

Analytical Quality by Design

Robust analytical methods, engineered from the very first experiment

A science and risk-based approach to method development, aligned with ICH Q14 and built to support validation under ICH Q2(R2) so your method is ready for its whole lifecycle, not just for its first run.

TRADITIONAL

Find a method that works

Test - Adjust - Repeat limited insight into variability



AQbD

Understand – Optimise – Control

Science, risk and data: a method designed for the lifecycle

THE AQbD DEVELOPMENT WORKFLOW



Analytical Target Profile

Defines intended purpose, scope and required performance.



Risk Assessment & CMPs

Prioritises Critical Method Parameters affecting performance.



Preliminary Development

Establishes a proto-method ready for optimisation.



Forced Degradation

Assesses selectivity and stability-related separations.



DOE & Optimisation

Multivariate design reveals robust operating conditions.



Design Region (MODR)

Defines ranges where performance is consistently met.



Control Strategy

Fixes final conditions, ranges and SST criteria.



Development Report

Traceable package, ready for validation & transfer.

DEFINE
UNDERSTAND
EXPERIMENT
OPTIMISE
CONTROL

Science + risk + data – a method designed for the lifecycle

Aligned with ICH Q14 - Supporting validation under ICH Q2(R2)

A method designed for the lifecycle

Turn method knowledge into a lasting business asset

THE COST OF STAYING WITH TRIAL-AND-ERROR

€50K-150K+

per market, for a single post-approval method variation filing

€5K-25K

typical cost of one QC out-of-specification (OOS) investigation

+20-30%

of method transfers not right first time, delaying supply

Illustrative ranges commonly reported in pharmaceutical quality & CMC literature. Verify against your own regulatory and QA cost data.

SIX WAYS AQbD PAYS OFF



More robust methods

Robust operating conditions, proven by design.



Fewer regulatory changes

Less post-approval change, less regulatory burden.



Lifecycle flexibility

Ready to accommodate future components & conditions.



Easier tech transfer

A method designed to travel between sites & labs.



Reduced OOS risk

Less method-related variability during routine use.



Knowledge for the future

A traceable package that supports lifecycle management.

THE KYMOS APPROACH

Kymos combines risk-based science, multivariate DoE and deep regulatory expertise to deliver ICH Q14-aligned, transfer-ready analytical methods for small molecules, biologics, oligonucleotides & peptides (TIDES), and cell & gene therapies (CGTs).

One method. Designed for change.