

AM INTERACTION DAYS

Gregor Reischle

Qualification in AM



EU Industry Week
2021
#EUIndustryWeek



Qualification in AM

Ensuring the industrial adoption of
Additive Manufacturing via
standardized qualification



Mehr Wert.
Mehr Vertrauen.

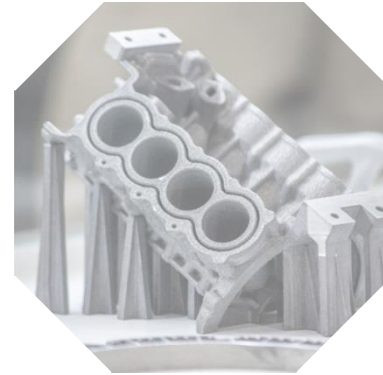
Add value.
Inspire trust.

Gregor Reischle
Global head of Additive Manufacturing
EU Industry week, 10.03.2021

Top-down requirements – Fulfillment of Quality & validation requirements within different industries



EN 9100 (8.5.1.2 **Validation**)
For processes where the *resulting output cannot be verified by subsequent monitoring or measurement*, the organization shall establish arrangements for these processes



IATF 16949 (8.3.4.2 **Validation**)
During validation, it is examined *whether the product produced in this way (e.g. within the framework of the prototype program) meets the product requirements.*

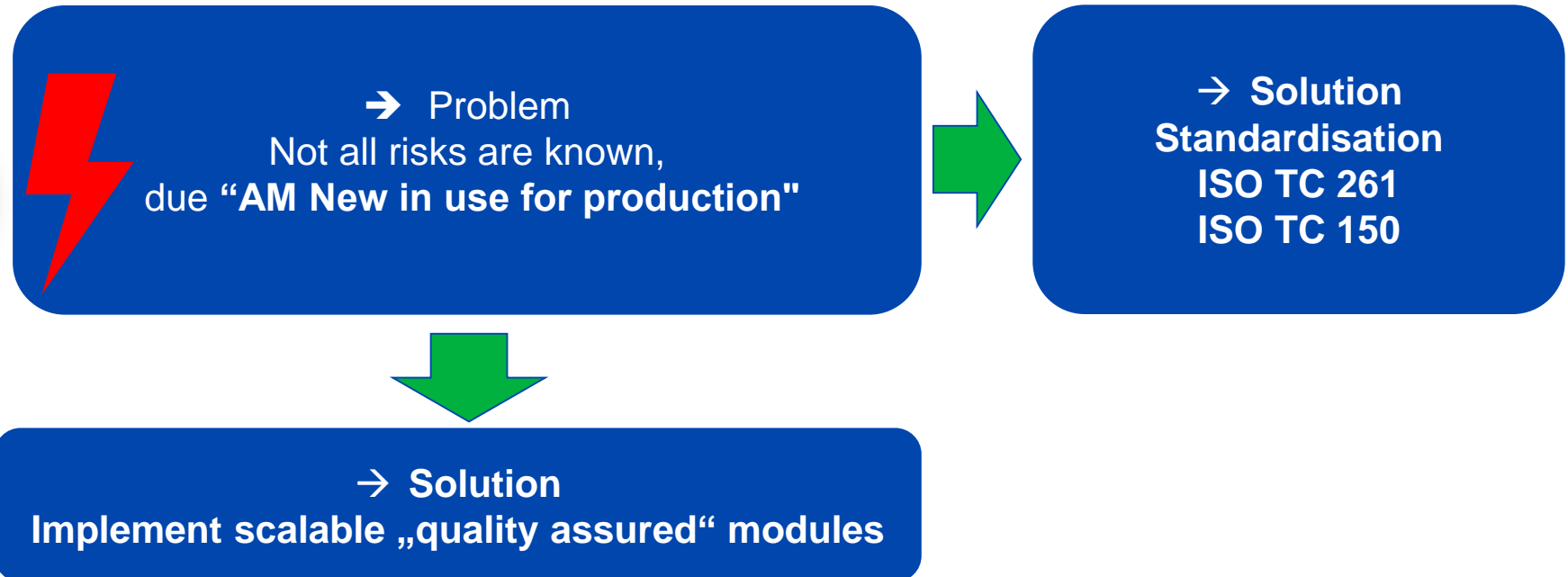
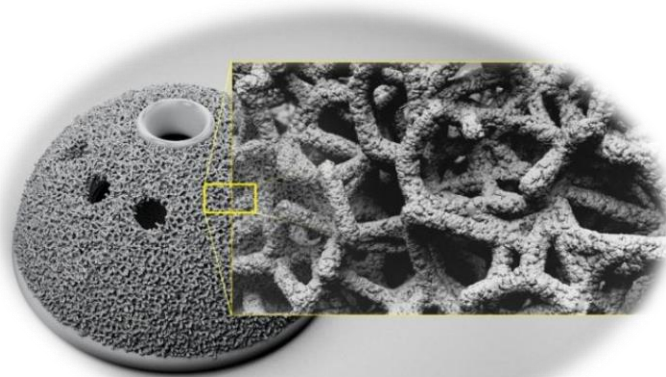


ISO 13485 (7.5.6 **Validation**)
The organization shall *validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement*

The AM technology specific approach – Manufacturers needs to establish a **risk management system** which targets application & AM technology specific risks

1. Application centric view:

Surface roughness + Powder removability + Sterilization + Design Verification + Material property etc.

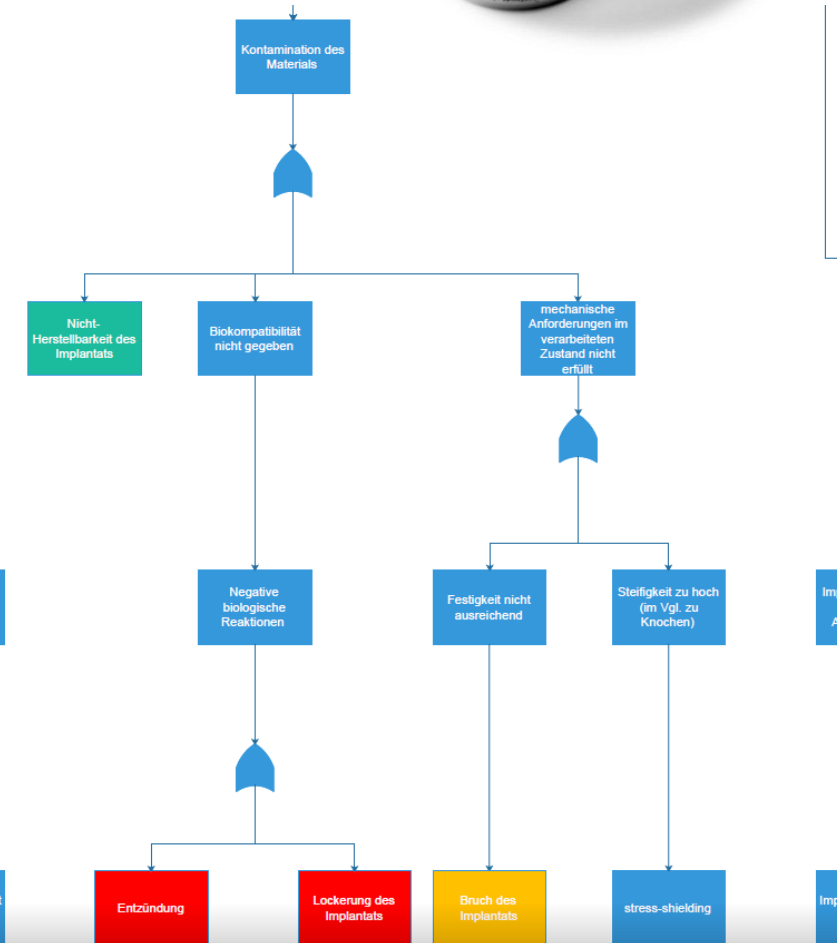
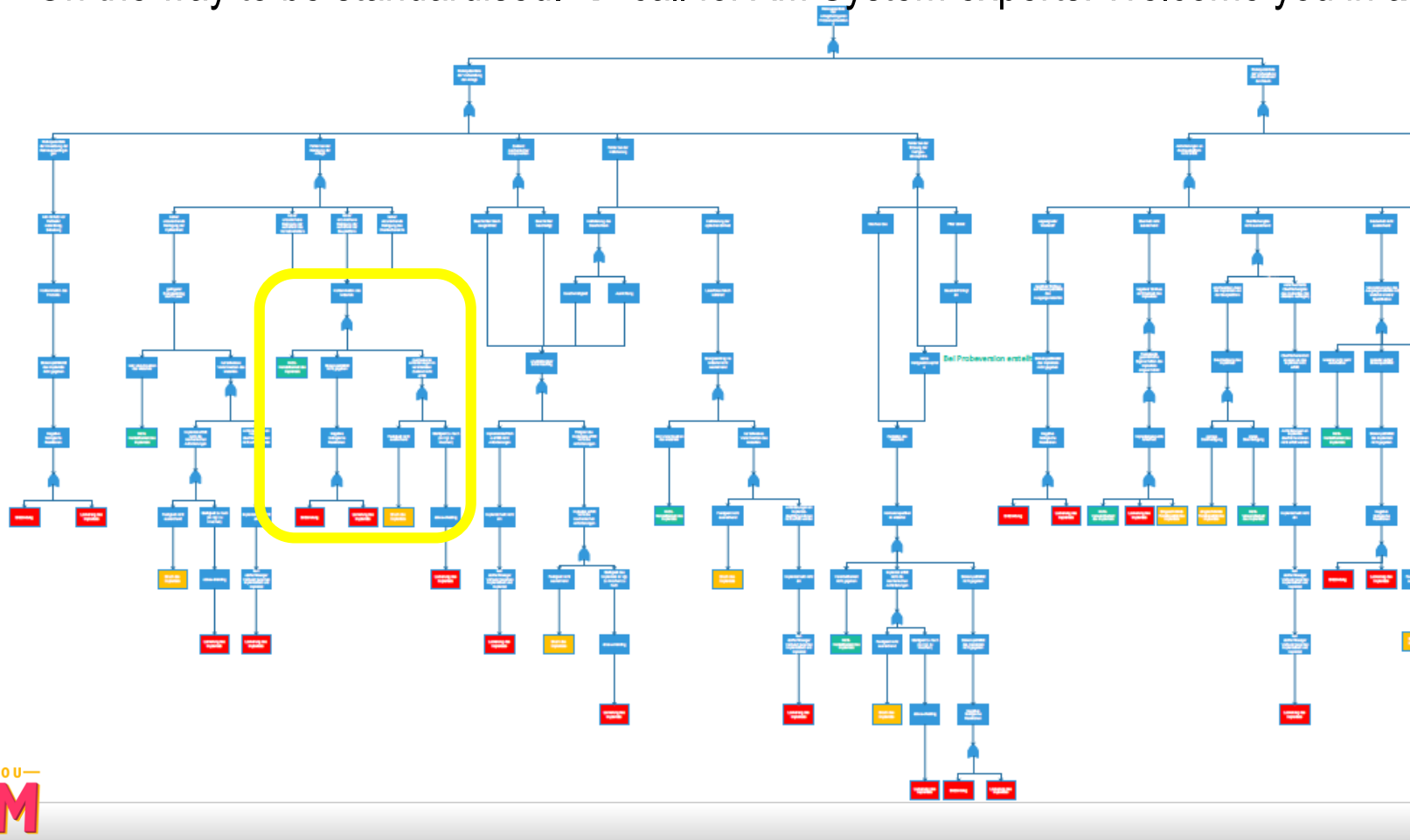
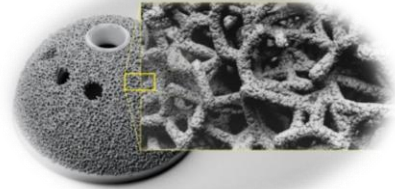


2. AM technology risks needs to be eliminated via quality assurance & standards:

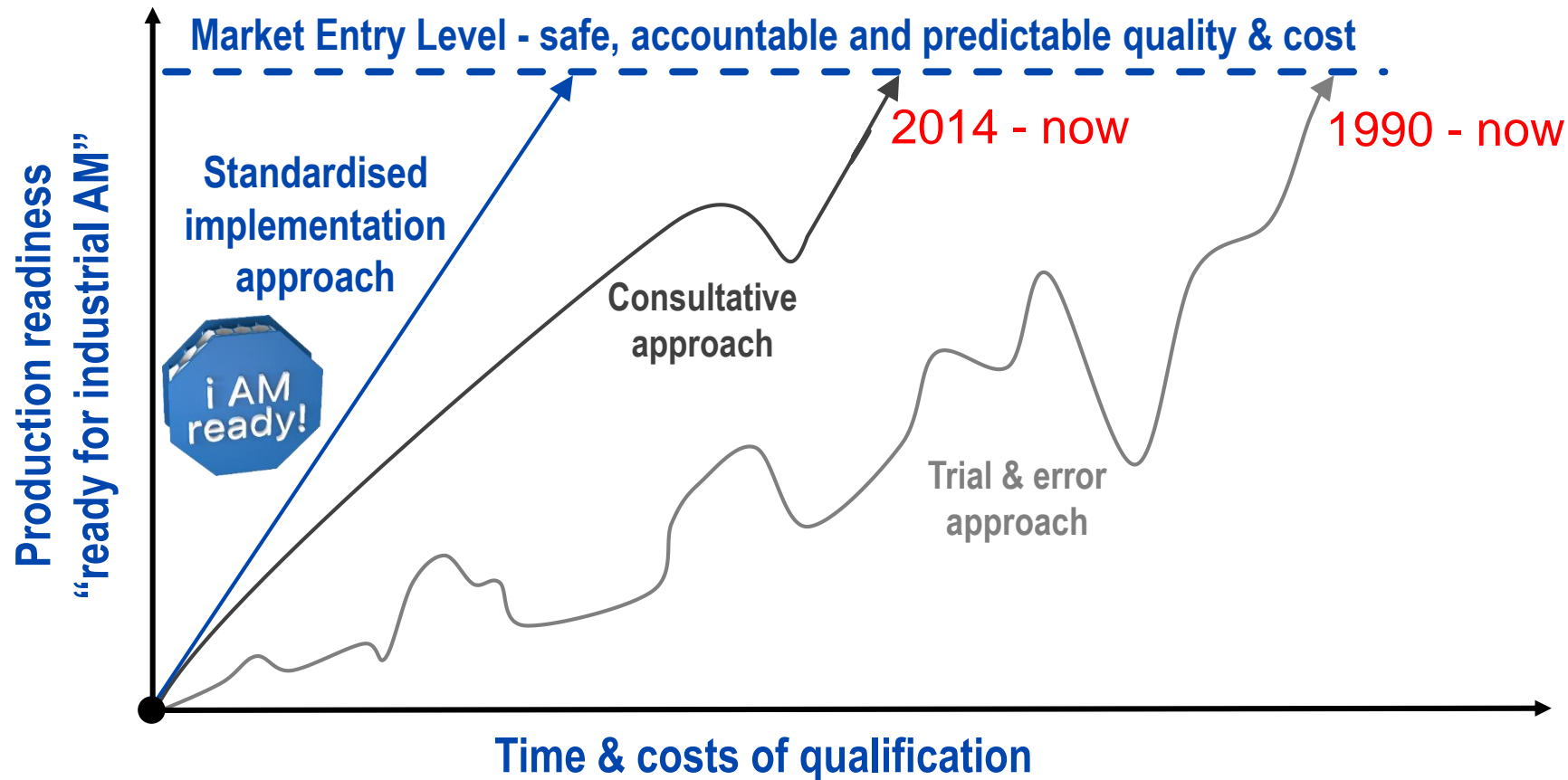
AM build process anisotropy, Feedstock management, Quality assurance of working steps

Exemplary risk mapping on AM technologies – See also risk assessment trainings TUV SUD

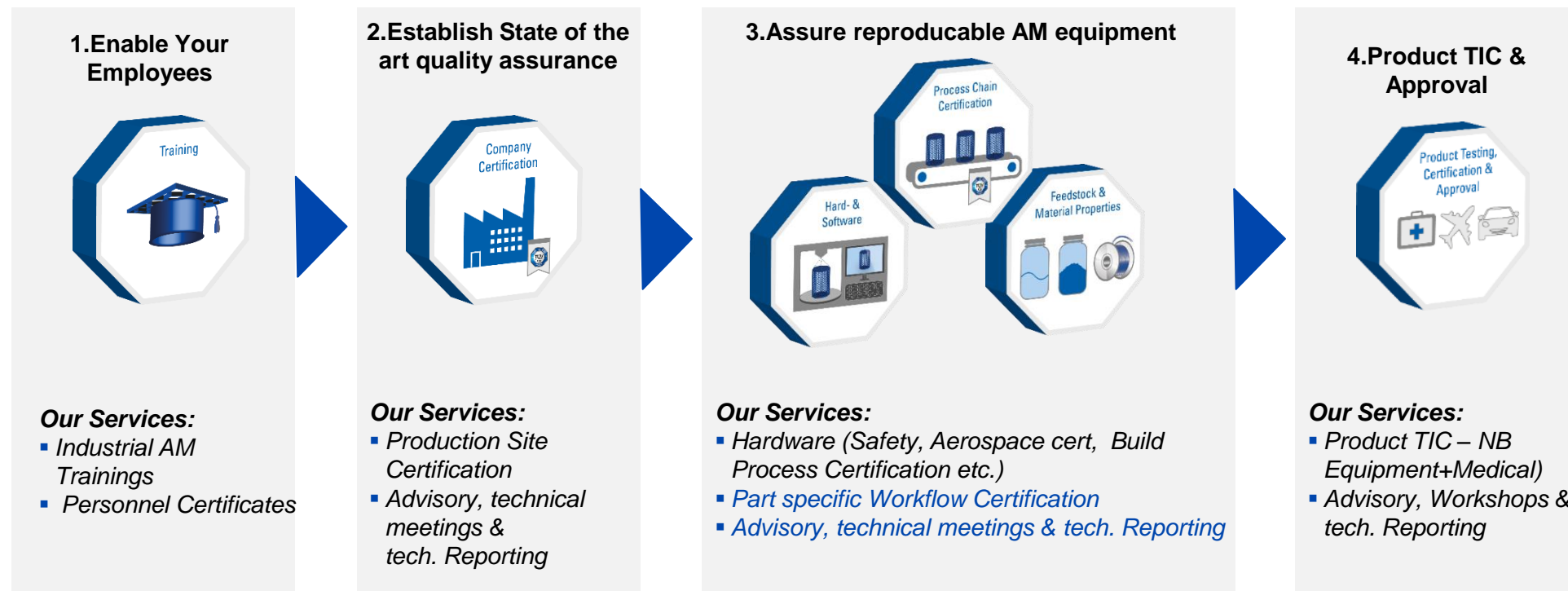
- On the way to be standardised. → call for AM System experts! Welcome you in **theTC 261 / JG 75**



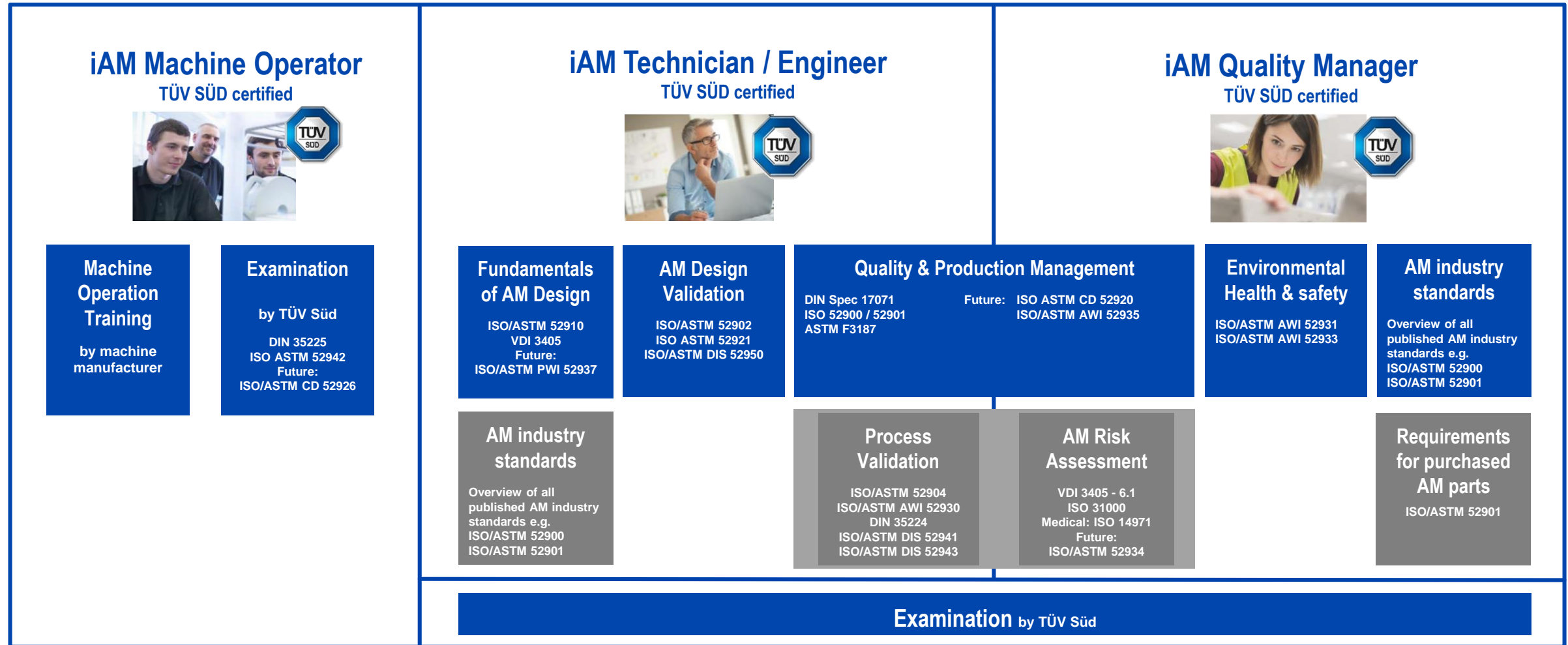
Bottom-up implementation approach - “state of the art & standardised” technology implementation → Quality assurance of AM specific risks



The standardized implementation path of industrial AM readiness with trainings, audits, technical meetings and certification



Mastering AM roles - iAM expert trainings – interested in collaboration?



The project perspective of industrial AM readiness – Plan your TEAM enablement with our standard training modules - Make it your way!

<p>Quality & Production Management in AM</p> <p>(2 days)</p>	<p>Health and Safety in AM</p> <p>(1 day)</p>	<p>Industry Standards in AM</p> <p>(1 day)</p>	<p>Fundamentals of AM</p> <p>(1 day)</p>	<p>Status quo of AM for Decision-Makers and Analysts</p> <p>(1 day)</p>
<p>Risk Assessment & Management for AM</p> <p>(1,5 days)</p>	<p>Process Validation</p> <p>(1 day)</p>	<p>Change Management</p> <p>(1 day)</p>	<p>Business Modell Workshop for AM</p> <p>(1 day)</p>	<p>DIN SPEC 17071 (ISO/ASTM 52920)</p> <p>(0,5 day)</p>
<p>Specifications of AM parts for purchase</p> <p>(1 day)</p>	<p>Materials in AM</p> <p>(1 day)</p>	<p>Designvalidation in AM</p> <p>(2 days)</p>	<p>Fundamentals of Design in AM</p> <p>(1 day)</p>	<p>AM Part Substitution scheme</p> <p>(1 day)</p>

Exemplary Profiles:

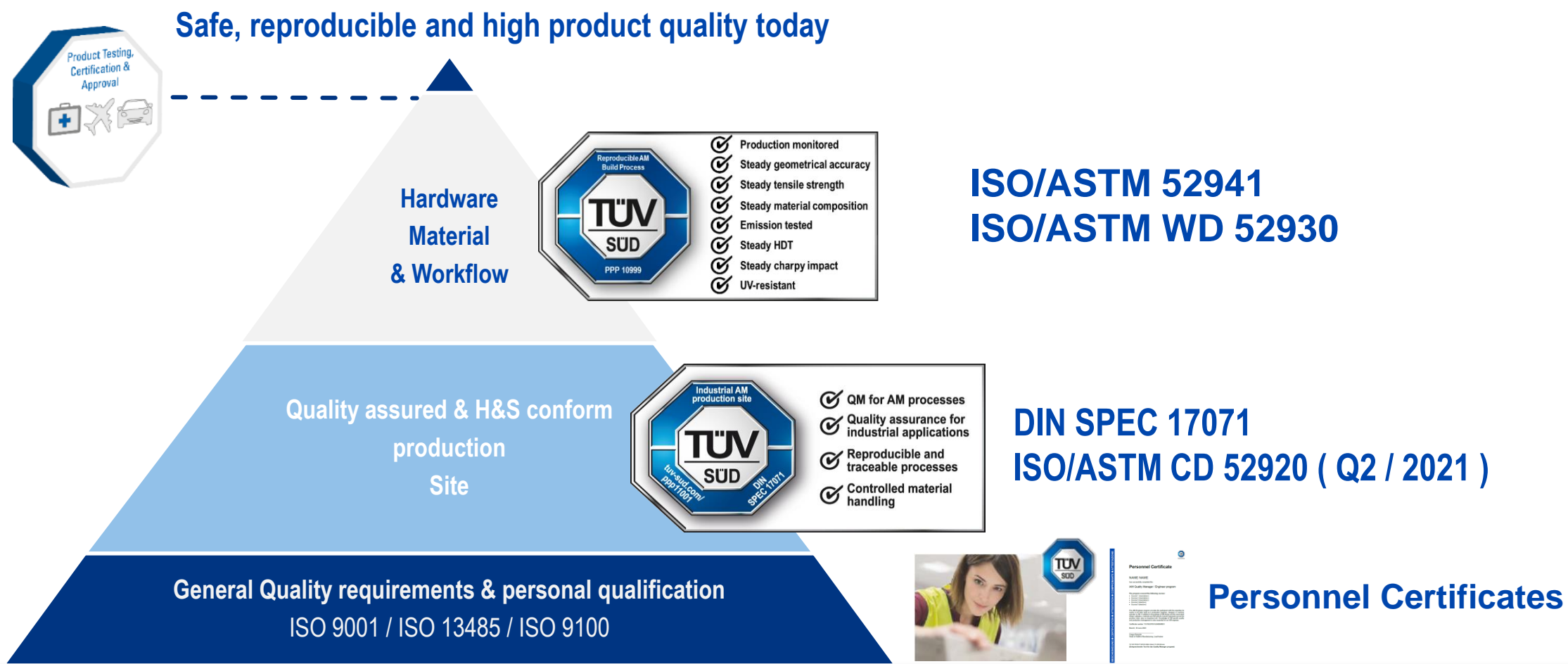
1. AM project leader needs to evaluate **the AM potential & implementation costs**

2. AM Project leader needs to **plan & set up an AM production site**

3. AM Project leader needs to **fulfill the requirements of regulated industries**

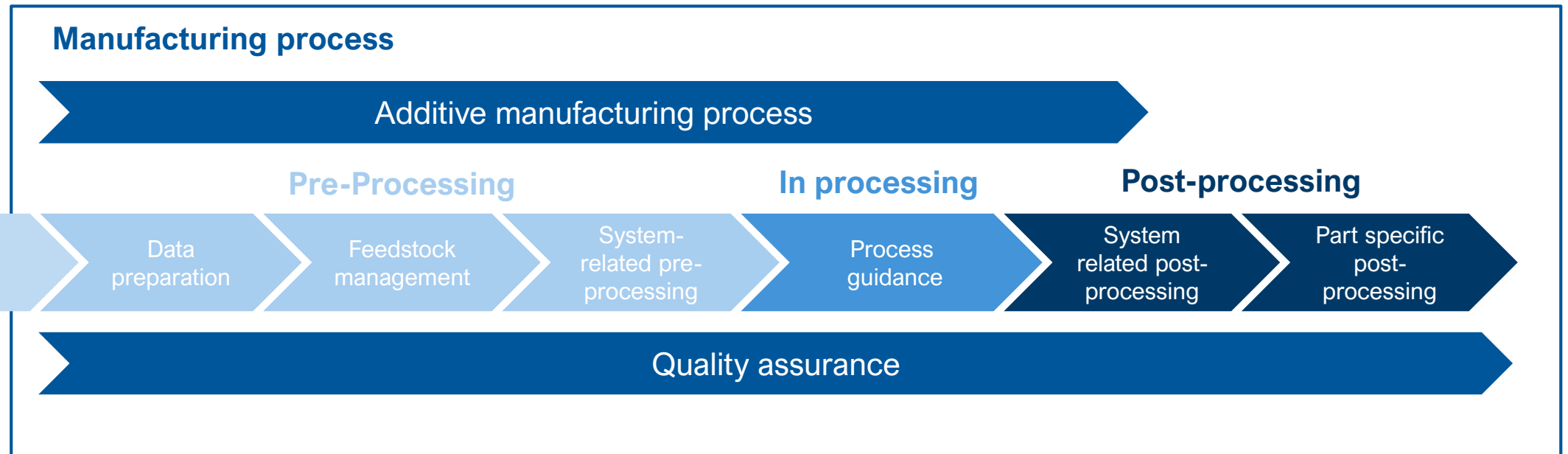
<https://www.tuvsud.com/en/industries/manufacturing/machinery-and-robotics/additive-manufacturing>

Standardized qualification approach – state of the art iAM readiness implementation



Exemplary AM specific QMS according DIN SPEC 17071

→ ISO/ASTM CD 52920 (Draft available in Q2 2021)

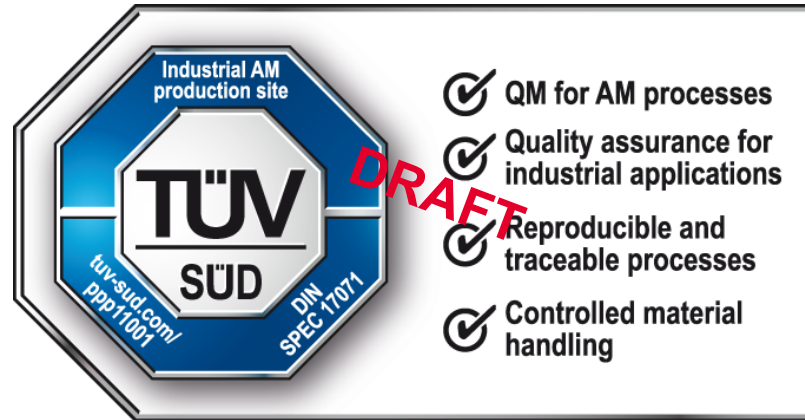


Download link:

<https://www.beuth.de/de/technische-regel/din-spec-17071/315351232>



The today's qualified & certified manufacturing sites – Quality assurance perspective



"The satisfaction of our customers is our greatest asset. That's why the quality of our 3D printing processes, and additive-based products is so important. The basis for this is our quality management system, which was audited and certified by TÜV Süd in accordance with DIN SPEC 17071.

Dr. Ralf Gärtner, CEO PROTIQ GmbH

"The audit was carried out very professionally in a constructive atmosphere.

We at Evonik can further optimize our Additive Manufacturing QM process through your objective information."

Johannes Ehrlich, Head of Special Plant Construction & Technical Conformity at Evonik

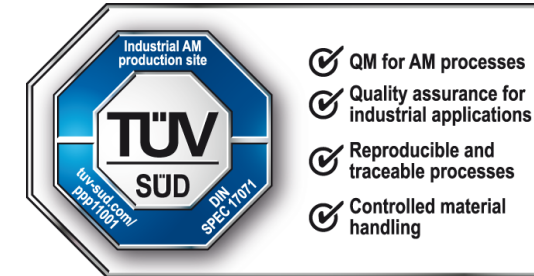
Soon to be certified



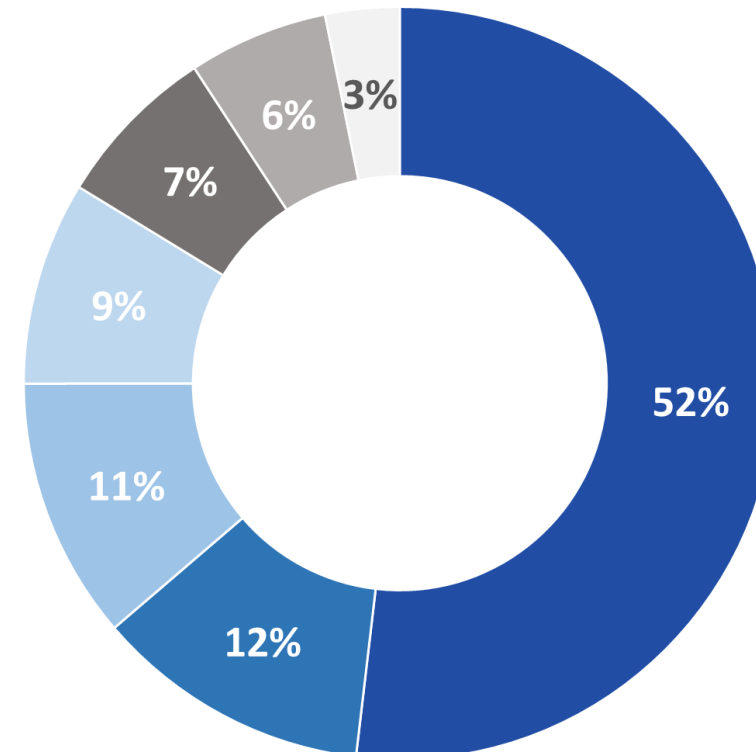
Volkswagen

Structure and content of the qualification & certification scheme

	Company management <ol style="list-style-type: none"> 1. Implementation of AM strategy 2. Positioning in the AM market 3. Distribution planning
	Customer Management <ol style="list-style-type: none"> 1. Sales planning 2. Management of customer expectations 3. Preparation of quotation
	Order Management <ol style="list-style-type: none"> 1. Purchase requisitions 2. CAD/CAM processes 3. QA in the manufacturing process
	Production Management <ol style="list-style-type: none"> 1. Production planning 2. Material handling 3. Consumption and spare part management
	Additive manufacturing <ol style="list-style-type: none"> 1. Hardware requirements 2. System operation 3. Production control
	Finishing <ol style="list-style-type: none"> 1. Unpacking processes 2. Order handling/rework 3. Component testing and supply

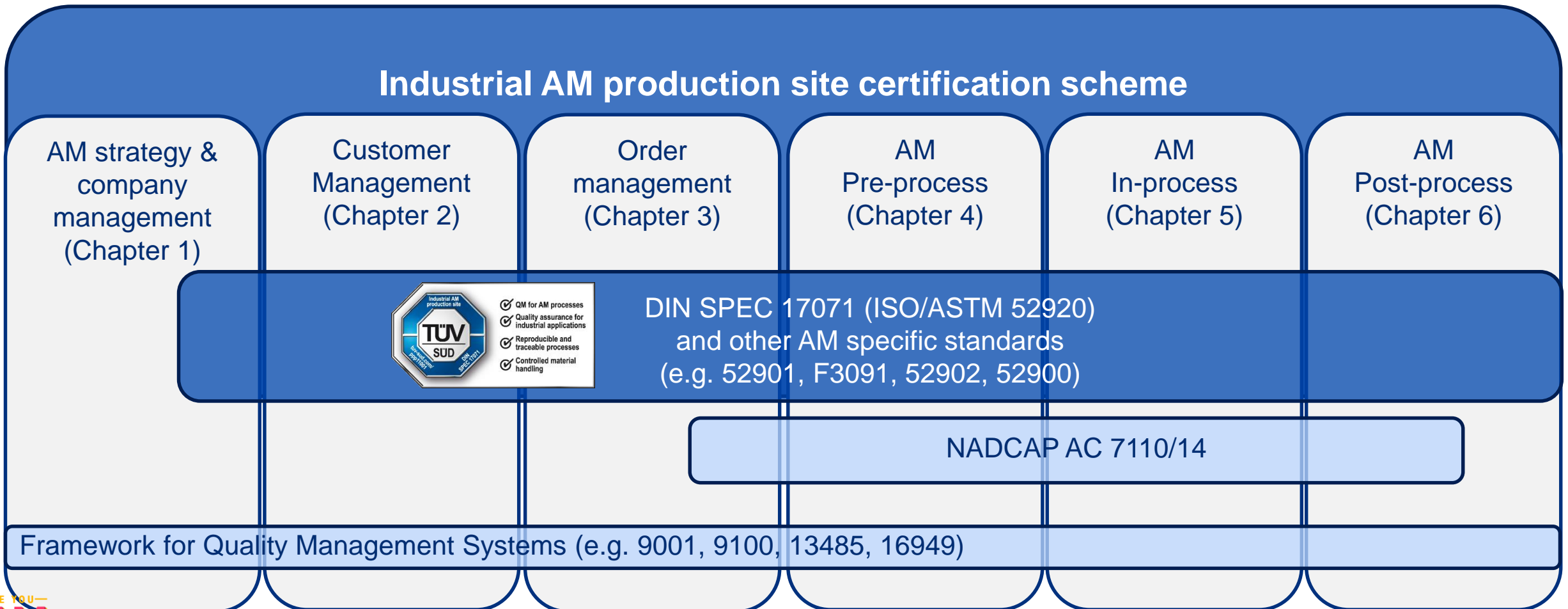


Ready for:
ISO/ASTM CD 52920



- DIN SPEC 17071
- Internal testing criteria
- ISO 52901
- ISO 9001
- Further standards
- ASTM F3091
- ISO 17296

The AM production site audit program perspective - covers the whole value chain on the AM specific processes



The application perspective – today's validation efforts are partly already standardized

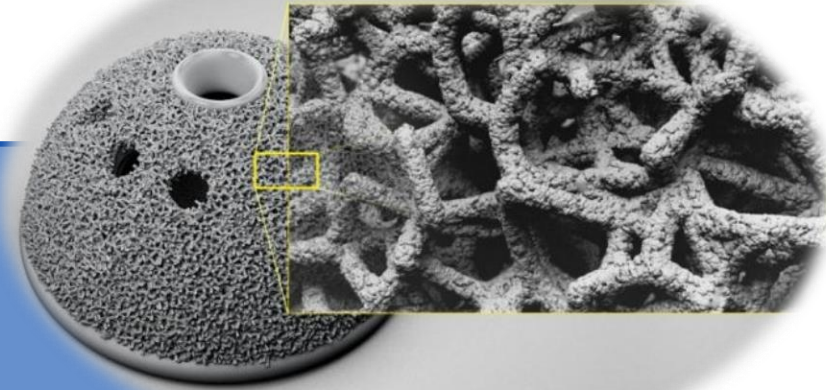


Quality assurance for AM technologies

AM production site
DIN SPEC 17071
ISO ASTM CD 52920



- ✓ QM for AM processes
- ✓ Quality assurance for industrial applications
- ✓ Reproducible and traceable processes
- ✓ Controlled material handling



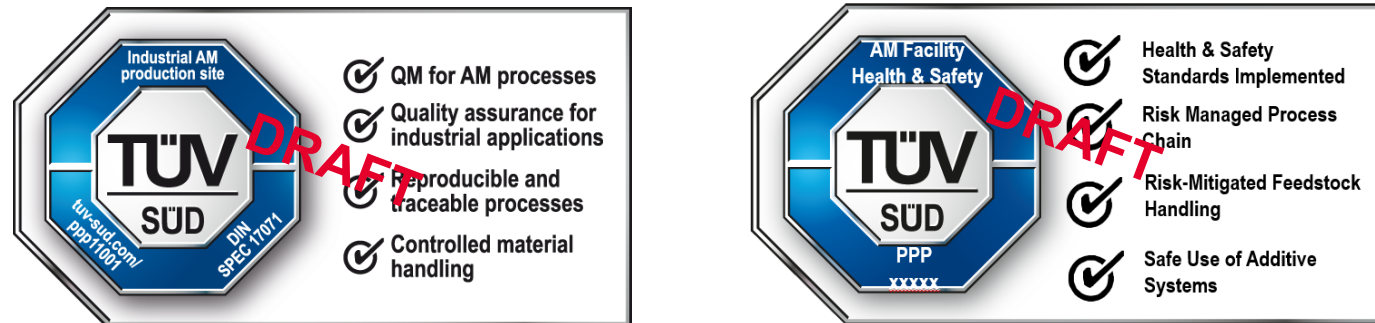
Quality System Audit ISO 13485 & Personnel qualification



Quality assurance requirements for part specific workflows

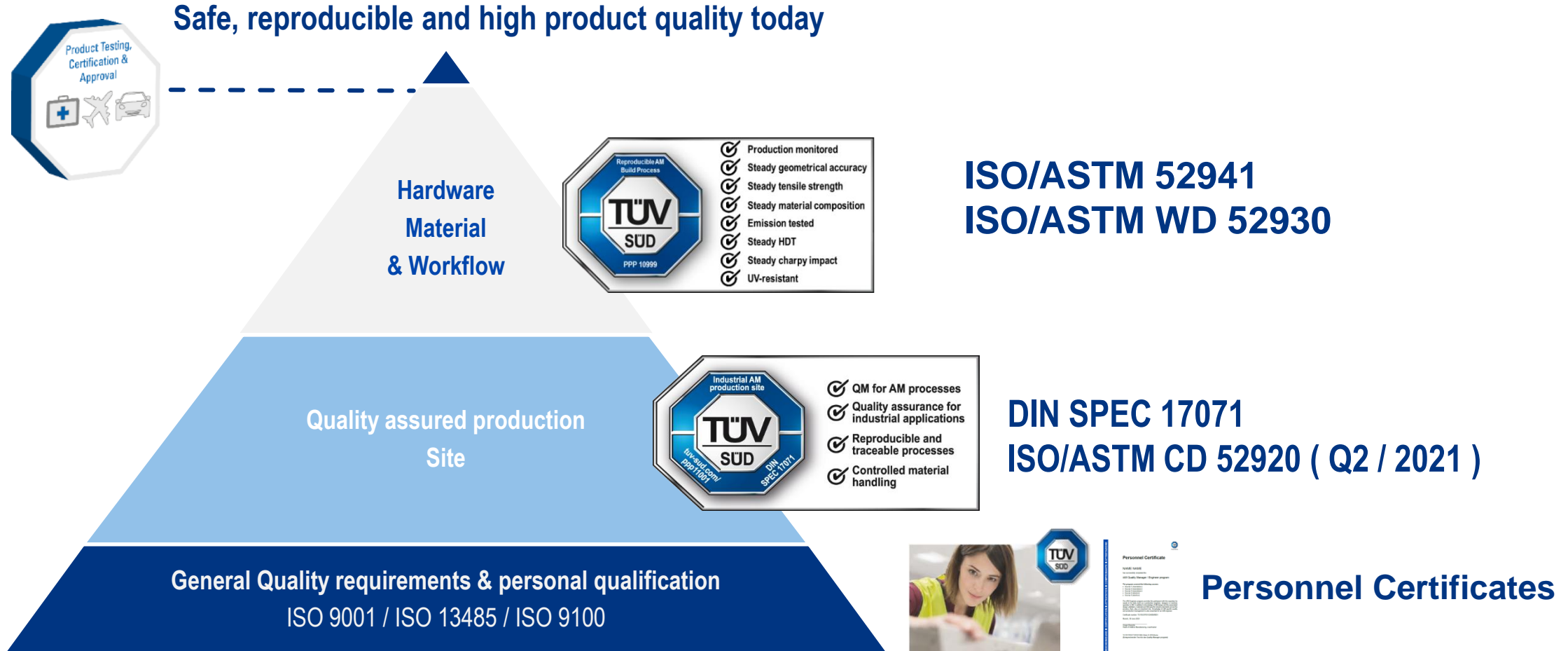
Source: <https://3dprint.com/11266/3d-printed-lpt-177x/>

Setting up an quality assured AM production site is from now on standardized!

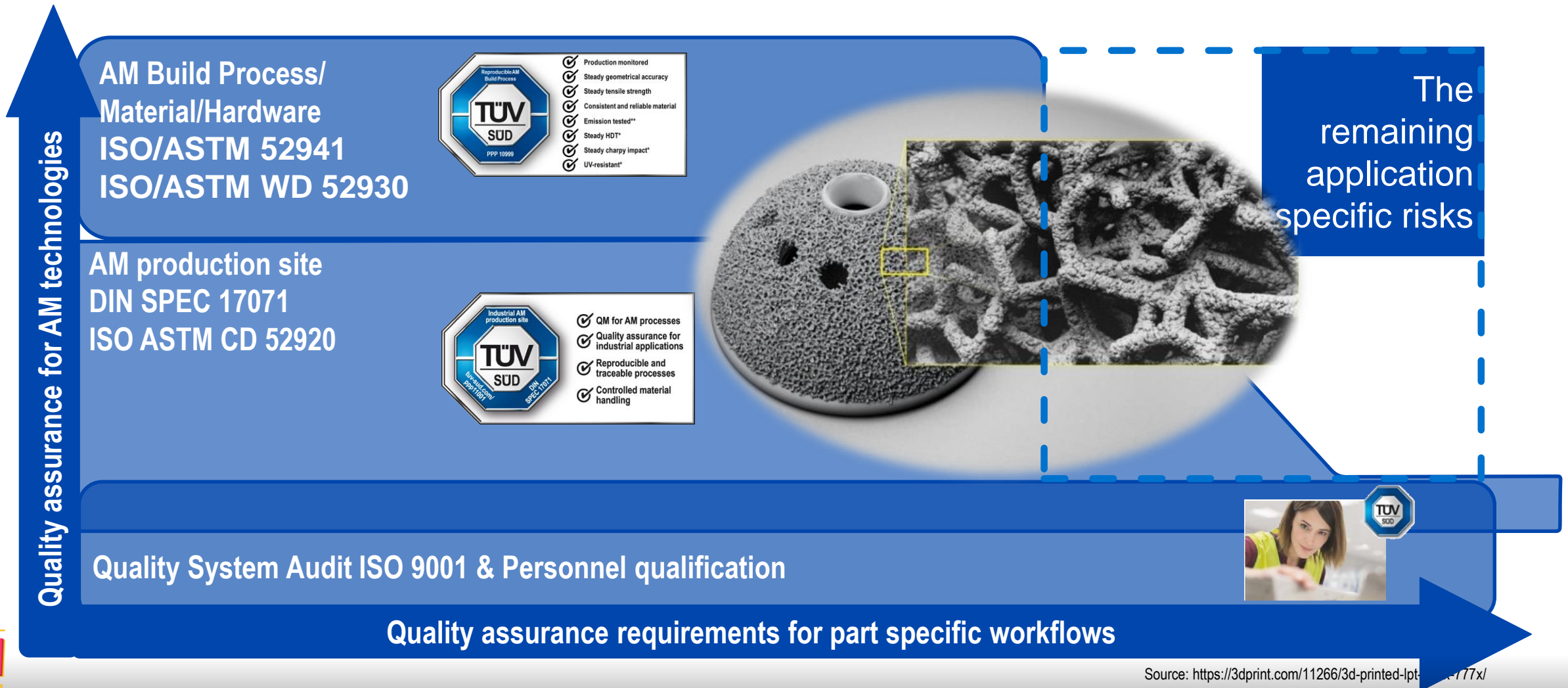


The implementation according the DIN SPEC 17071 and the upcoming ISO/ASTM CD 52920 helps to target safety critical components risks while adresssing AM technology quality assurance

Standardized qualification approach – state of the art iAM readiness implementation – Here we are today



The validation efforts are on the way to be standardized → Its time to initiate “pre qualified” AM build processes

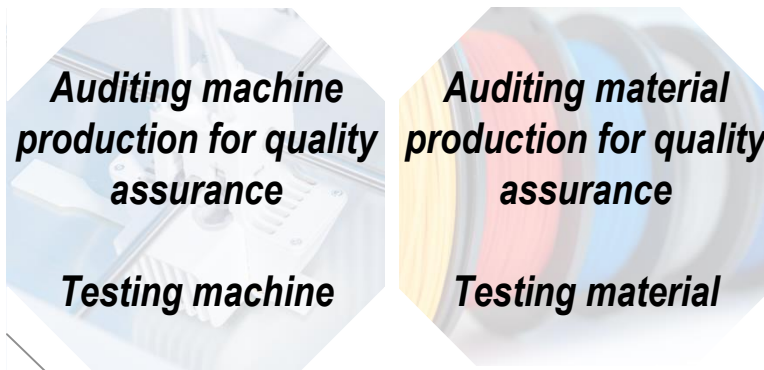


Fulfilling this requirement with the Build Process Certification

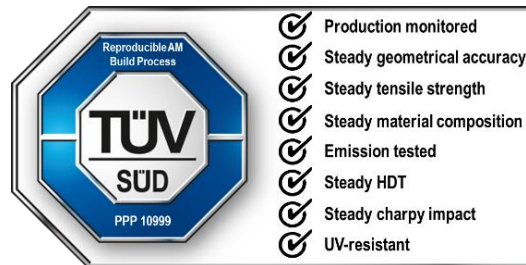
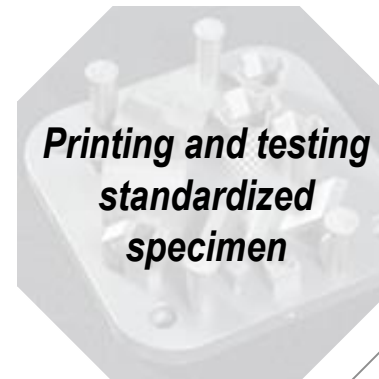
Within 6 months to a certified AM build process

Content and procedure of certification

Auditing and testing



Printing process and test specimen



Benefit for the system user

Qualification time saving and cost reduction

Challenging IQ procedure and documentation

Reduced OQ effort through existing, validated specs

Validated specs for easy and requirement fulfilling part designing

Reduced technology and investment risk with reproducible AM system

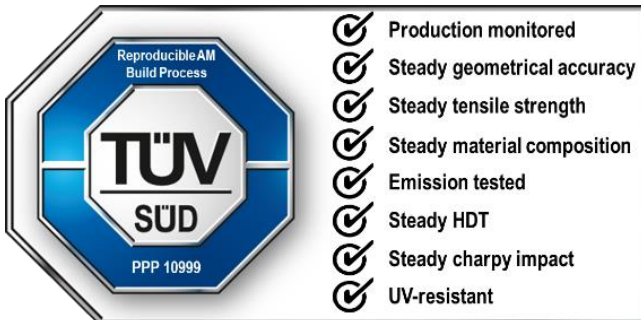
Complying with requirements of regulated industries

Certificate Handover for the reproducible AM build process

Ultimaker LUVOCOM® 3F
Additive manufacturing solutions

Validating reproducibility of the 3D-printing process and the material characteristics:

- ✓ Cost & time savings
- ✓ Ready for regulated industries
- ✓ AM serial production readiness



<https://press.ultimaker.com/ultimaker-and-lehvoss-group-receive-certification-of-filament-and-printing-process-from-tuev-sued/>

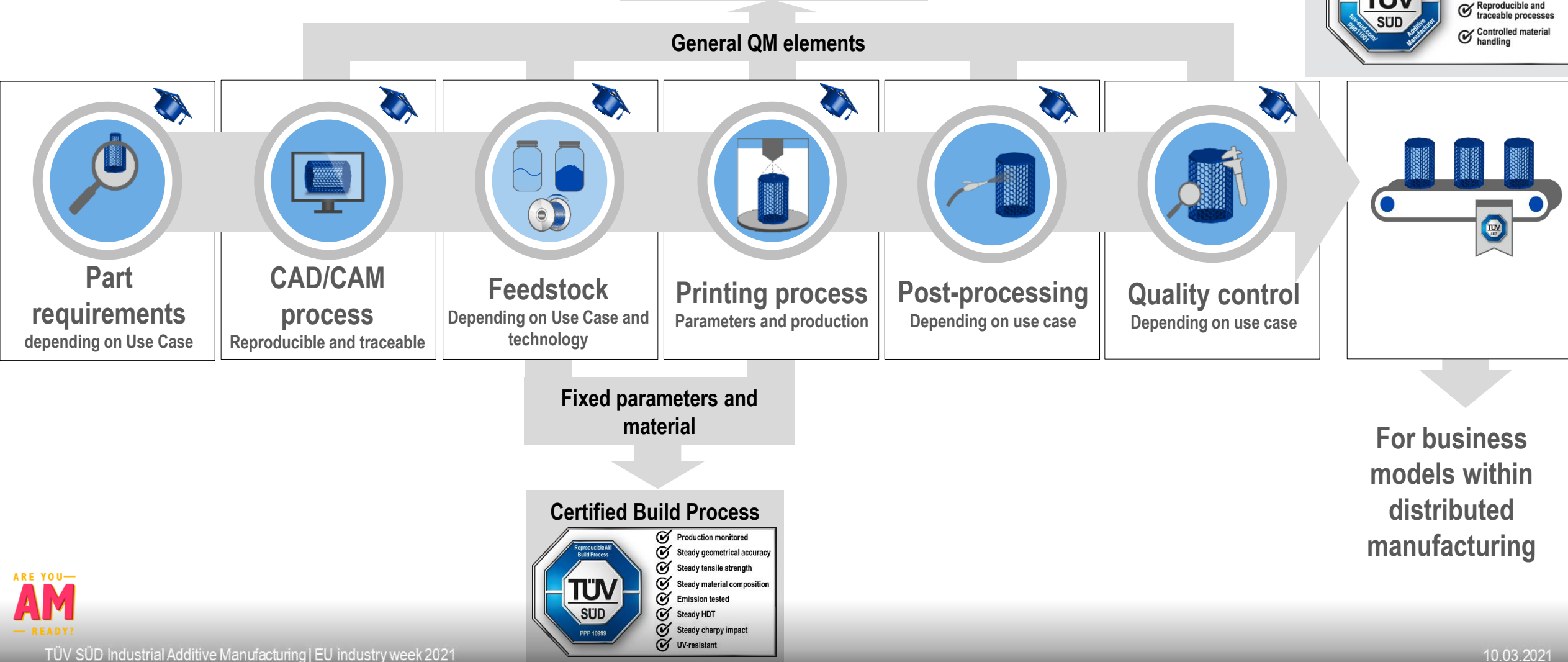
Application specific Process Chain perspective

iAM production site Certification

- ✓ QM for AM processes
- ✓ Quality assurance for industrial applications
- ✓ Reproducible and traceable processes
- ✓ Controlled material handling

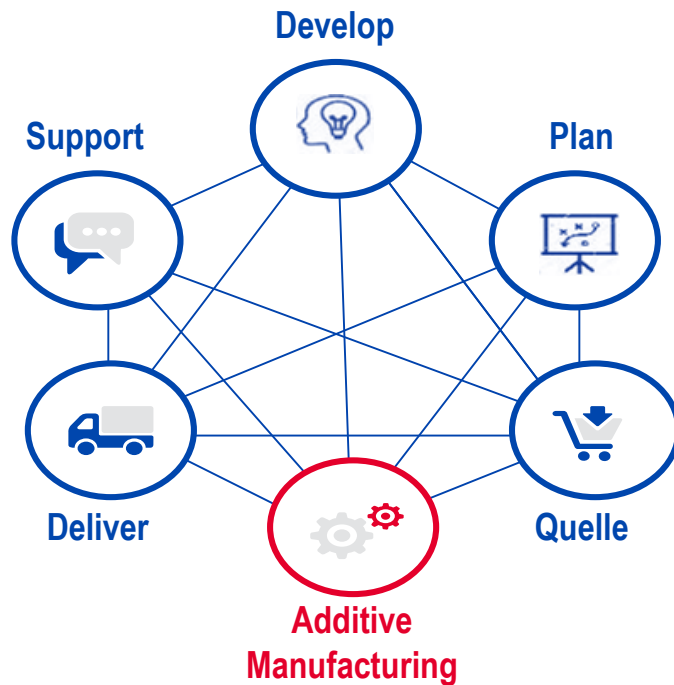
**Certified Application& part
group specific process chain**

- ✓ QM for AM processes
- ✓ Quality assurance for industrial applications
- ✓ Reproducible and traceable processes
- ✓ Controlled material handling

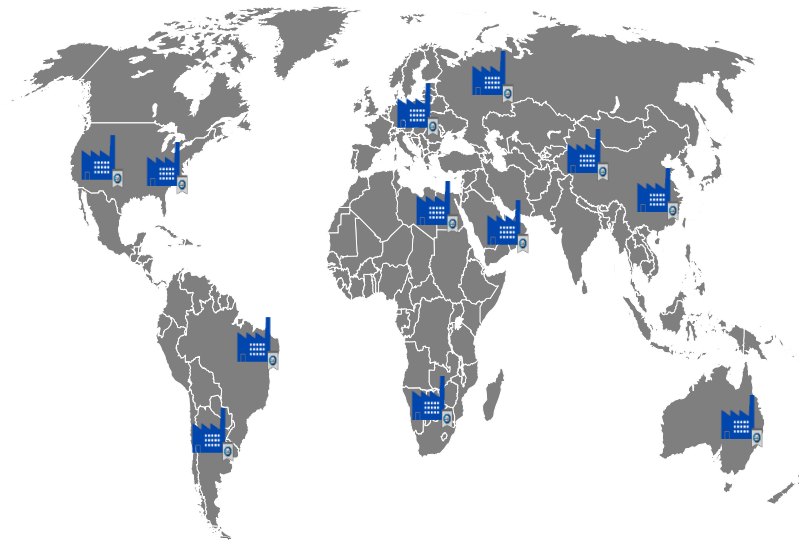


Industrial AM readiness with the „DIN SPEC 17071 and the upcoming ISO/ASTM CD 52920“ is key to establish robust supply chains using 3D printers

Distributed Supply Network



Quality assured AM manufacturing sites



<https://www.tuvsud.com/en/industries/manufacturing/machinery-and-robotics/additive-manufacturing>

Sustainability considered?

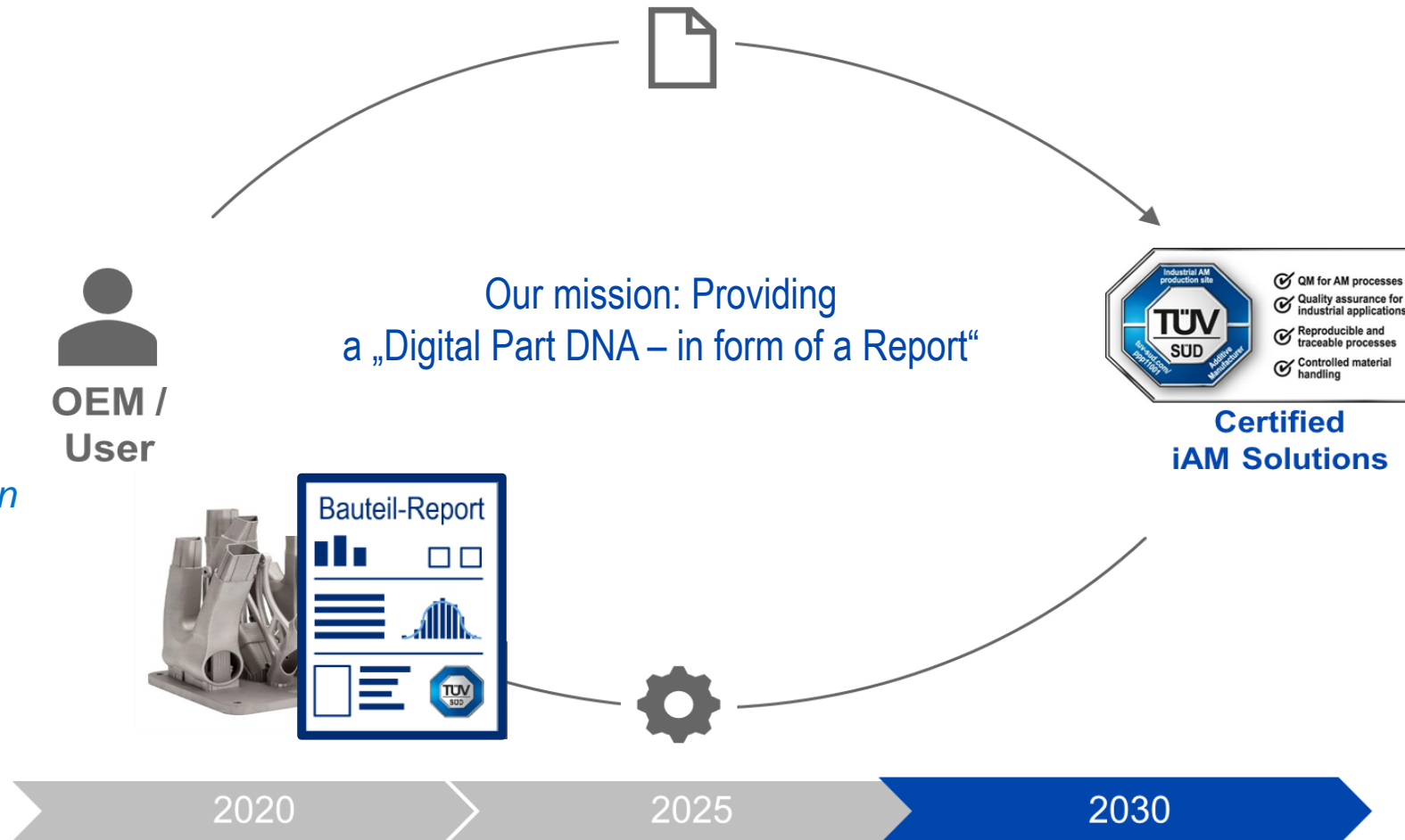


<https://www.tuvsud.com/en/services/sustainability>

Our pilotproject to enabel transition to advanced manufacturing.

→ Digital Part DNA (Our digital substitution and quality assurance service)

Pain point:
Requirements and compliance of an AM component according to qualification & regulation



What's next? → Bundling with other emerging technologies within the advanced manufacturing sector to enable industrial transformation

With the “standardized implementation approach: We are theoretically here



**Component /
system**



Connected



Dynamic



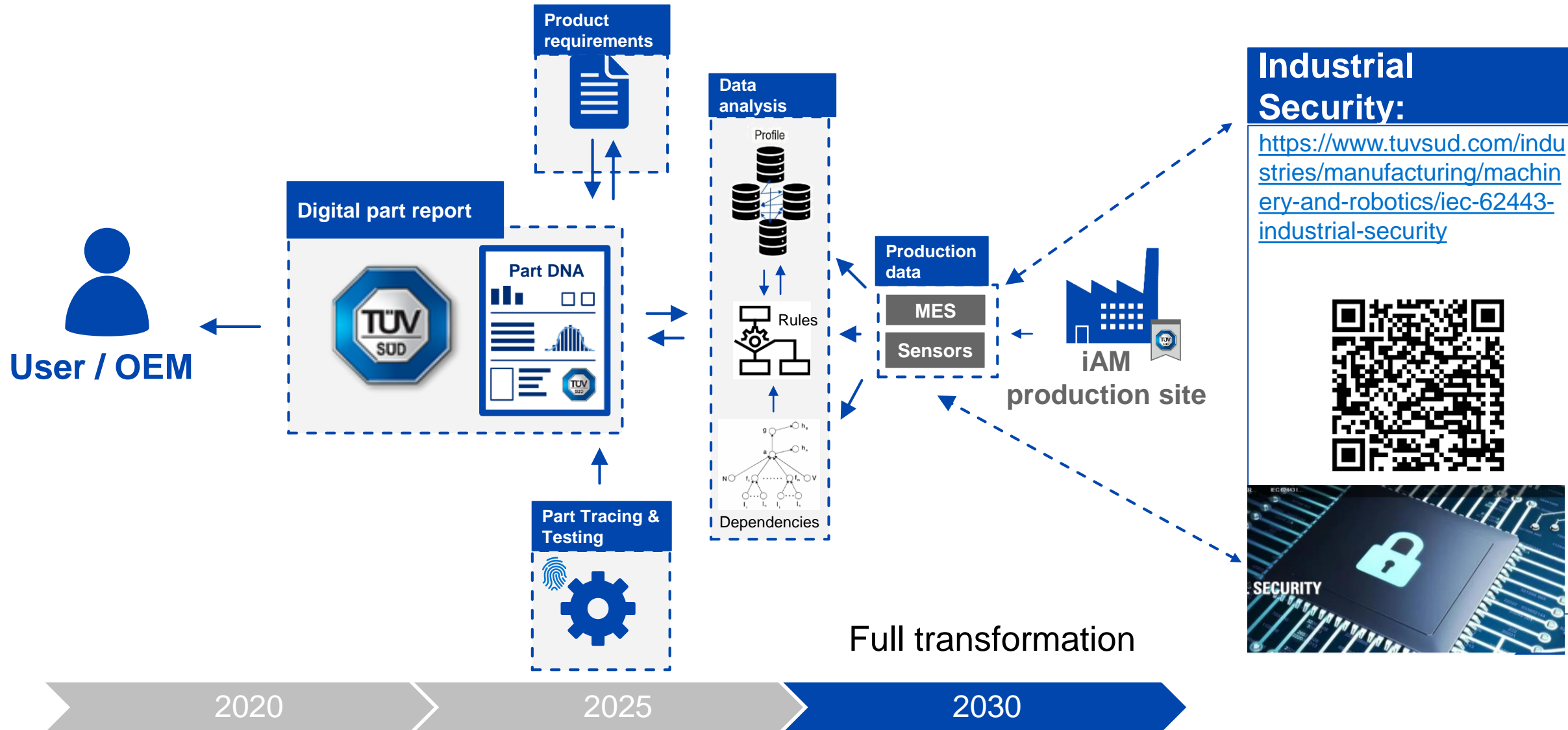
Smart

Industry 3.0

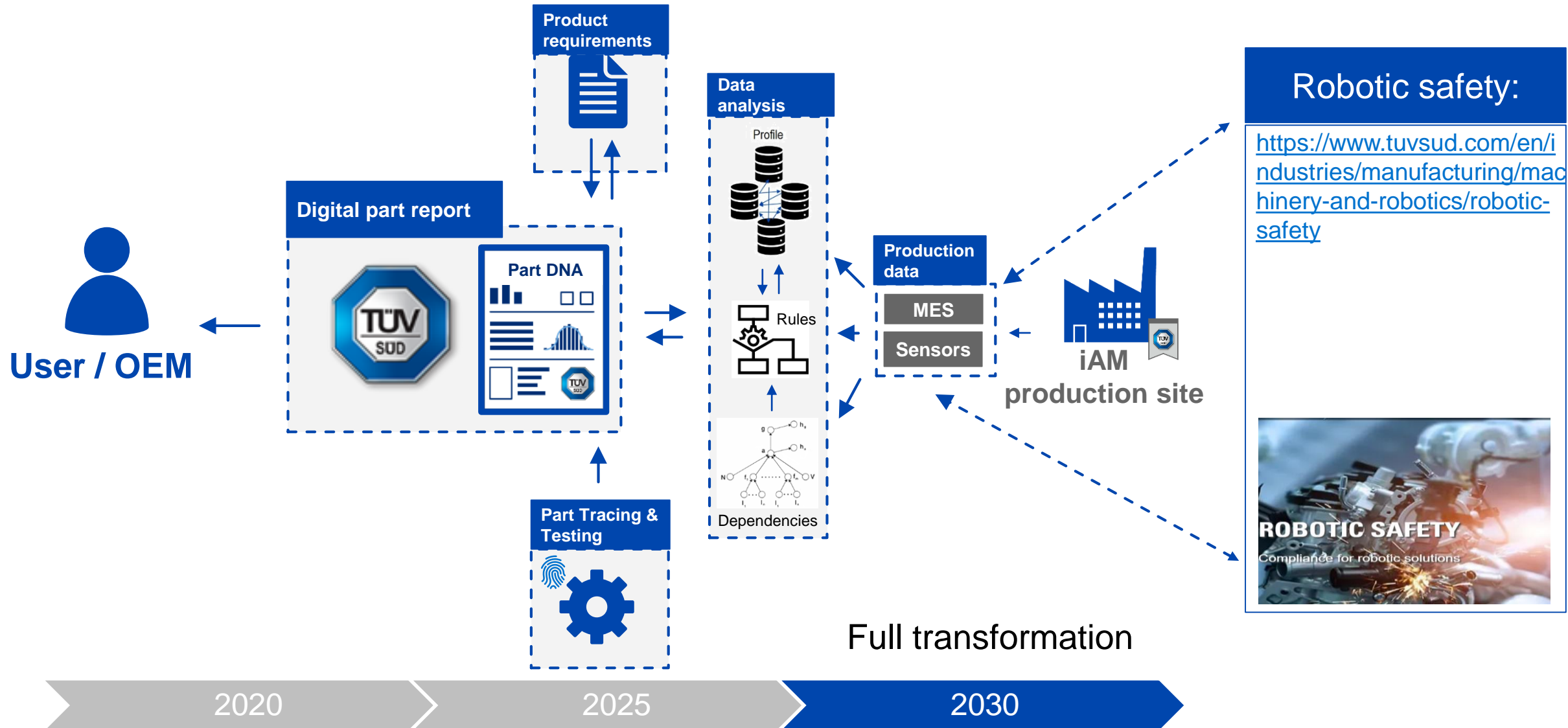
Transition to advanced manufacturing

Full transformation

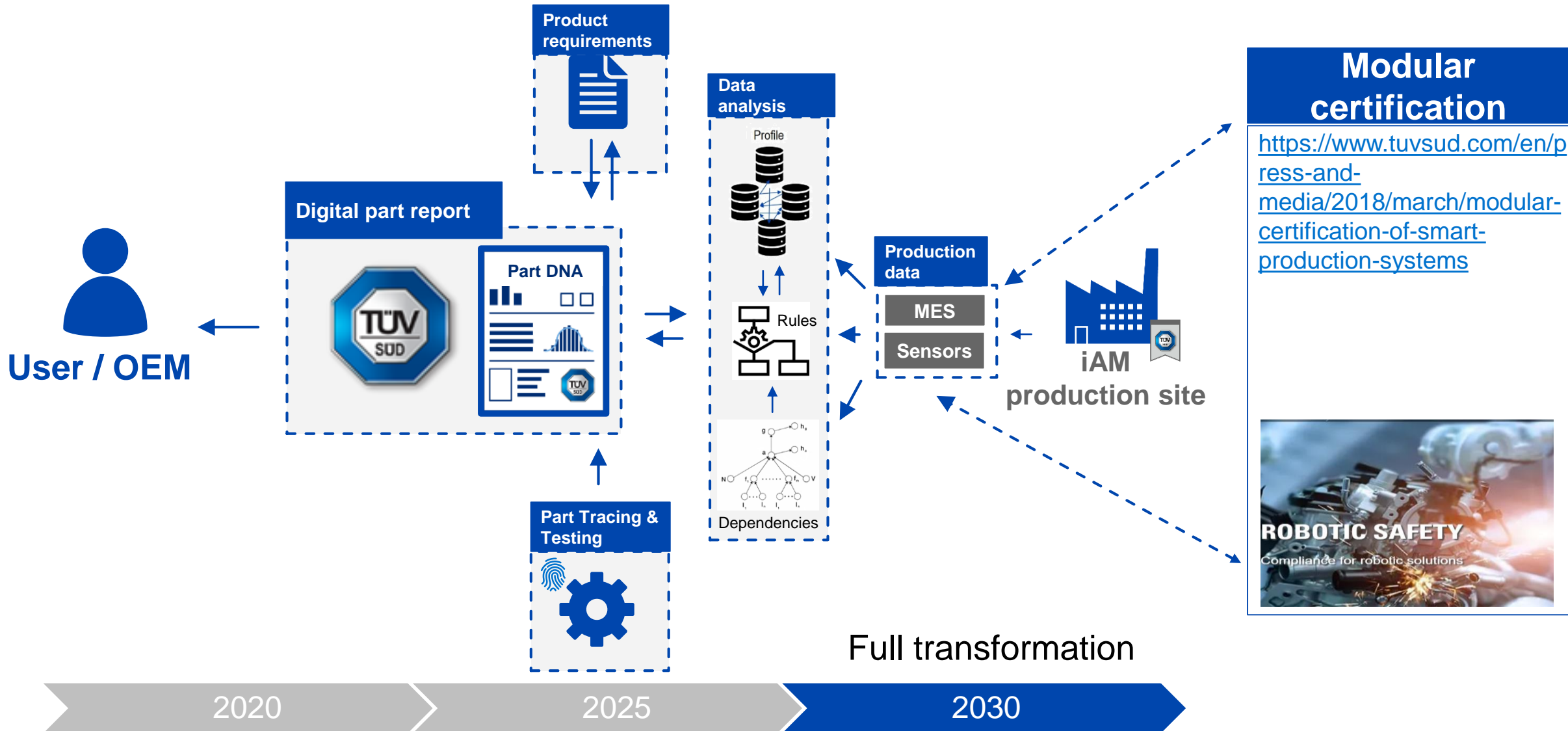
Colaboration landscape within the advanced manufacturing sector



The collaboration landscape within the advanced manufacturing sector



The collaboration landscape within the advanced manufacturing sector

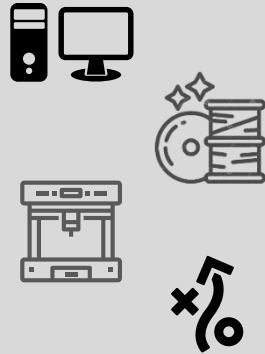


Which moduls are driving useful data collection and connectivity?

Module 1 Production Parameters / History

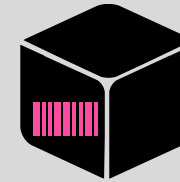
Monitoring and evaluation of the **main quality aspects**

- **Software** Parameters
- **Material** Parameters
- **Machine** Data
- **Process** Parameters



Product Lifecycle Tracing / Part Marking

Module 3



Enabling a product lifecycle tracing by **adding a physical part marking** onto the part.

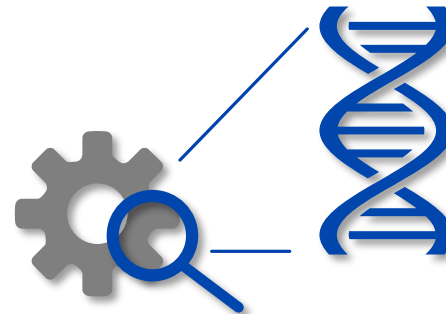
Documentation of meta data such as event, installation place/date or responsible engineer allows **Maintenance management** and the **avoiding of counterfeits**.

Module 2 Part Testing & Aproval

Optional conventional part testing service to **verify the requested part requirements** (Tolerances, mechanical-, chemical-, biological-, optical properties etc.)



Digital Part DNA



IP-Protection and Escrow

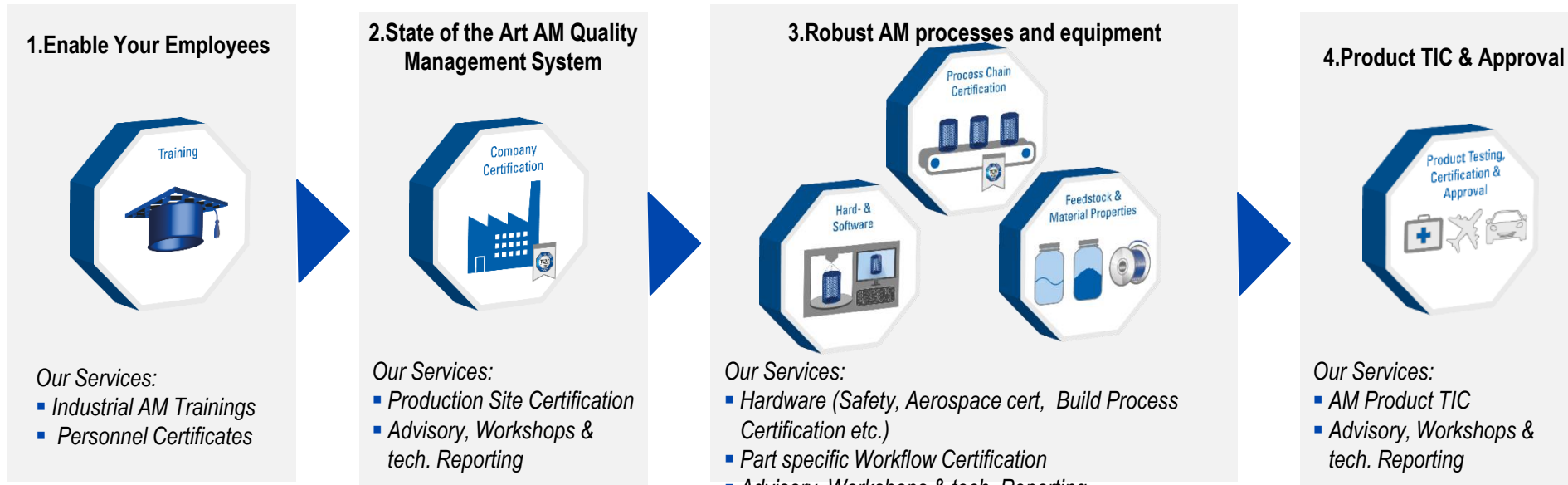
Module 4

Guaranteed **data safety & security** for the whole data handling. Additionally **high security cloud** for **sensitive IP-Data** (Unicon).

Optional **Escrow service for production data**. Data kept safe and all-time available even after manufacturer insolvency.



Standardized Implementation of industrial AM – We provide ready to use modules to enable “cost efficient” readiness for regulated industry requirements



Next Generation AM

Smart quality control & part approval of each AM part in realtime

Our Services:

- Advanced Manufacturing & Supply chain services

2030



Let's collaborate!

am@tuvsud.com

Gregor Reischle
Global head of Additive Manufacturing
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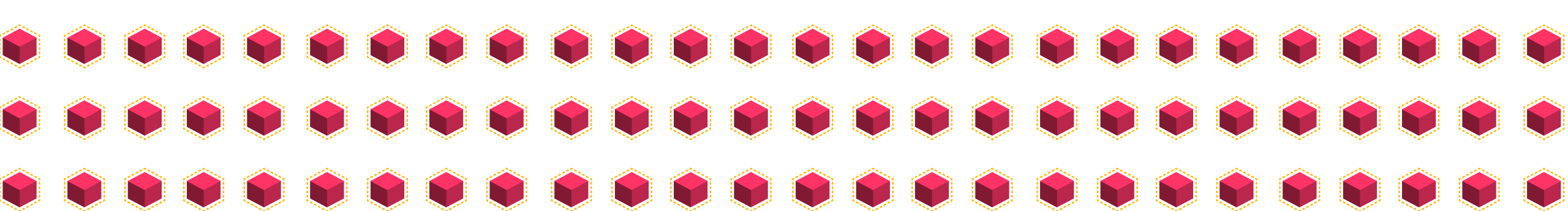
Web presence for our additive services:

<https://www.tuvsud.com/en/industries/manufacturing/machinery-and-robotics/additive-manufacturing>



**Mehr Wert.
Mehr Vertrauen.**

**Add value.
Inspire trust.**



Thank you!



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