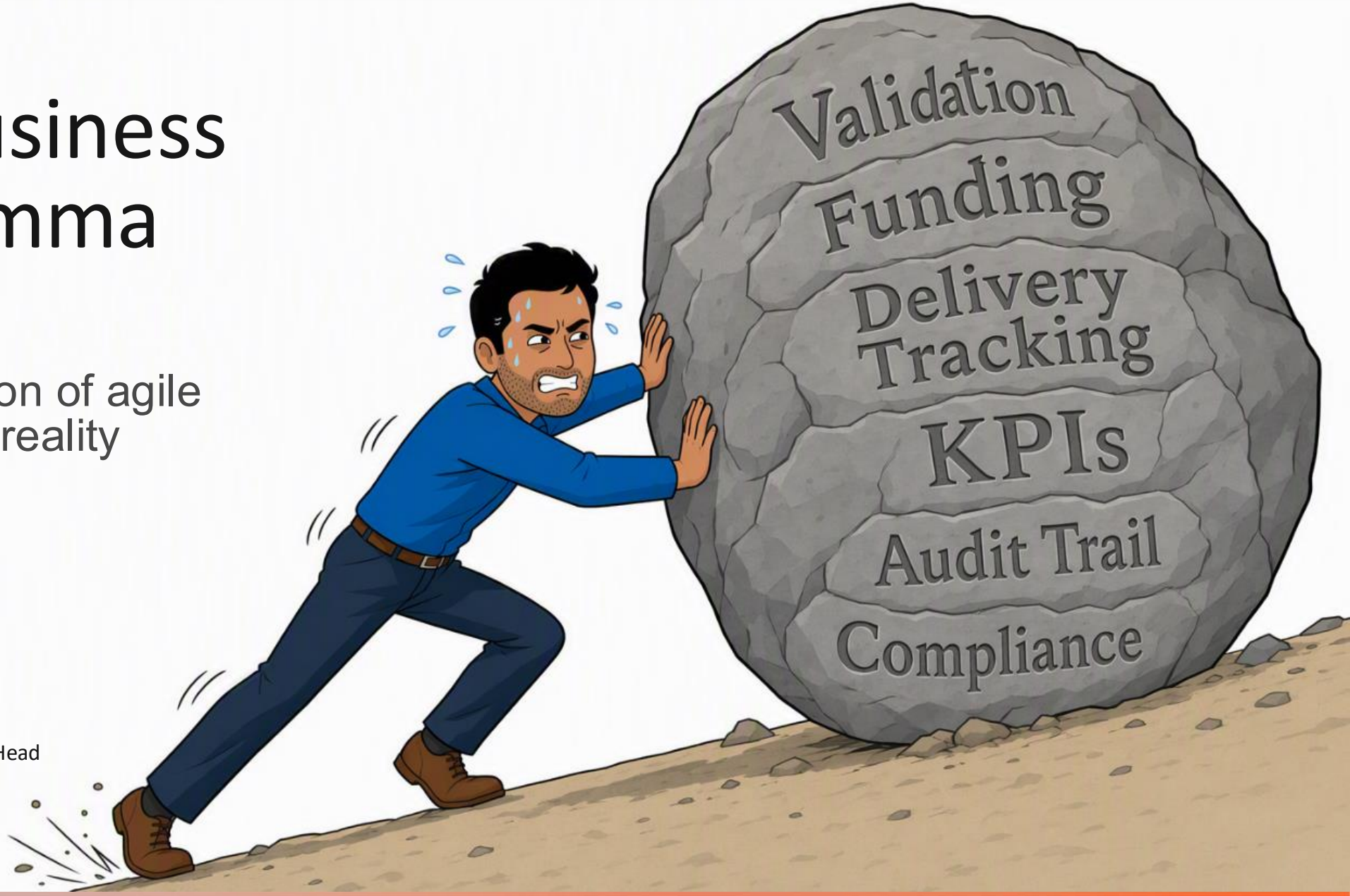
LI07 The Business Lead's Dilemma

Navigating the collision of agile aspirations and GxP reality



James Black

Executive Director, Advanced Tech Platforms Head
Technology and Scientific Computing
Advanced Quantitative Sciences
PHUSE EU | 2026 | Glasgow

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The last 10 years of my career

3

SCE Launches as Business System owner

2

Pharma companies (Roche/Novartis)

3

Clinical Trials,

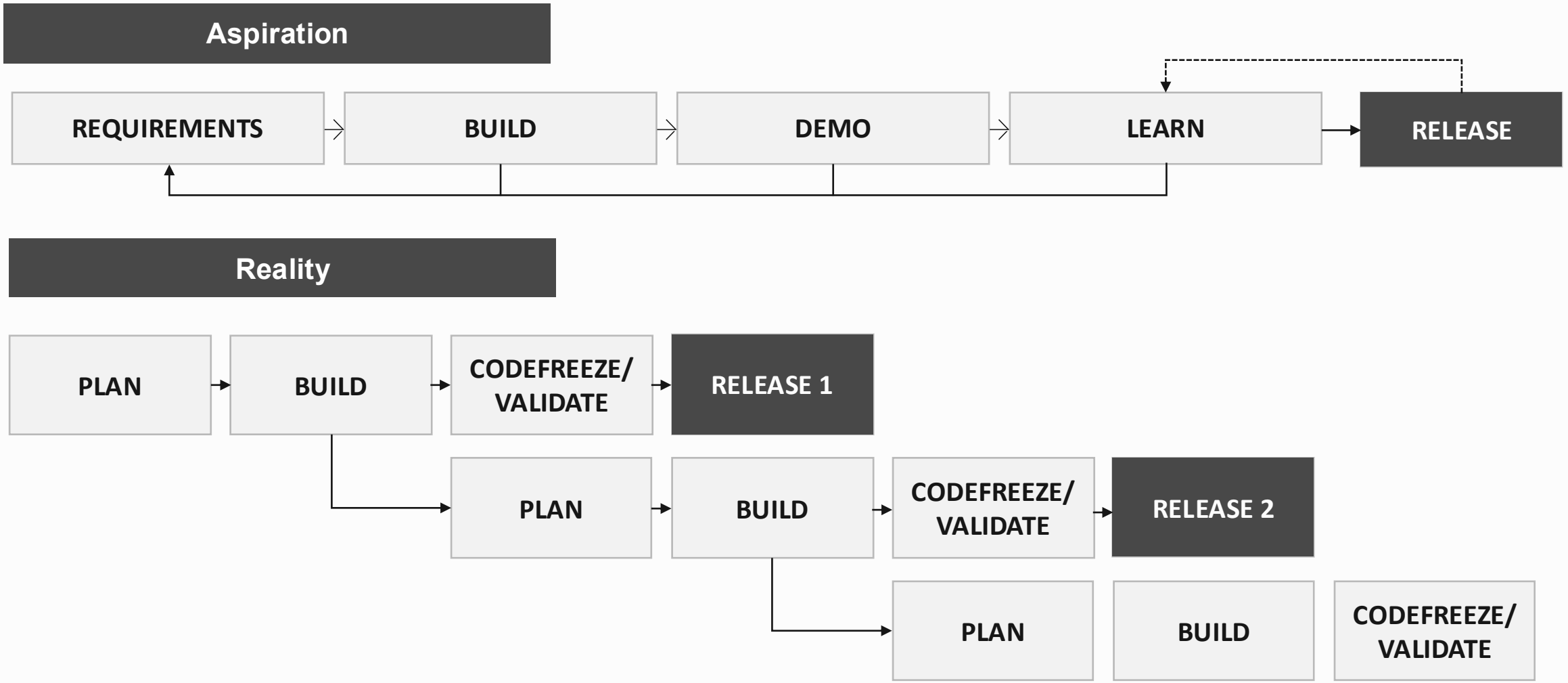
Real World Data,

PHC/Imaging

3

Attempts to be agile

The same collisions every time

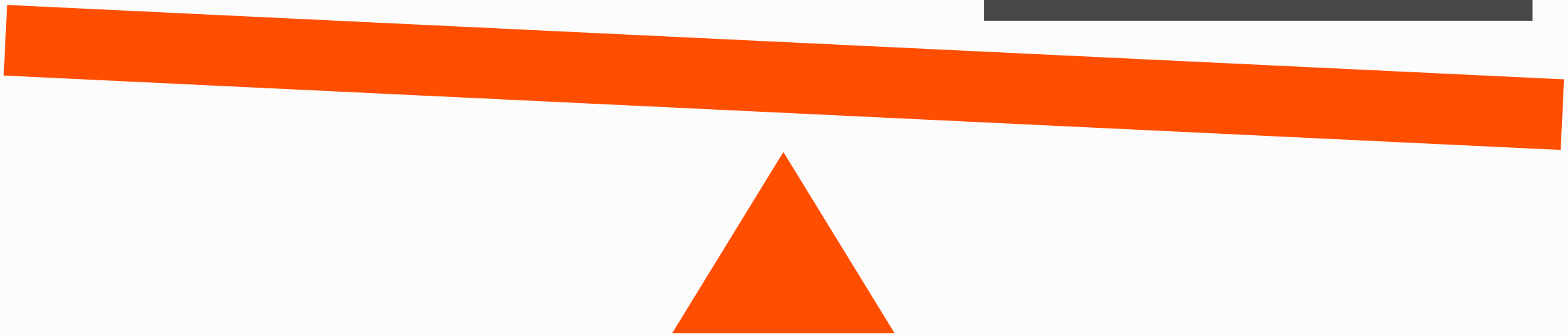

Aspiration
REQUIREMENTS
BUILD
DEMO
LEARN
RELEASE
Reality
PLAN
BUILD
CODEFREEZE/ VALIDATE
RELEASE 1
PLAN
BUILD
CODEFREEZE/ VALIDATE
RELEASE 2
PLAN
BUILD
CODEFREEZE/ VALIDATE

AGILE ASPIRATIONS

Ship quickly. Learn from users. Change your direction cheaply.

GxP REALITY

Extensively document and test. Multiple external compliance stakeholders



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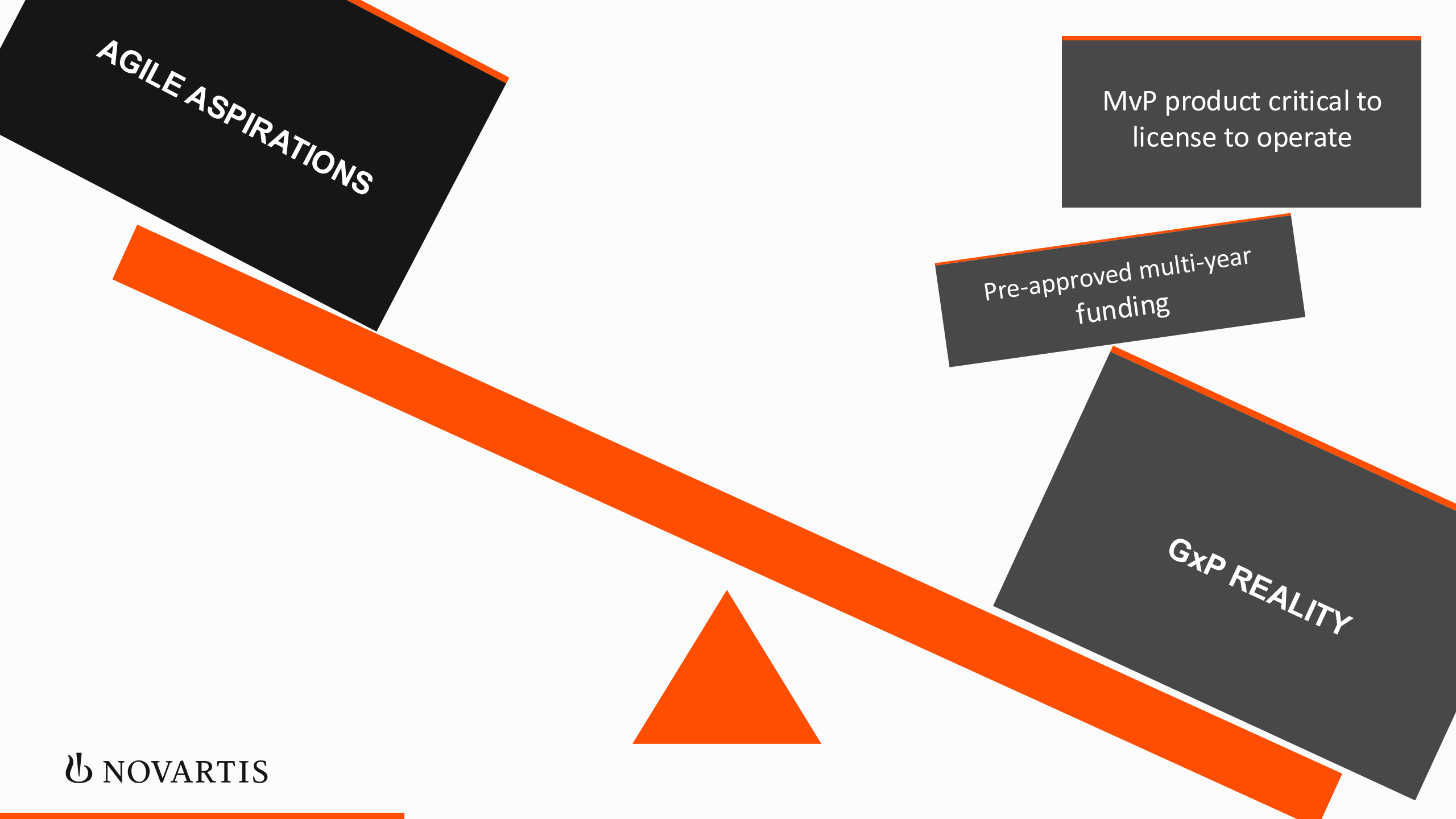
AGILE ASPIRATIONS
MvP product critical to license to operate
Pre-approved multi-year funding
GxP REALITY

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Success is being responsive to need

Agile & waterfall are frameworks. What matters is delivery – even if that means conceding to *water-scrum-fall.*



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Four mistakes I would not make again

1

Not acknowledge it's two delivery models at once

2

Not prioritise change management and SMEs as critical to success

3

Expect upstream and downstream teams to see us as more than a nuisance

4

Underestimate the effort to do risk-based validation

None of these mistakes were caused by the GxP requirements

All of these mistakes relate to our approach to GxP product delivery

Project management is dead

Long live agile…

…project management



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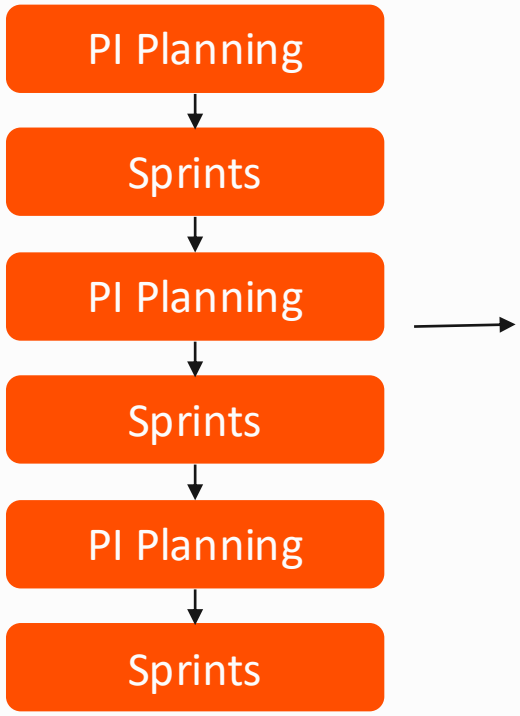
Water-scrum-fall in practice: bridging waterfall project management with agile

Benefits the users



Benefits your funders

- Tracking of delivery progress over year+ funding
- Internal Project Governance Tollgates and Documentation

95% of the project is tracked in agile tools ↣ project and product management must speak the same language.

The product can never commit beyond an increment ↣ sponsors must expect the product will pivot over horizons longer than 3 months

R1.0 of a GxP platform cannot be an ‘MVP’ ↣ Avoid GxP at go-live or accept year 1 will be challenging

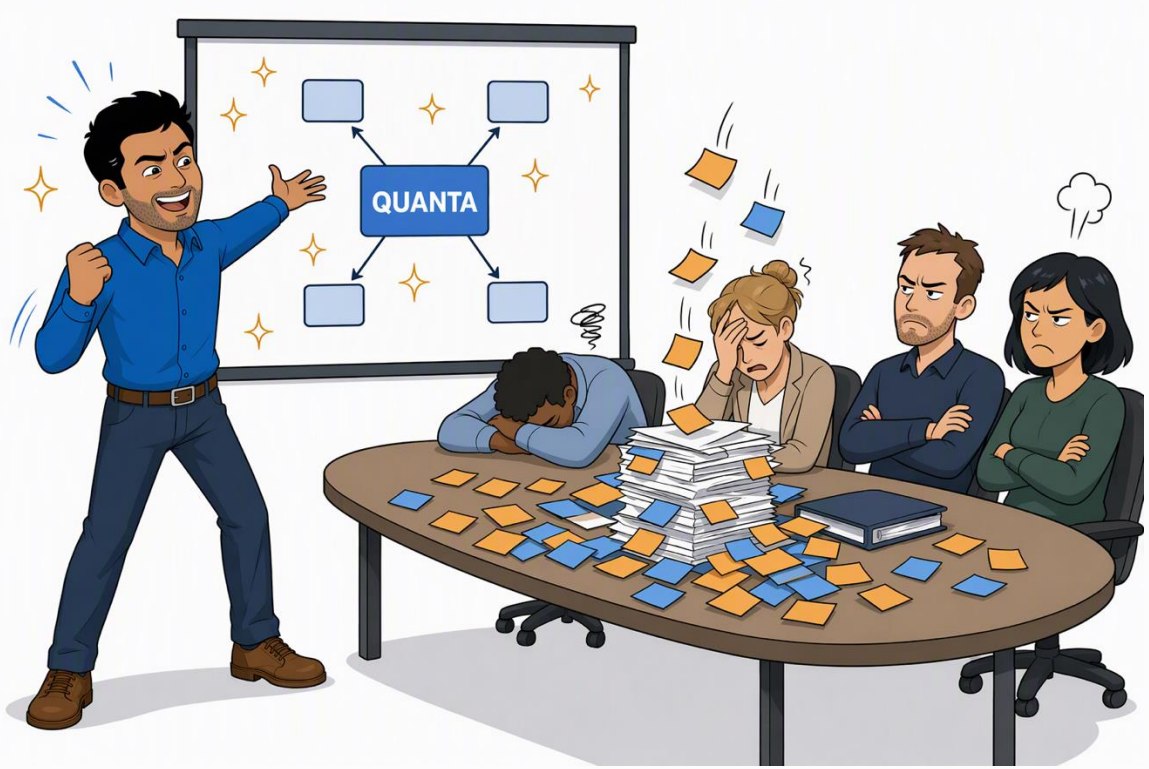
Customers submit tickets — partners share success

Customer	Partners
Tells you what is wrong. Owns none of the fix.	Co-owns scope, timing and the change itself.

A strong and committed set of SMEs, and Product Owners from the business are non-negotiable

The users co-own the success of the SCE, they are not a stakeholder group.

You are generating work everywhere you integrate



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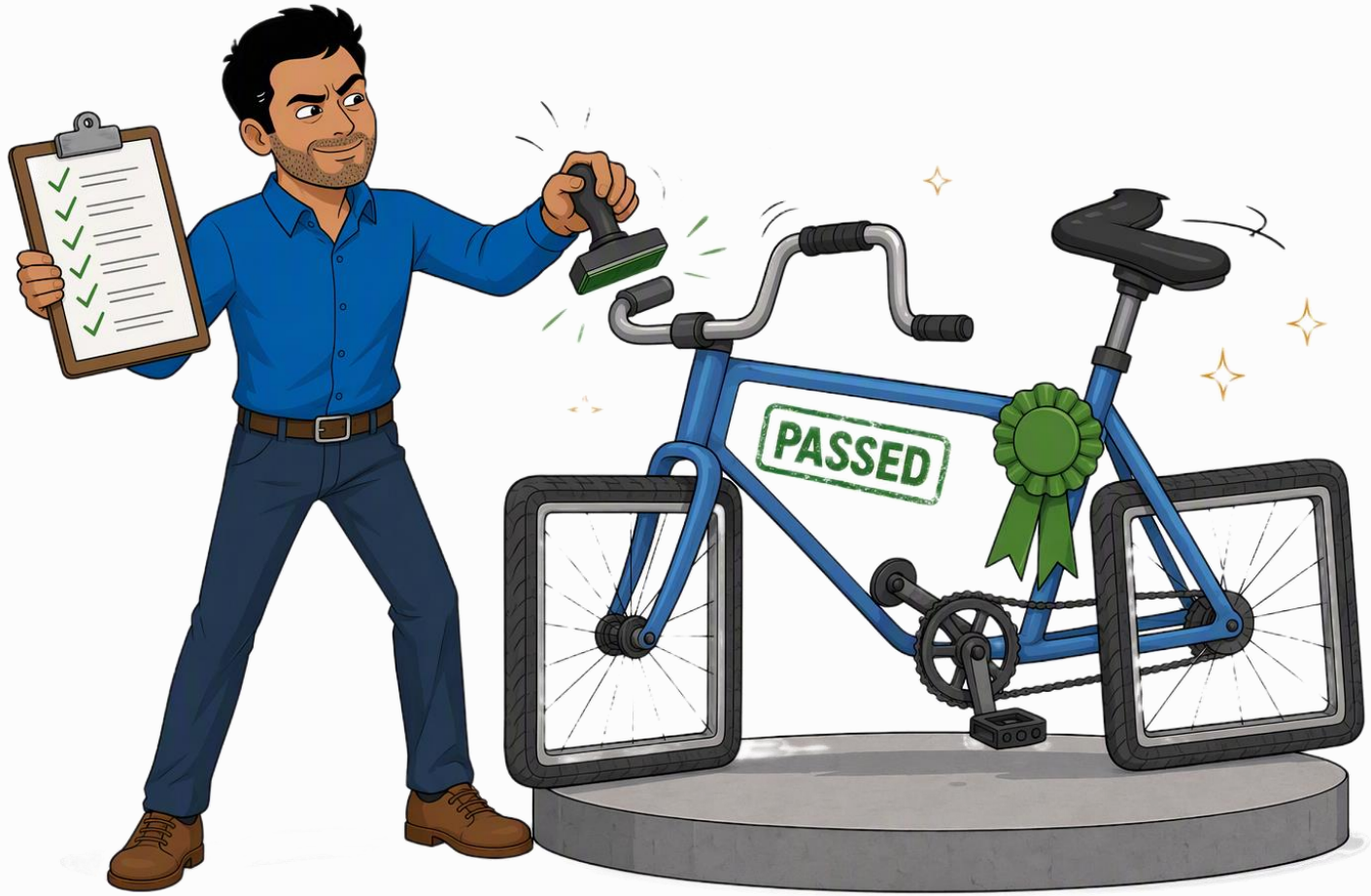
The evidence pipeline is in flux

From protocol authoring to CSR generation our pipeline is in flux – dedicated resources are needed to align project to project

Change management extends far beyond your department

From database developers on your ingestion platform to safety teams, package insert authors in manufacturing and PK scientists in research, the extent to which your platform impacts other teams often requires detective work

Validated
≠
Good



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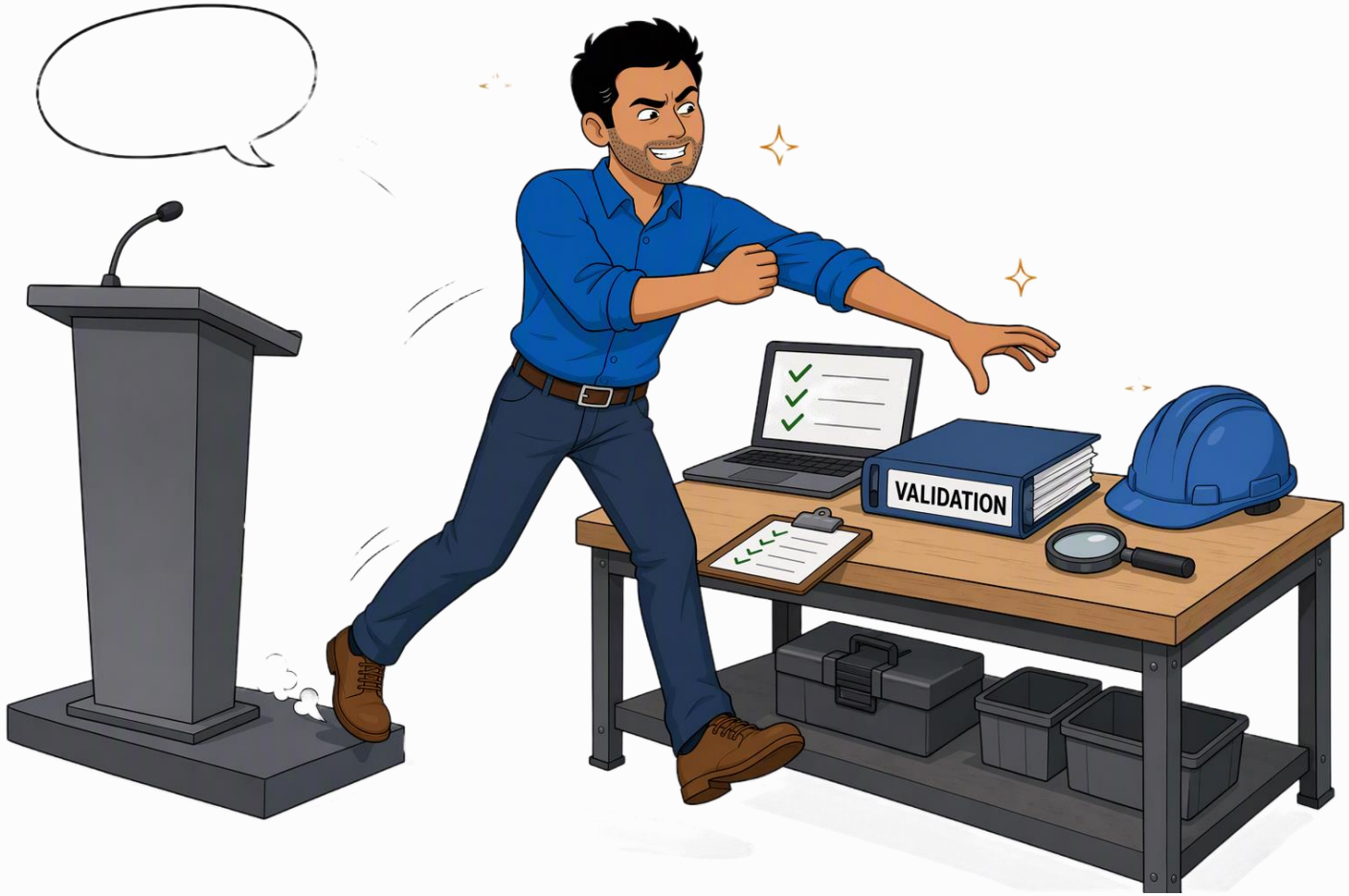
The pain point	The mitigation
The SCE is the unit of risk, so updating a unix dependency in the R environment takes weeks	Tier the platform and de-couple components Challenge the easy path
The system is GxP	The processes are GxP

Be aggressive on risk assessments, but disciplined on how you document

Let’s do risk based validation



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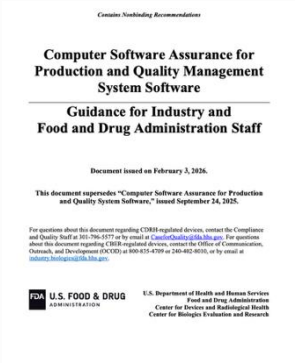
The regulations allow more agility than we often use

CSA for Production and Quality Management System Software
Feb 2026, FDA


Contains Nonbinding Recommendations

Computer Software Assurance for Production and Quality Management System Software

Guidance for Industry and Food and Drug Administration Staff

Document issued on February 3, 2026.

This document supersedes "Computer Software Assurance for Production and Quality System Software," issued September 24, 2025.

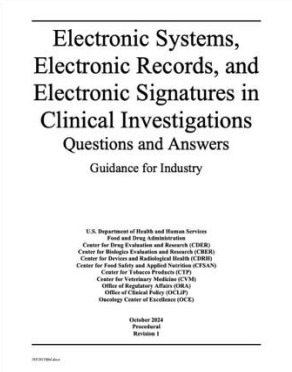
U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Governs medical devices & QMS

A credible analogy of risk based endorsement, including use of unscripted testing, enriching positions in the 24 year old FDA General Principles of Software Validation

Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations
Oct 2024, FDA


Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations

Questions and Answers

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Center for Food Safety and Applied Nutrition (CFSAN)
Center for Tobacco Products (CTP)
Center for Veterinary Medicine (CVM)
Office of Regulatory Affairs (ORA)
Office of Clinical Policy (OCLP)
Oncology Center of Excellence (OCE)

October 2024
Procedural
Revision 1

Directly relevant FDA Guidance

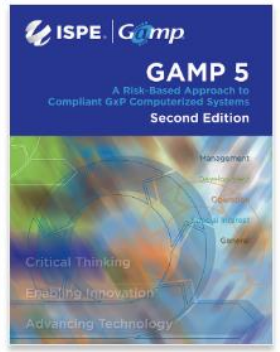
FDA recommends risk-based validation and explicitly states that the level of validation may vary for bespoke, configured and unaltered systems.

EU GMP Annex 11 revision (Computerised Systems) & Annex 22 (AI)
DRAFT, European Commission

Incoming update to European Manufacturing and Quality guidance

One to watch, but draft maintains mandate to document risk based decisions diligently

GAMP 5
July 2022, ISPE



Industry guidance position

Lays framework for allowing agility in delivery and risk based validation, while delivering GxP systems

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So what would I do differently?

The collision	The response
Two clocks, one team. A two-week sprint and a multi-month validation cycle, with nobody owning both.	Count the queue, be aggressive on putting the product before the project

Fund change management and reserve your SMEs ↣ they are central to the delivery model

Be aggressive on risk assessments, disciplined on documentation ↣ the regulations already allow more agility than we use.

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Q&A

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