From Innovation to Qualification: Enabling Industrial Additive Manufacturing at Scale

Transforming from experimental technology into a trusted, risk-managed industrial production system

via software-driven and AI-supported AM qualification

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AM Qualification Expert

Convener of ISO/TC 261 JG 75: Quality of AM, JG 80: Quality of AC, JG 84: LCA of AM

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The story of Qualified AM: From AM Pioneer to Qualification Leader

From first serial AM proof to software-driven digital qualification at scale

2008–2010	2010–2017	2017–2021	2021–2024	2024–2025	2026
First Serial AM experience First industrial serial AM use case Prototyping → production	**Multiplying first serial applications** Global serialisation at EOS AM in industrial supply chains	**Qualification & Standards in regulated industries** First risk-based AM qualification ISO/ASTM-aligned compliance base **DIN SPEC 17071**	**Start up Qualified AM GmbH** Global audits: semiconductor, rail, medical — regulator-ready **ISO ASTM 52920** **ISO ASTM 52964** **ISO ASTM 5295**	**Digital Qualification Era** Software-based qualification Guided evidence-based decisions	**Mission-Critical Applications** Defence, medical, space, semi-conductor — structured go/no-go

Trusted Across Regulated Industries

FLUSSFISCH

eos

ASTM INTERNATIONAL

ISO

DIN

TÜV SÜD

TÜVNORD

DB

toolcraft

GrOwnValve

BAM

KME

WILTING andra tech group

lpe laser prototypes europe ltd

VDL ETG EINDHOVEN

UKM Universitätsklinikum Münster

NTS

CRM GROUP

Agen$med

CRETEX Medical

rms

FIELDMADE MOBILE ADDITIVE MANUFACTURING

DCU

dilapro

3D SYSTEMS

DANISH TECHNOLOGICAL INSTITUTE

inkbit

Tongtai

Built on 15+ years of real-world AM experience across regulated industries.

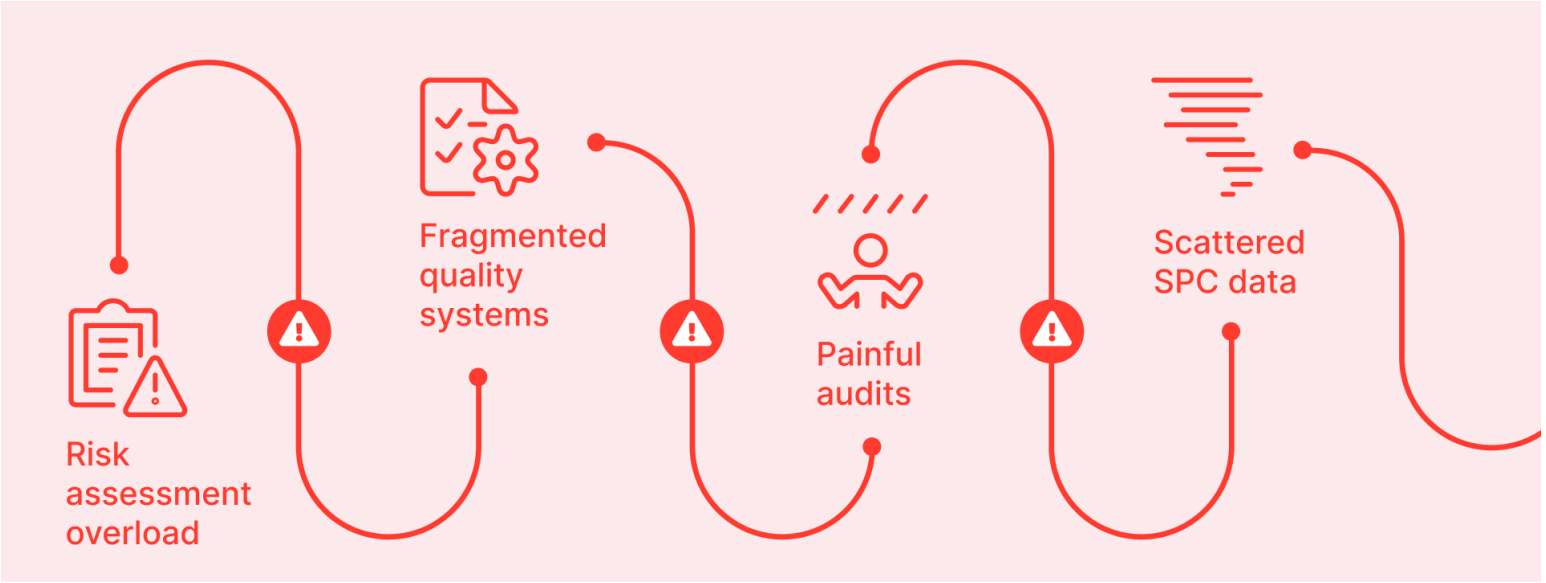
Why Conventional Qualification Does Not Scale

Repetition, delays, and fragmented evidence slow down industrial adoption

Repeated Effort
Every new project restarts the same qualification work from scratch

Fragmented Evidence
Inconsistent records make audits difficult and scalability impossible

Delayed Readiness
Documentation bottlenecks and approval delays push production start



Without reuse, qualification becomes a bottleneck instead of an enabler.

The Fast Lane to Scalable Production Readiness

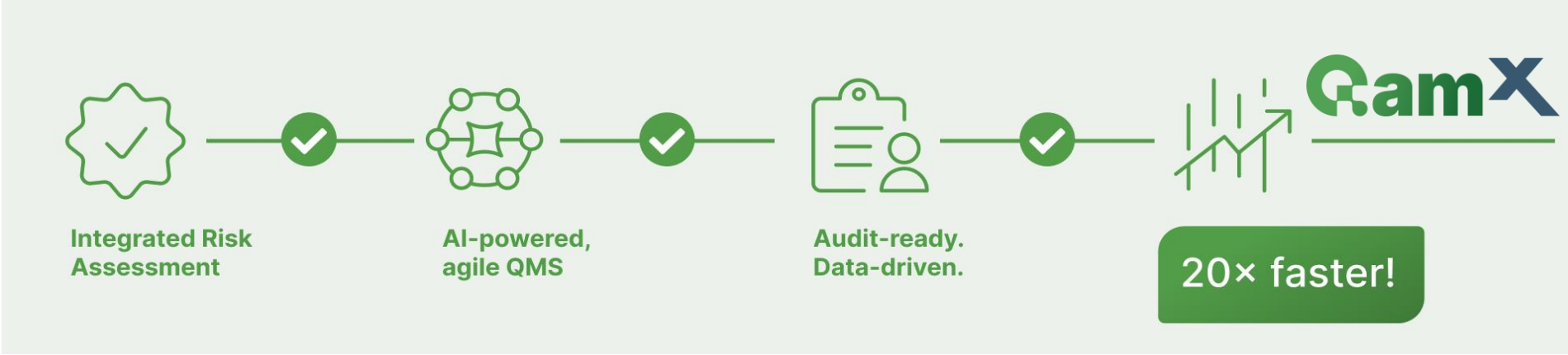
Integrated, guided, and data-driven qualification workflows

Reuse Qualification Work
Qualification assets created once are reused across future projects

Accelerate Production Readiness
Faster onboarding with a pre-established production base

Reduce Repeated Effort
Eliminate redundant documentation, testing, and approval cycles

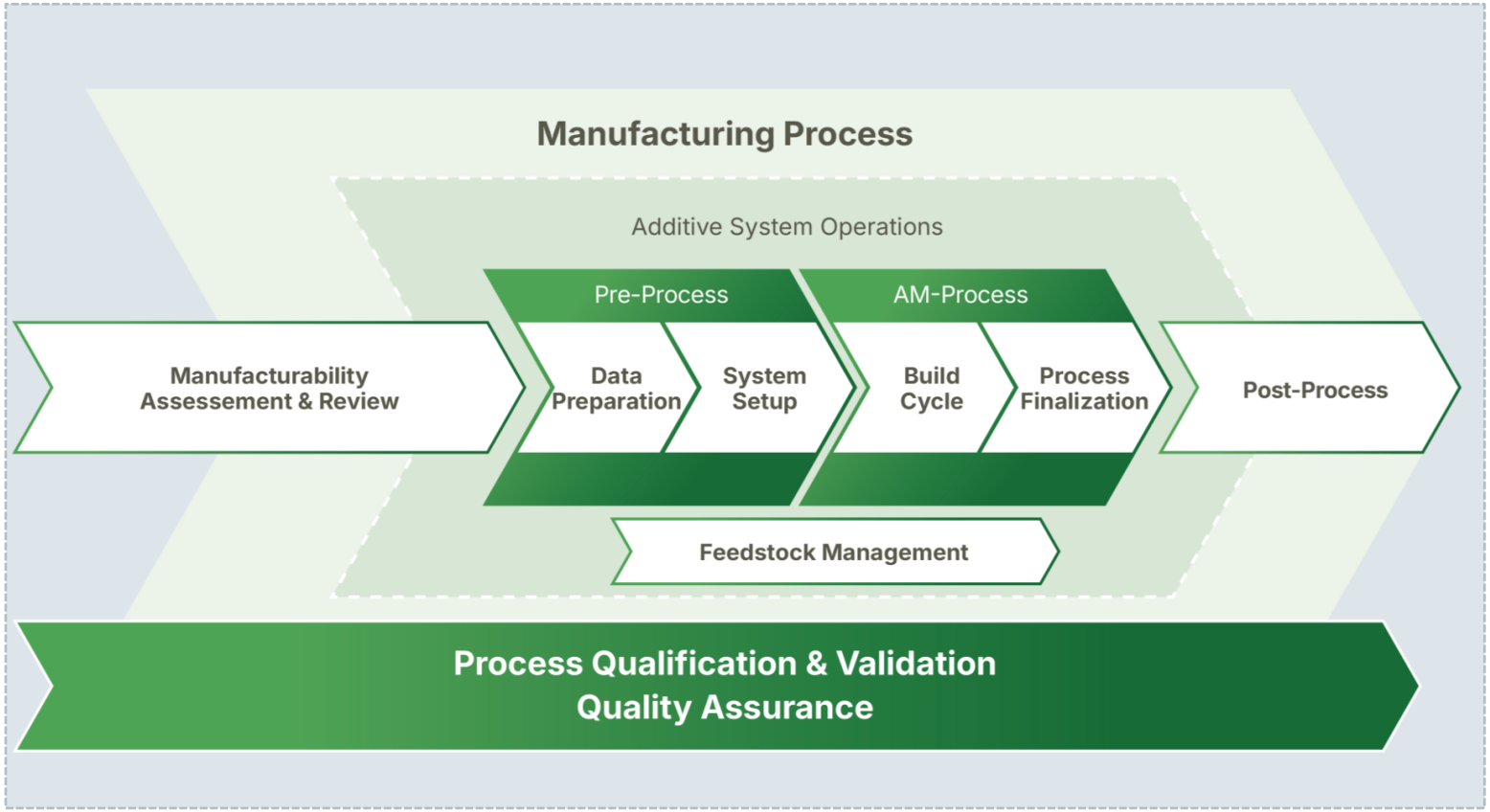
Improve Confidence
Traceable, evidence-based documentation strengthens customer trust



The key is to reuse qualification work instead of restarting it.

ISO/ASTM 52920:
The Qualification Backbone for Industrial AM

The core standard for reproducible, risk-managed additive manufacturing



01 Defines the qualification backbone for industrial AM production

02 Connects process quality, risk control, and repeatability

03 Creates the basis for auditable and scalable AM operations

A structured qualification standard is what turns AM from experimental capability into trusted industrial production.

Case Study - Supply chain qualification for ASML Semiconductor Manufacturing Systems

Extreme ultraviolet (DUV) lithography

AM parts in ASML systems:

- Fixtures
- Jigs
- Customized cooling devises

Deep ultraviolet (EUV) lithography

ASML

- **Fast** prototyping and improvement iterations.
- Critical for **weight reduction** and **customer specific customization**.
- Impactful applications across all regulated industries such as semiconductor**, Artifici Intelligence** and **Virtual Reality**.

Production for Rail spare parts.

Industry: RAIL

In only 3 months to a qualified AM site.

Setting up approvable QA system withing regulated industries.

AM Process Qualification at Hospitals

ISO 13485

Industry: MEDICAL

In only 4 months to a qualified process

UKM
Universitätsklinikum Münster

Qualification of Production line for Aerospace components

TODAY

QamX DIGITAL BACKBONE BASED ONISO/ASTM 52920 and ECSS STANDARDS

ArianeGroup - Injector head

Part A (Supplier 1)

Full Qualification

~75% reused

ArianeGroup - ISCAR bracket

Part B (Supplier 2)

Full Qualification

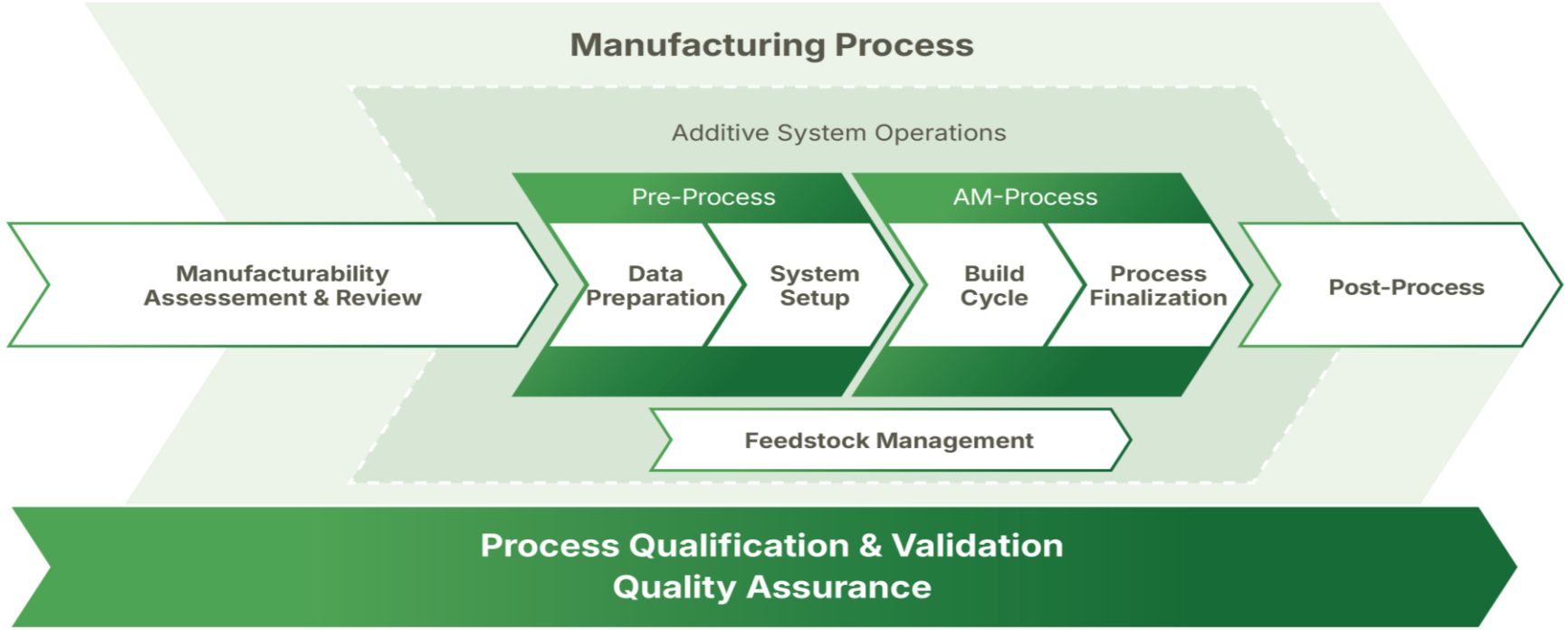
~65% reused

ArianeGroup - Combustion chamber

Part C (Supplier 3)

Full Qualification

~80% reused



↓ Non-recurring qualification efforts

↑ On Demand readiness for new PBF-LB parts

↑ Accountable path to new space components

↑ Scalability

Process qualification & validation data ~75 - 80 % can be reused

esa | Qualified AM

QamX

Typical Qualification of Production line

A structured pathway from qualification scope definition to certification

✓ Certification goal

Define Qualification Scope

QamX

Tailor the qualification pathway to the specific production setup

1–2 weeks

Assess Current Readiness – QMS build up

QamX QMS

Review systems, processes, and quality status

Month 1

Stage 1 Audit

QamX CERT

Preliminary audit and structured gap analysis

Month 4

Gap Closing Support

QamX RISK

Close gaps and finalize production readiness

Month 5

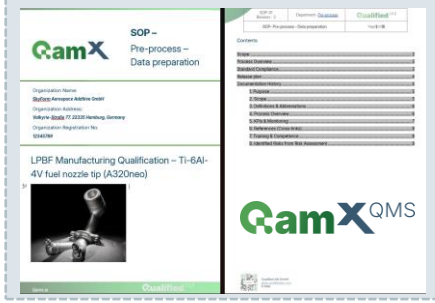
Stage 2 Audit & Certification

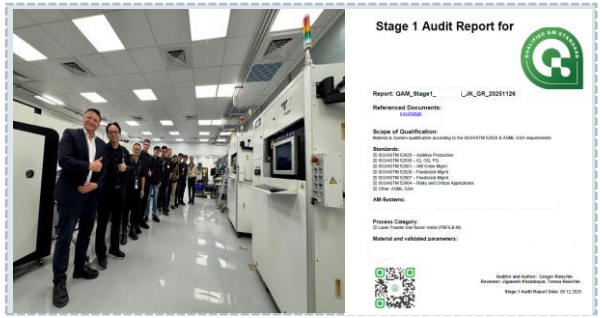
QamX CERT

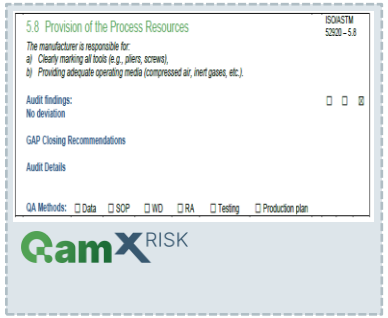
Final audit and formal certification award

Months 6–7

ISO/ASTM 52920 – Additive Production
ISO/ASTM 52930 – IQ, OQ, PQ
ISO/ASTM 52901 – AM Order Mgmt.
ISO/ASTM 52928 – Feedstock Mgmt.
ISO/ASTM 52907 – Feedstock Mgmt.
ISO/ASTM 52904 – Risky and Critical Applications
ASML GSA-02-0001







The new era of digital compliance is just starting!

From qualified production and part-specific mitigation to customer-ready evidence

Traceable Documentation

Every decision, mitigation, and risk assessment is logged with full traceability

Standard-Compliant Reporting

Reports are structured to ISO/ASTM 52920 requirements for audit readiness

Customer-Ready Evidence

Approval packages are formatted for direct use in customer and regulator approval workflows

QamX

Risk Assessment Report

Organization Name:
Deutsche Bahn AG
Organization Address:
Potsdamer Platz 2, 10785 Berlin, Germany
Organization Registration No:
AG Berlin-Charlottenburg HRB 50000

DB

The Hängelasche

Qamx.io

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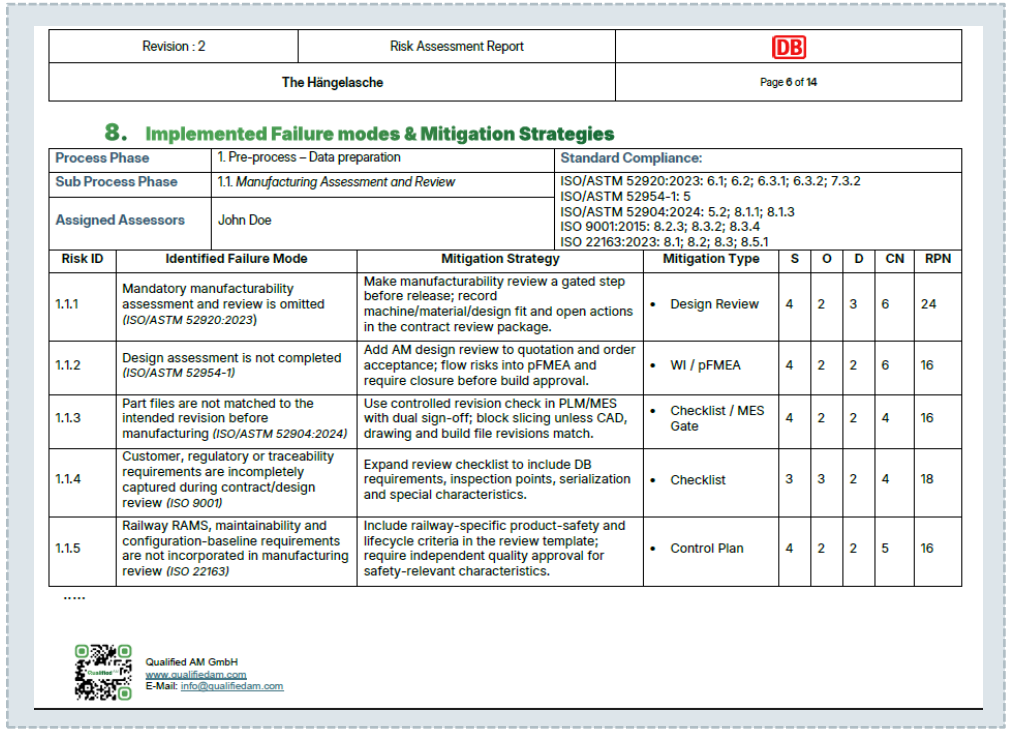

Revision : 2	Risk Assessment Report	DB
The Hängelasche		Page 6 of 14

8. Implemented Failure modes & Mitigation Strategies

Process Phase	1. Pre-process – Data preparation	**Standard Compliance:**
Sub Process Phase	1.1. *Manufacturing Assessment and Review*	ISO/ASTM 52920:2023: 6.1; 6.2; 6.3.1; 6.3.2; 7.3.2 ISO/ASTM 52954-1: 5 ISO/ASTM 52904:2024: 5.2; 8.1.1; 8.1.3 ISO 9001:2015: 8.2.3; 8.3.2; 8.3.4 ISO 22163:2023: 8.1; 8.2; 8.3; 8.5.1
Assigned Assessors	John Doe	

Risk ID	Identified Failure Mode	Mitigation Strategy	Mitigation Type	S	O	D	CN	RPN
1.1.1	Mandatory manufacturability assessment and review is omitted *(ISO/ASTM 52920:2023)*	Make manufacturability review a gated step before release; record machine/material/design fit and open actions in the contract review package.	• Design Review	4	2	3	6	24
1.1.2	Design assessment is not completed *(ISO/ASTM 52954-1)*	Add AM design review to quotation and order acceptance; flow risks into pFMEA and require closure before build approval.	• WI / pFMEA	4	2	2	6	16
1.1.3	Part files are not matched to the intended revision before manufacturing *(ISO/ASTM 52904:2024)*	Use controlled revision check in PLM/MES with dual sign-off; block slicing unless CAD, drawing and build file revisions match.	• Checklist / MES Gate	4	2	2	4	16
1.1.4	Customer, regulatory or traceability requirements are incompletely captured during contract/design review *(ISO 9001)*	Expand review checklist to include DB requirements, inspection points, serialization and special characteristics.	• Checklist	3	3	2	4	18
1.1.5	Railway RAMS, maintainability and configuration-baseline requirements are not incorporated in manufacturing review *(ISO 22163)*	Include railway-specific product-safety and lifecycle criteria in the review template; require independent quality approval for safety-relevant characteristics.	• Control Plan	4	2	2	5	16

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The workflow ends in approval-ready documentation, not just internal analysis.

Qualified AM

INNOVATION + COMPLIANCE

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