Diligent

A DILIGENT PHARMA GUIDE
FOR CLINICAL TRIAL SPONSORS

VENDOR QUALIFICATION · SPONSOR GUIDE

Qualify a Vendor **with Questionnaires.**

When a questionnaire is enough, how to run it defensibly, and where it actually outperforms an audit.

8-PAGE GUIDE

WITH ANTHEA DRANSFIELD
HEAD OF QUALITY, DILIGENT PHARMA

INSIDE THIS GUIDE

A **defensible shortcut** many Sponsors overlook.

The industry defaults to audit-first qualification. ICH E6(R3) doesn't require that. Oversight has to be *proportionate to risk, and* For many Vendors, a well-run questionnaire process can be completely defensible.

This guide distills when to use a questionnaire-led process, how to run it well, and where it outperforms an audit, drawn from a conversation with Diligent's Head of Quality, Anthea Dransfield.

CONTENTS

01

What qualification actually means under R3.

FROM ICH E6(R3)

"The sponsor is responsible for assessing the suitability of and selecting the service provider to ensure that they can adequately undertake the activities transferred to them. The sponsor should provide the service providers with the protocol where necessary as well as any other documents required for them to perform their activities."

ICH E6(R3), Section 3.6.7

ICH E6(R3) doesn't tell Sponsors *how* to qualify a Vendor, but rather that they are responsible for assessing the Vendor's suitability.

Anthea described being asked to both collect questionnaires and conduct an audit on the same Vendor. When she asked the Sponsor's team what the Vendor would be used for, no one could tell her. Operations had simply been told to qualify them. Without that answer, there's no way to know whether the qualification was proportionate, sufficient, or even the right approach.

The regulation **is less concerned with how you qualify a Vendor than about your evidence that you made an informed, documented decision about their suitability.** How you do that is a design choice.

"Qualification is not a checkbox exercise. It's a relationship building exercise."

ANTHEA DRANSFIELD · HEAD OF QUALITY, DILIGENT PHARMA

02

When questionnaire-led is the right approach.

The most useful filter is simple: does the Vendor support a primary or secondary endpoint?

If they do, an audit is almost always warranted. If they don't, in Anthea's words, *"you have latitude."* That latitude is conditional on documented due diligence: evidence that the Vendor has the capabilities, resources, and protocol understanding to deliver.

R3's risk-based principle is what creates the flexibility. In practice, it lets Sponsors tier Vendors by the significance of their contribution and apply oversight accordingly.

VENDOR'S ROLE IN THE TRIAL	QUALIFICATION APPROACH
Supports a primary or secondary endpoint	**An audit is almost always warranted**
Contributes to trial conduct but not to endpoint data	**A questionnaire-led approach is defensible**
Supports participants without contributing to trial data	**A questionnaire is the right instrument**

A CONCRETE EXAMPLE

A production company creating an educational video to help participants understand the condition they're living with isn't supporting a primary or secondary endpoint. They're providing information. A questionnaire, evaluated against regulatory and Sponsor expectations, is qualification enough.

03

How to do it well.

Three things separate a defensible questionnaire from a paper exercise.

"If it's not written down, it never happened."

ANTHEA DRANSFIELD

01 · FOUNDATION

Documentation

The non-negotiable. That includes the written justification for choosing the questionnaire route, the risk assessment that led to it, and the assessment of the Vendor's responses.

If it's not captured, it isn't defensible, regardless of how good the reasoning was.

02 · DESIGN

Question design

Questions should be clear, free of ambiguous acronyms, and tied to a specific regulation. When a Vendor asks why you're asking, you should be able to point to guidance from a particular authority.

Regulators enforce regulations, not industry best practices. A question built on best-practice alone gives you no basis to act on a response.

03 · JUDGMENT

Evaluation

The comments matter as much as the answers. A Vendor may answer "no" and then, in the comments, describe a process that meets the regulation's intent even if it doesn't match the question's literal wording.

The right test is whether the Sponsor can defend the Vendor's approach to an inspector, not whether the Vendor strictly does what the question asks.

YOUR EVIDENCE TRAIL

What to keep on file

- **Risk assessment** that tiers the Vendor by contribution.
- **Written justification** for choosing the questionnaire route.
- **Questionnaire responses and reviewer assessment**, plus any supporting SOPs the Vendor uploaded.

04

Where questionnaires have the advantage.

The clearest argument for a questionnaire-led approach isn't that it's lighter. It's that, in several respects, it can give you *more* information than an audit. Neither replaces ongoing performance monitoring, which tells you whether the Vendor is meeting expectations.

	Audit	Questionnaire · VQQ
TIMEFRAME	Point in time, typically a one or two-day visit.	Can be reissued, updated, or extended. Targeted re-qualification when something changes.
CONSISTENCY	Depends on the auditor's experience and what they happen to ask.	Person-agnostic. Every Vendor in a category gets the same questions, and responses are directly comparable.
DEPTH OF INFORMATION	Bounded by the visit's scope and duration.	Often gathers more information than a one or two-day audit visit.
VENDOR CAPACITY AND SCALABILITY	Can be covered, but isn't the natural focus of a visit.	Easier to surface. The 11th or 12th Sponsor on a specialty lab's portfolio becomes visible through the questionnaire.
LIMITATION	Auditees present their work in the best light; a one or two-day window may miss what isn't volunteered.	Self-reported. Mitigated by asking for evidence: SOPs, forms, and supporting documents uploaded alongside responses.

05

What best practice looks like.

Sponsors who run questionnaire-led qualification well share a few habits.

"Keep track of what's changing with your Vendors, rather than necessarily going back in and qualifying everything again."

ANTHEA DRANSFIELD

A Add custom questions.

Standard regulatory coverage can't anticipate every trial-specific need. An oncology trial, for example, generates significantly more data and assessments than other therapeutic areas. A Vendor can be fully regulation-compliant and still unable to meet a specific trial's requirements. Custom questions, written against what your trial actually needs, are how you catch these gaps.

B Score the responses against risk.

A complete questionnaire produces a lot of information but doesn't on its own tell the Sponsor where to focus. Scoring each response turns the questionnaire into a decision tool: the Sponsor can see where a Vendor falls short and target follow-up there, including a focused audit on specific gaps, rather than defaulting to a full audit. At Diligent, our SMEs work with Sponsors to define trial-specific risk criteria and build a scoring model weighted against those needs.

C Track the metrics you set.

KPIs and KRIs only matter if someone is reviewing them on a regular cadence and acting when the trends shift. The qualification step gets you in the door. The performance data is what tells you, over time, whether the Vendor is meeting expectations.

D Communicate.

The relationships that hold up through a trial are the ones with established escalation pathways and an honest two-way exchange. Where things tend to break down is at the points where the Sponsor changes a requirement mid-trial without discussing it with the Vendor.

E Track the delta both ways.

Vendor SOPs change. Vendor resources change. Sponsor requirements change. Staying on top of both sides is what keeps qualification an ongoing process, not a single event you file away after selection.

PUTTING THIS INTO PRACTICE

Talk with the **Diligent team.**

For Sponsors building or reassessing their qualification process, Diligent's team can meet with you to assess your current approach, identify compliance gaps, and offer consultative support to help you bridge them.

Our qualification platform provides immediate access to completed questionnaires and audit reports for thousands of clinical trial Vendors, designed to meet the most rigorous compliance standards.

Book a consultation →

Anthea Dransfield

Head of Quality · Diligent Pharma

Anthea Dransfield is Head of Quality at Diligent Pharma. Her background spans GMP and clinical trial environments, and she brings a practical, regulatory-grounded perspective to Vendor qualification and oversight under ICH E6(R3).

ABOUT THIS GUIDE

Adapted from the Diligent Pharma blog *"How to Qualify a Clinical Trial Vendor with Questionnaires."* Written for clinical operations, procurement, and quality leaders at Sponsors.

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