of goods can be done remotely"**
>
> MICHAEL BOTHE

ICT STANDARDS AND LEGAL PROTECTION

In the area of technology (ICT), clear specifications are needed from the regulatory authorities in terms of collaboration tools, data exchange, voice and video quality and the availability of documents. These specifications are expected from the authorities by 81% of the participants. As a result, the participants expect to receive a simple checklist including an "approved tools list," which will serve as a valid basis for all virtual audits. Similar guidelines exist for other standards and have been approved by the authorities [9,10].

However, time is pressing because a large number of tools are currently being utilized, which increases the complexity for companies as well as notified bodies. Furthermore, the lack of standardization in video quality and the availability of records complicates processes and reduces efficiency.

The new form of virtual audit execution must be reflected in the contracts between manufacturers and notified bodies, so that data storage/ security as well as the handling of recordings or screen captures during the process is agreed upon. Even though the subject of data capture is already included in the standard contracts between auditors and auditees, the contracting language often does not apply to virtual audits.

REGULATION

An extended range of application areas for virtual audits is necessary. At least MDR inital audits have to be allowed for the duration of the Corona pandemic. Similar regulations already exist for the directive (MDD) and have been recently published in Pharma[8].

A decision is needed before the summer break to take advantage of the remaining time until May 2021 and to ensure that the market can be supplied with safe medical devices.

> **"It is very simple. We need virtual audits to get the new devices on the market under MDR."**
>
> OLIVER BISAZZA

FUTURE OPPORTUNITIES

In order to leverage the potentials in the area of virtual audits, or at least be prepared, manufacturers need to keep an eye on:

- the infrastructure,
- the product/process documentation and
- the qualification of the employees.

The establishment of an adequate infrastructure in terms of bandwidth and collaboration equipment is usually relatively easy to achieve. The digital provision of all necessary documents for products and processes poses greater challenges for companies.

> **"Virtual audits are another use case that demonstrates the need for the digitalization of product documentation and processes. Here, medical technology can still learn a lot from other regulated industries"**
>
> KLAAS RACKEBRANDT

BUT THE EFFORT IS WORTH IT.

If an eQMS, ideally business driven and supported by a BPM tool as well as a digital product file are available, it is possible to realize significant increases in efficiency across all end-to-end process chains within the company in addition to virtual auditing (e.g. in the area of traceability requirements).

Furthermore, it is recommended to prepare employees adequately for the new requirements of virtual audits. Audit processes have to be adapted and employees have to be trained and coached as all of the preparation phases have to be established.

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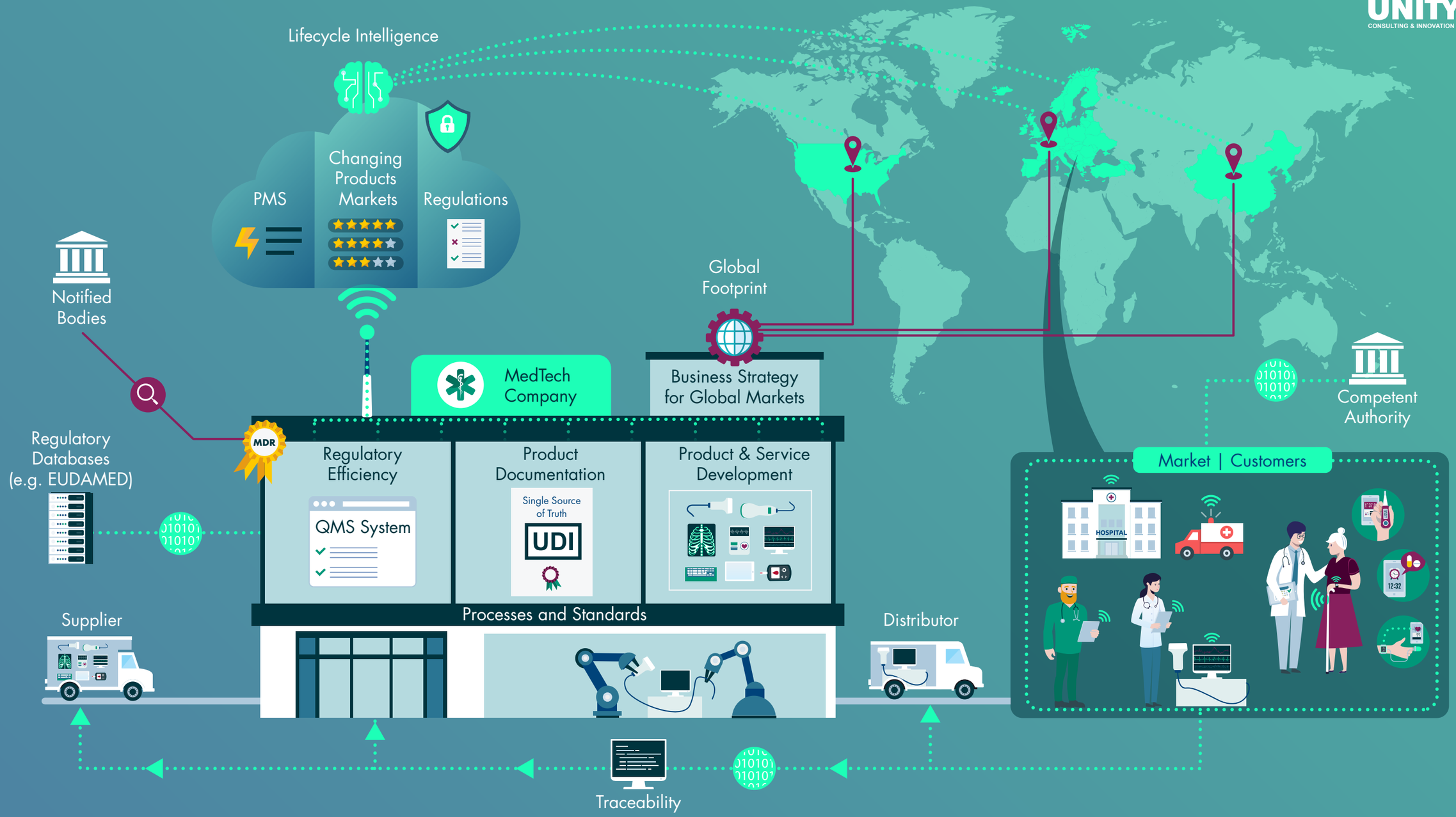

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