2025–26 Playbook: ATMPs, QMSR & AI for Biotech, MedTech & CGT

Get the free readiness checklist

- **The rules (and the tools) are changing fast.**
- **Win by designing inspection-ready operations from Day 1.**
- **This deck = what’s new, why it matters, and what to do now.**

2025–26 will reward the prepared: ATMP rigor, ISO-aligned device QMS, trustworthy AI, and country-by-country MDR labeling

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AUG 2025

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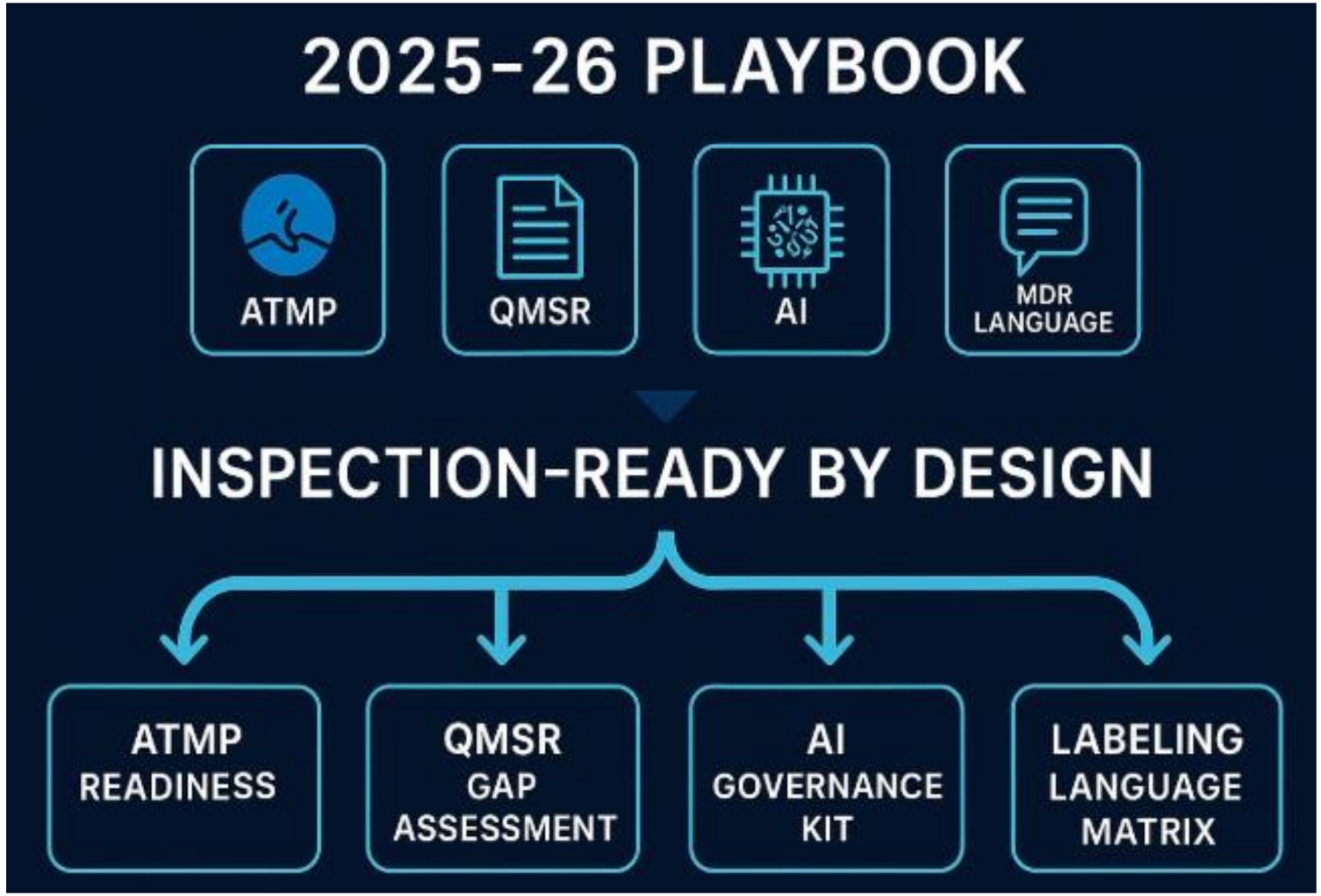
The FDA’s new Quality Management System Regulation will be enforced starting February 2, 2026

From 1 July 2025, EMA requires investigational ATMP trial applications to present quality data in a CTD-style Module 3 and manufacture under ATMP-specific GMP (EudraLex Vol. 4, Part IV



ICH E6(R3) was adopted on 6 Jan 2025 and becomes effective in the EU on 23 July 2025

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The Four Forces

What will reshape your plans in the next 12–18 months

EMA ATMP Guideline (effective 1 Jul 2025) raises CMC, potency & comparability expectations in trials

FDA QMSR (effective 2 Feb 2026) aligns US devices with ISO 13485

EU AI Act + MDCG Guidance tighten AI governance for MDR/IVDR

MDR Language Req. (Rev. 3, 2025): Member-State specific rules for labels/IFU/FSN

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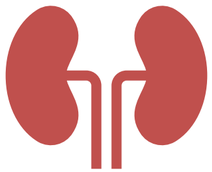
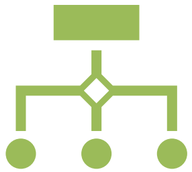
Executive Summary: What It Means



Cleaner, faster filings when CQA/CPP, potency and comparability are set early



Devices/Diagnostics: Think ISO 13485 in the US now; re-work takes longer than readiness.

AI in GxP: Expect data fitness, transparency, human oversight & validated systems.

Labeling: Country-by-country language matrices must be embedded in artwork SOPs.

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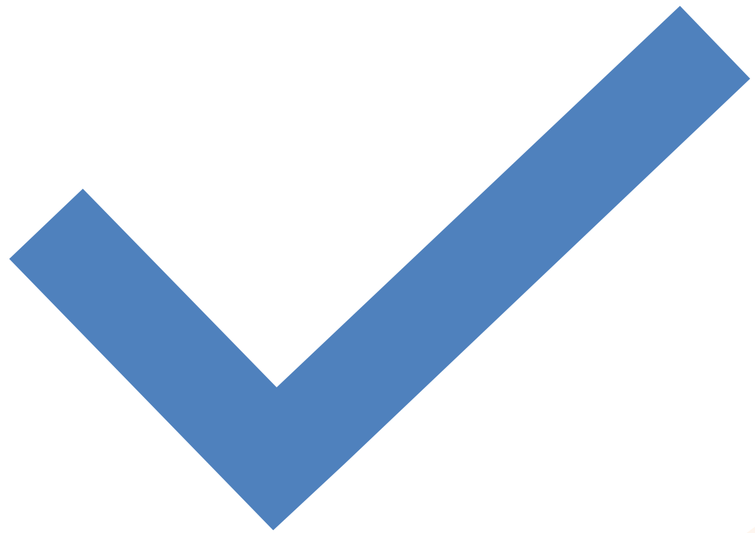
EMA ATMP Guideline: What’s Non-Negotiable

- CTA/IMPD quality section follows clear structure; show GMP alignment and phase-appropriate controls.
- Demonstrate potency strategy (often a matrix) and comparability from Day 1.
- Plan for manufacturing changes and site moves without losing clinical evidence.



ATMP Playbook (How to Win)

Map **CQA → CPP → control strategy** (ICH Q8/Q9).

Lock **potency** approach; define acceptance criteria & trending method.

Pre-write **bridging/comparability** narratives for known changes.

Make CMC tell **one coherent story** across IND/IMPD/BLA/MAA.

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FDA QMSR: US Devices Go ISO

21 CFR 820 becomes QMSR; ISO 13485 alignment with FDA clarifications.

Focus areas: Design Controls, CAPA, Supplier Quality, Risk (ISO 14971), Records/Documentation.

Effective 2 Feb 2026 (transition window—don’t wait).

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QMSR Transition: 90-Day Roadmap

Gap-assess vs ISO 13485; build a “delta binder”.

Refresh **Design Control** files; align **CAPA** to root-cause/verification rigor.

Tighten **supplier controls** & risk interfaces (**14971**).

Train auditors; schedule internal audits; update management review cadence.

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EU AI in Healthcare: Interplay with MDR/IVDR

High-risk AI requires governance: data quality, explainability, human oversight.

MDCG guidance clarifies how AI Act obligations sit alongside MDR/IVDR.

Expect staged application and controls for significant changes.

Bottom line: Treat AI like **software + clinical risk**, not “magic”.

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OriPeutic’s Role in Achieving These KPIs

Data fitness	• Representativeness, bias checks, drift monitoring
Explainability & documentation	• Model card, intended use, limits
Human-in-the-loop	• Define override/escalation
Validation	• Part 11/Annex 11 evidence; audit trails; change control
Post-market	• Performance monitoring & incident handling

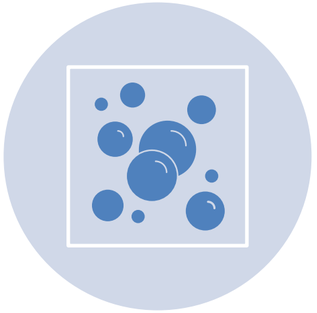
MDR Language Requirements (Rev. 3, 2025)

Member States define languages for labels, IFU, implant cards, FSNs, conformity docs.

English often accepted for professional-use devices in some states; others require national language(s).

Build a language matrix by country and route through artwork change control.

ICH E6(R3): Clinical SOPs to Update



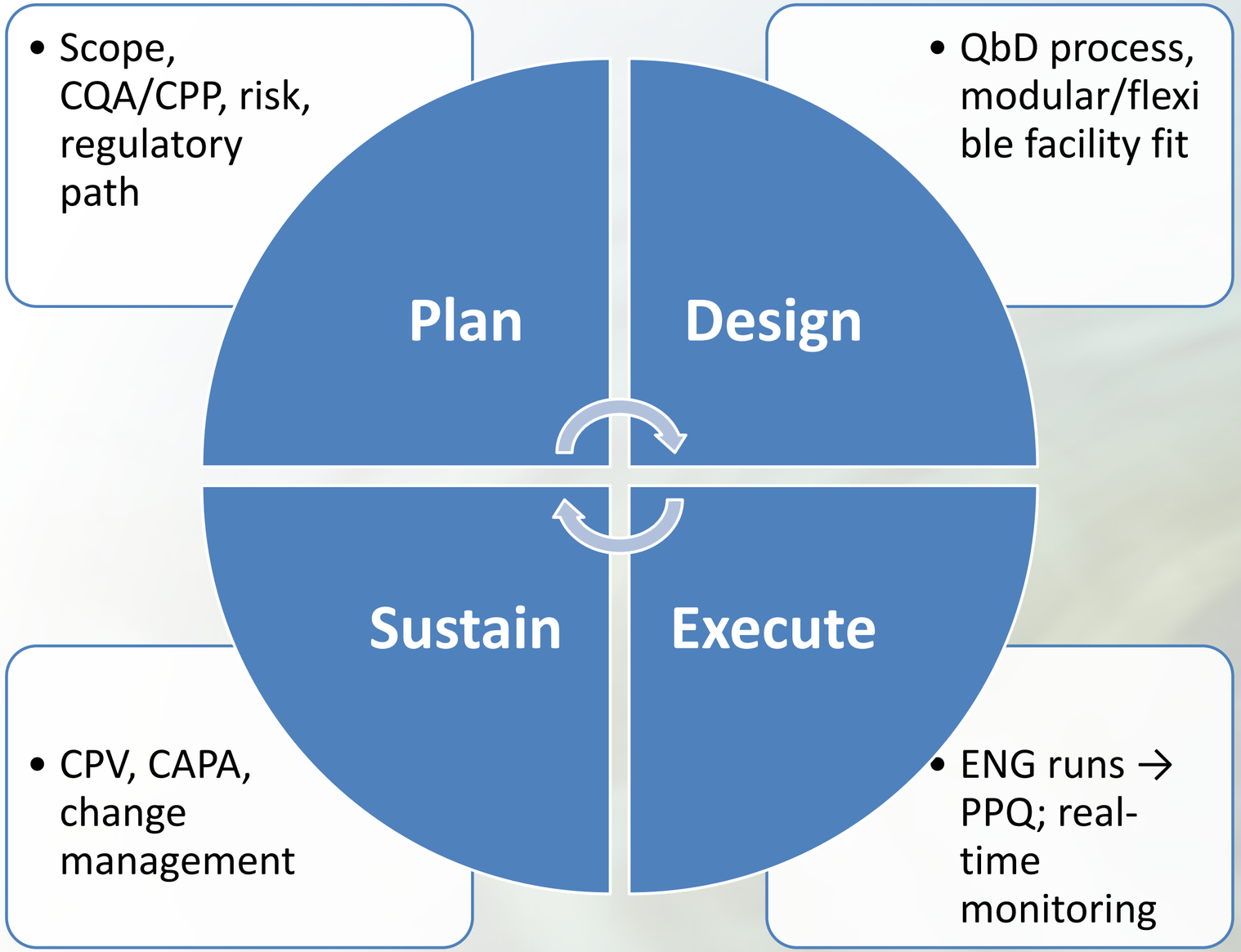
QbD/Critical-to-Quality in protocols (not afterthoughts).

RBQM across the study; centralized monitoring plans.

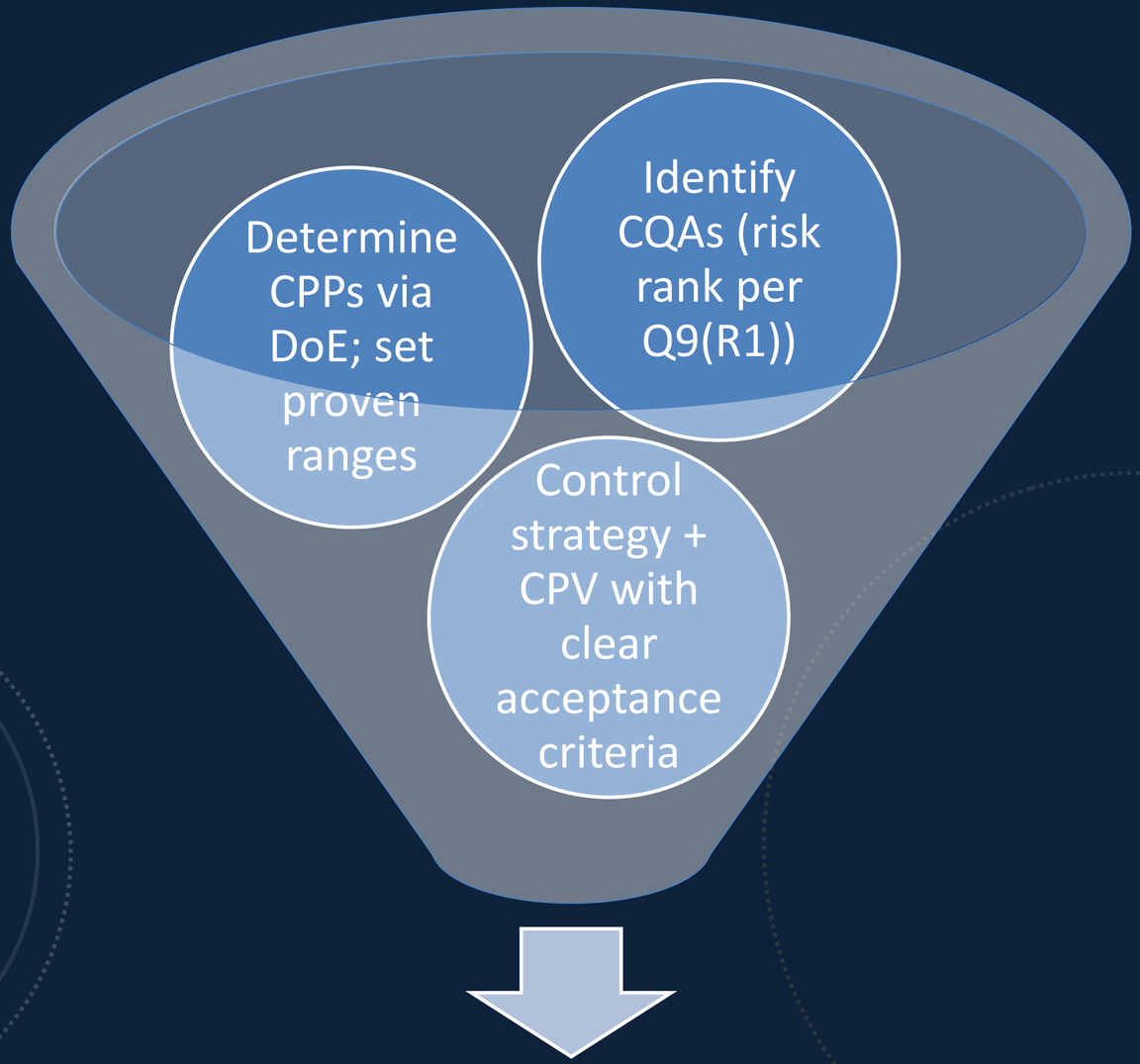
PI oversight documented; role clarity for vendors/CROs.

Validated e-systems; inspection-ready eTMF during the study.

Tech Transfer & NPI: The Formula



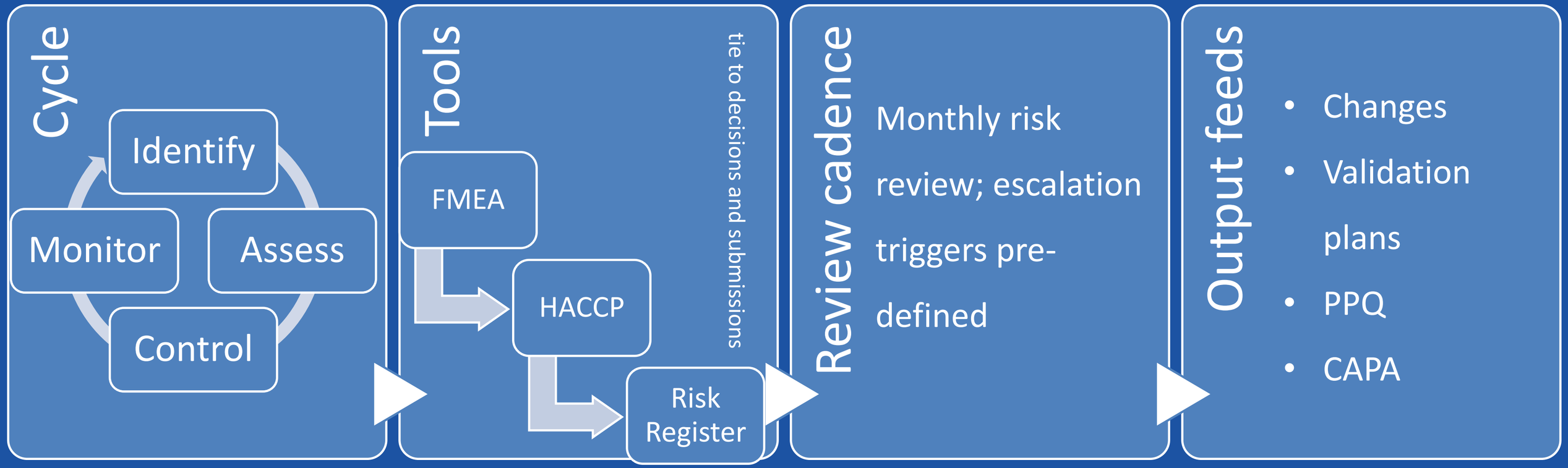
Managing CQA & CPP (3-Step Flow)



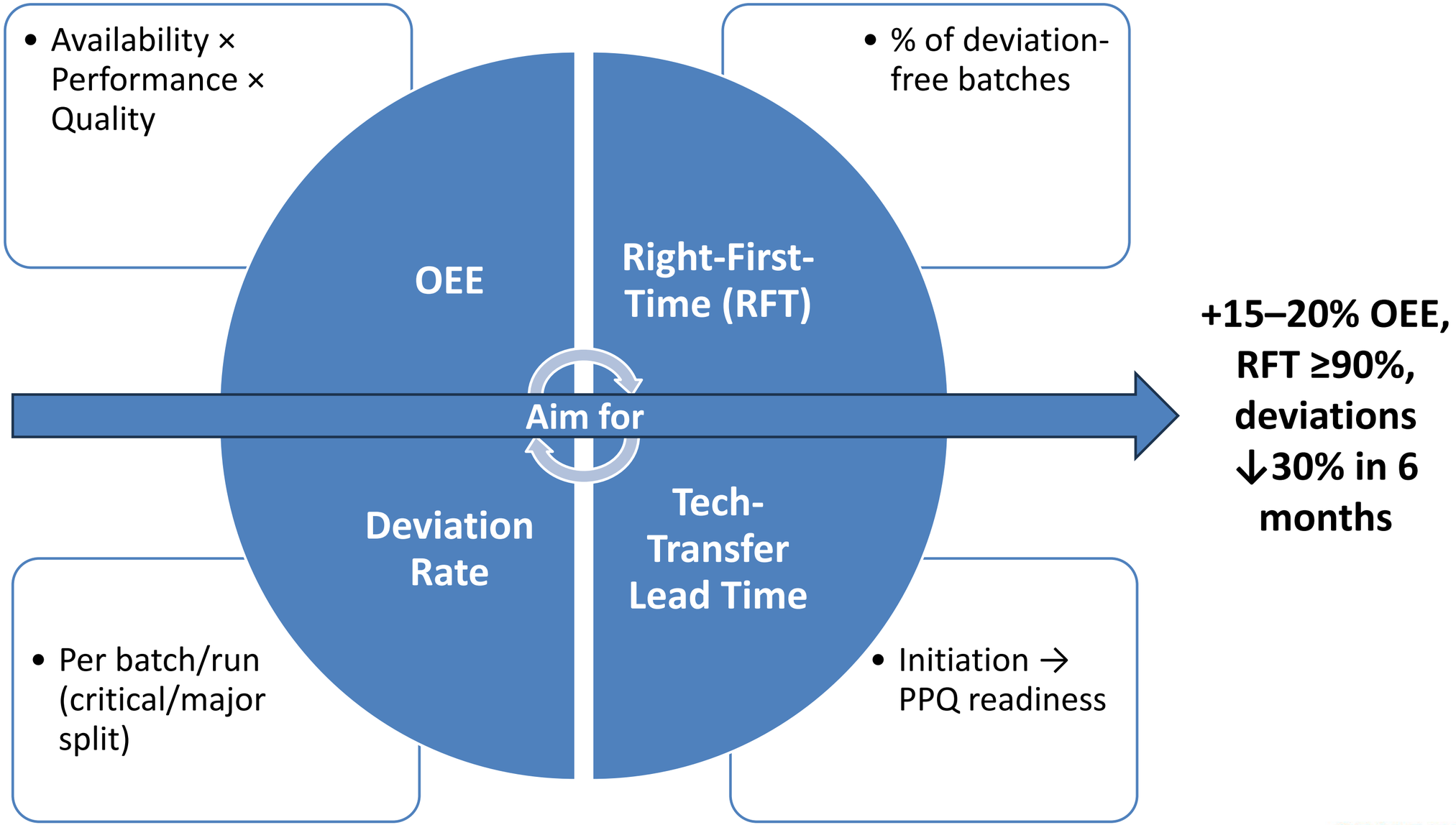
Outcome: consistency at scale, faster approvals, fewer deviations

The Four Forces

What will reshape your plans in the next 12–18 months



KPIs & Operational Excellence



Case Snapshot (De-identified)

Modular/adaptive workflow → changeover time ↓ 68% (12 days → 3.8 days).

Capacity ↑ ~22% with single-use & scheduling optimization.

Zero criticals in pre-approval inspection after DI/CSV uplift

Lesson: Design for flexibility; measure relentlessly.

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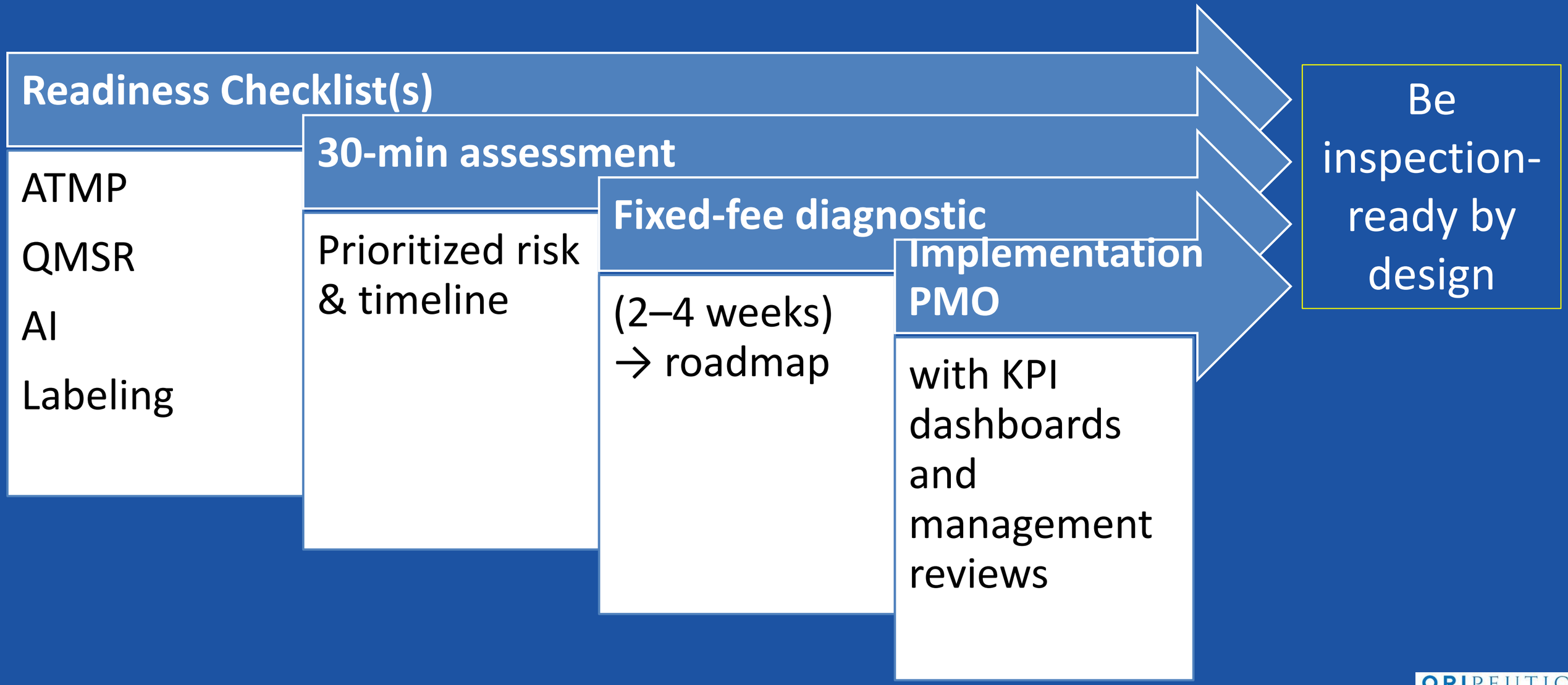
Offer Ladder (Lead Magnet → Engagement)



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