GENERAL PEPTIDE MONOGRAPH · NO. GPM 17 · RESEARCH USE ONLY

Testing Therapeutic Peptides

Analytical methods, certificates of analysis, independent verification, and laboratory reliability

A purity percentage is not a molecule, and a tidy PDF is not a proof. Therapeutic peptides — approved drugs, clinical-trial material, compounded preparations, custom synthesis lots, lyophilized research vials and suspected counterfeits — are evaluated one claim at a time. This monograph explains which analytical question each method can answer, how certificates of analysis are built and broken, how sampling and chain of custody bound inference, and how laboratory competence should be judged without mistaking popularity for qualification.

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References 32 cited
Local corpus 1,561 reading-tier full-text assets · 27,143 page-equivalents
Laboratory landscape reviewed through 5 August 2026
Constraint No human use, dose, route or schedule is recommended anywhere in this document

PART ONE

The trust problem: why peptide testing exists

SECTION 01

A test answers one question

Every familiar number on a peptide certificate — “99% HPLC purity,” “mass confirmed,” “endotoxin passed,” “sterile” — answers a different question. Confusing those questions is the most common analytical error in both regulated pharmaceutical work and informal research-peptide markets. Identity is not purity. Purity is not assay. Assay is not net peptide content. Net peptide content is not

potency. Potency is not sterility. Sterility is not endotoxin control. None of those attributes prove that the sample was representative of a lot, that the laboratory was competent for the method, or that the PDF was issued by the laboratory named on it.

That separation is not pedantry. Contemporary regulatory-science writing on protein and peptide therapeutics treats identity, purity, potency, quantity and stability as separately argued attributes, each requiring methods fit for the claim.[617] ICH Q6B supplies the classic specification grammar for biotechnological products built from proteins and polypeptides; synthetic peptides sit partly beside that frame, which is why later sections return to both Q6B principles and the EMA synthetic-peptide guideline that became legally effective on 1 June 2026 (EMA/CHMP/CVMP/QWP/367182/2025). Orthogonal characterisation is not a slogan in that guidance ecology; it is the practical admission that one chromatogram cannot see everything that matters.

> READER'S CONTRACT
>
> This monograph explains analytical principles, industrial history, certificate literacy and laboratory-qualification logic for research readers. It does not recommend that any person use any peptide, and it specifies no dose, route or schedule. Laboratory rankings are fit-for-purpose comparative assessments as of 5 August 2026, not consumer endorsements. Inclusion of a laboratory name is not an endorsement.

The controlling idea is therefore blunt. **A result may not stand in for an attribute it does not test.** The rest of the monograph is the unpacking of that sentence across identity, purity, content, potency, microbiology, residuals, particles, sampling, documentation and laboratories.

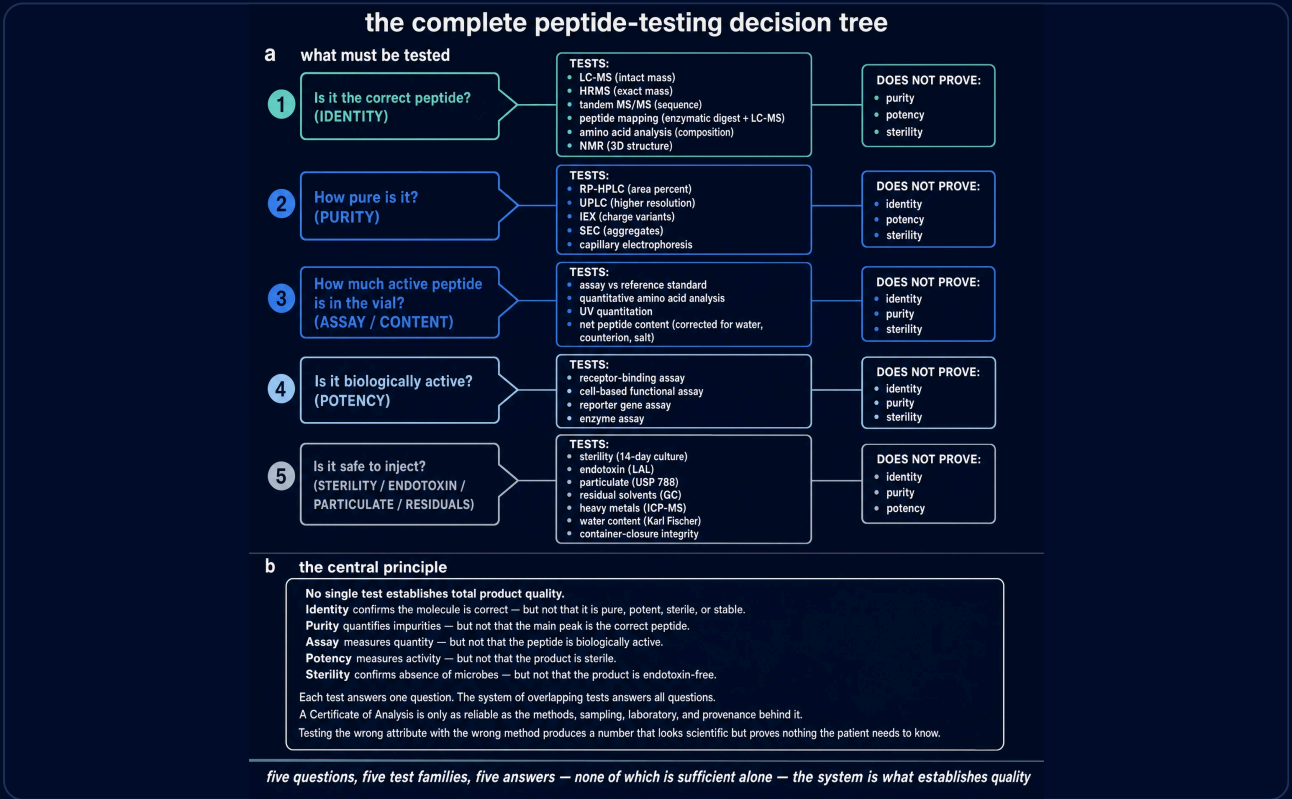

FIGURE 1 **The complete peptide-testing decision tree.** Five primary claim lanes — identity, purity, assay/content, potency, and safety-adjacent attributes — each with methods that answer one question and do not prove the others. Central principle: no single test establishes total product quality. Commissioned plate.

SECTION 02

From bioassay to chromatography

Before there were reverse-phase purity claims, there were animals, organs and international units. Early insulin quality was a physiological argument: how much glucose-lowering activity a preparation carried relative to a standard. That bioassay world taught a lesson modern COAs still forget — activity and chemical composition are not synonyms. Sanger's sequencing of insulin made primary structure a public fact; Moore and Stein's amino-acid analysis made composition quantitative; Edman degradation made stepwise sequencing a laboratory craft. Each advance answered a new claim lane without retiring the older ones.

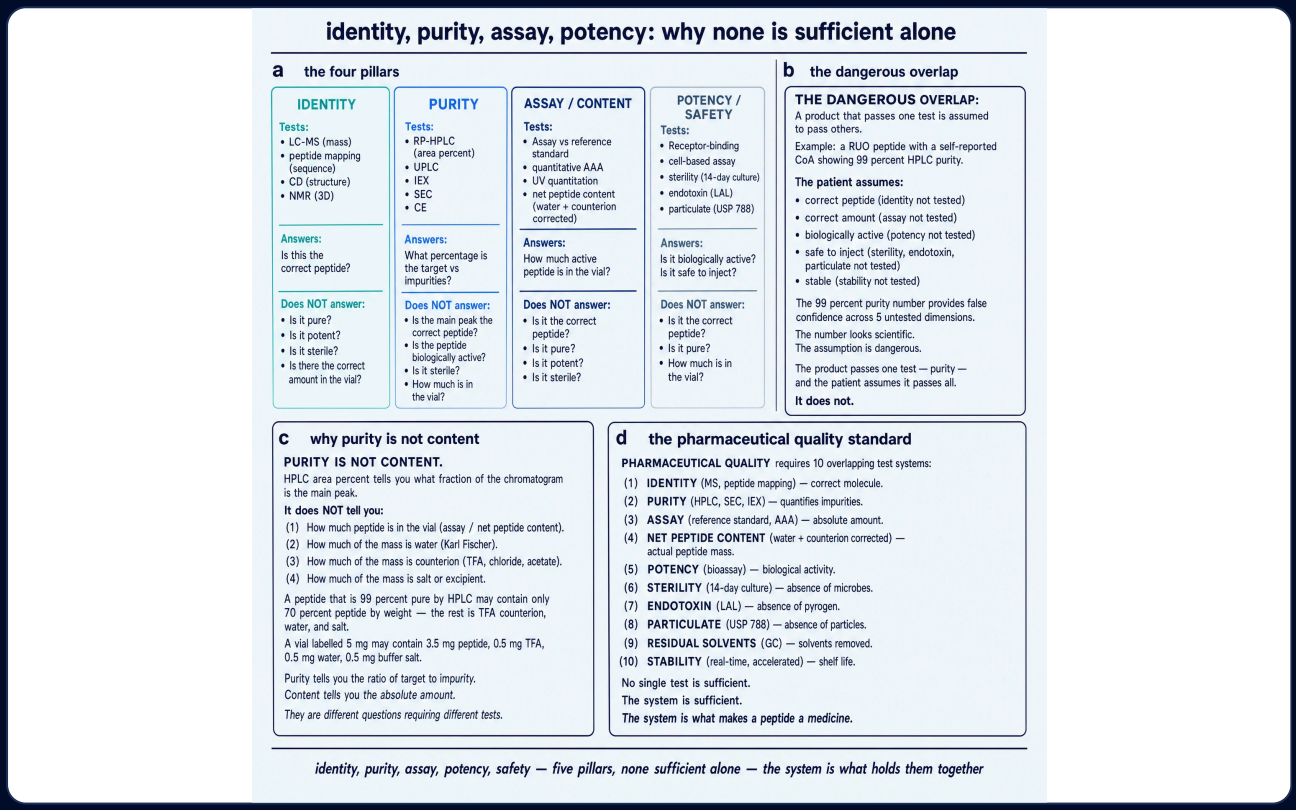

FIGURE 2 **Identity, purity, assay, potency: why none is sufficient alone.** Four-pillar comparison showing what each lane answers and what it cannot. Chromatographic purity is not content; content is not potency; none substitutes for sterility or endotoxin control. Commissioned plate.

Solid-phase peptide synthesis, inaugurated by Merrifield, then changed the impurity grammar. Deletion sequences, truncations, insertions and incompletely deprotected species became expected companions of the desired chain. Chromatography became not merely a purification tool but the public language of "how clean" a synthetic peptide looked. High-performance liquid chromatography and, later, UHPLC made area-percent purity a portable number — portable enough to be misunderstood. Mass spectrometry joined the release conversation by giving molecular mass and, with tandem methods, sequence-supporting fragment maps. None of those tools abolished bioassay where mechanism and immunogenicity still matter; they relocated where each claim is argued.[1810]

SECTION 03

Limulus, sterility and the sampling problem

Parenteral peptides imported two older pharmaceutical anxieties: living microbes and fever-inducing endotoxin. Sterility testing evolved as a destructive sampling ritual under growth-promotion and bacteriostasis/fungistasis controls — a method that can fail to find contamination that is still present in untested units. Endotoxin testing, from rabbit pyrogen assays to limulus amebocyte lysate (LAL) modalities and recombinant Factor C reagents, measures a different hazard with different false-negative pathways, including inhibition/enhancement and low-endotoxin recovery. A report that says only “endotoxin passed” without method, limit, units, dilution and recovery has omitted the grammar that makes the claim scientific.

The historical point is practical. Microbiology taught pharmaceutical science that *absence of evidence in a sample is not evidence of absence in a batch*. That lesson applies equally to a single research vial mailed for HPLC.

SECTION 04

Orthogonality becomes a regulatory habit

As peptide drugs lengthened, lipidated, cyclised and entered biosimilar and generic pathways, reviewers learned to distrust single-method comfort. Insulin and incretin case studies show multi-attribute characterisation packs: intact mass, peptide mapping, impurity profiling, higher-order structure tools where relevant, aggregates, potency and microbiological attributes.[10][11][14] The EMA synthetic-peptide guideline likewise expects structural confirmation by complementary techniques and impurity control aligned with peptide-specific thresholds rather than a casual transplant of small-molecule ICH Q3A thinking. Orthogonal purity modes exist because co-elution is real.

SECTION 05

Two COA cultures

In pharmaceutical development and commercial release, a certificate of analysis is an output of a quality system: validated or verified methods, qualified reference standards, audited laboratories, retain samples and change control. In many research-peptide markets, a COA is often a marketing attachment — sometimes genuine third-party screening, sometimes a recycled template, sometimes a category error that treats HPLC purity as total quality. Both cultures use similar words. They do not use similar evidence. Later Parts teach how to tell the difference without pretending that every research screen is fraudulent or that every GMP logo is scope-relevant.

SECTION 06

The quality-attribute map

The Apparatus carries the full taxonomy. The working map for the reader is simpler: chemical identity and sequence; chromatographic and orthogonal purity; assay and net peptide content; biological potency; water and counterions; residual solvents and elementals; aggregates and particles; bioburden, sterility and endotoxin; container-closure integrity; stability over time. API bulk and finished sterile products emphasise different subsets of that list.



FIGURE 3 **API vs finished-product matrix.** Sterility and container-closure claims attach to finished sterile products. Bulk API programmes emphasise purity, content and residuals.

No monograph section will let a single lane borrow authority from another.

PART TWO

Chemical claims: identity, purity, content, sequence, potency

SECTION 07

Identity testing

Identity asks whether the material is the labelled peptide under stated methods — not whether it is “good,” potent, sterile or correctly filled. Intact-mass measurement establishes that a dominant ion envelope is consistent with an expected molecular mass within the method’s tolerance. High-resolution mass spectrometry strengthens elemental-composition arguments. LC-MS couples separation to mass detection so that the measured species is the chromatographic peak of interest. Tandem MS and peptide mapping after enzymatic digestion support sequence confirmation. Amino-acid analysis checks composition. NMR can be decisive for short or highly characterised peptides. Chromatographic retention against a qualified reference standard remains a classical identity tool. Terminal modifications, disulfide connectivity, stereochemistry and counterion identity are separate identity sub-claims; each needs methods that can see them.

Limitations are the point of literacy. Correct nominal mass does not prove correct sequence. Isobaric amino acids complicate interpretation. Coexisting impurities may be missed if they are not resolved or ionised. Incorrect stereochemistry or disulfide connectivity may preserve molecular mass. Low-resolution mass is not full sequence verification. Database matching is not equivalent to validated identity confirmation against a qualified reference standard in a release setting.[186]

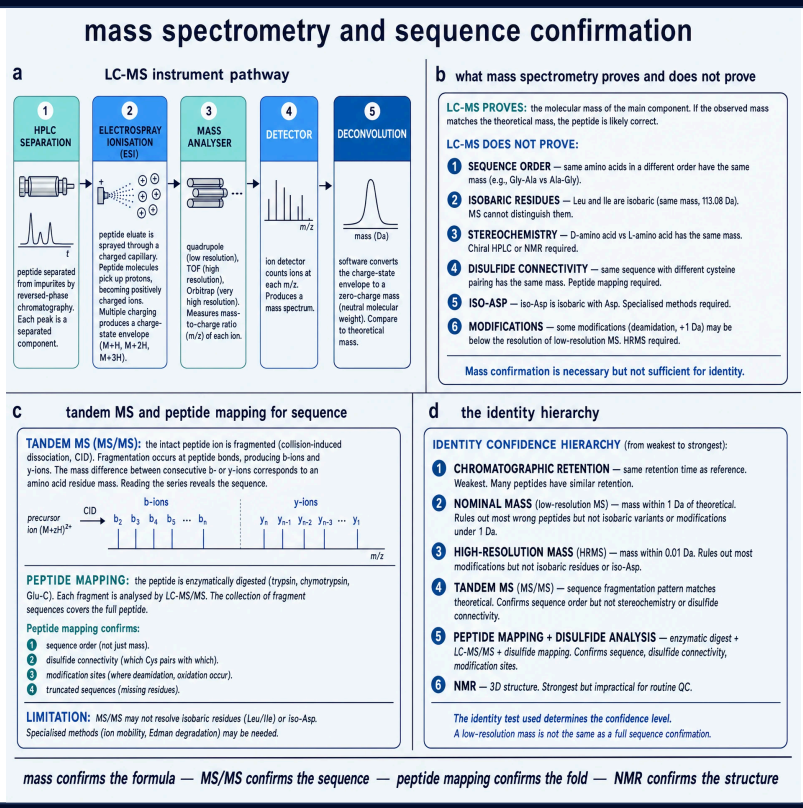

FIGURE 4 **Mass spectrometry and sequence confirmation.** LC-MS pathway, what intact mass does and does not prove, tandem MS/peptide mapping for sequence support, and an identity-confidence hierarchy from retention to NMR. Commissioned plate.

SECTION 08

Purity testing

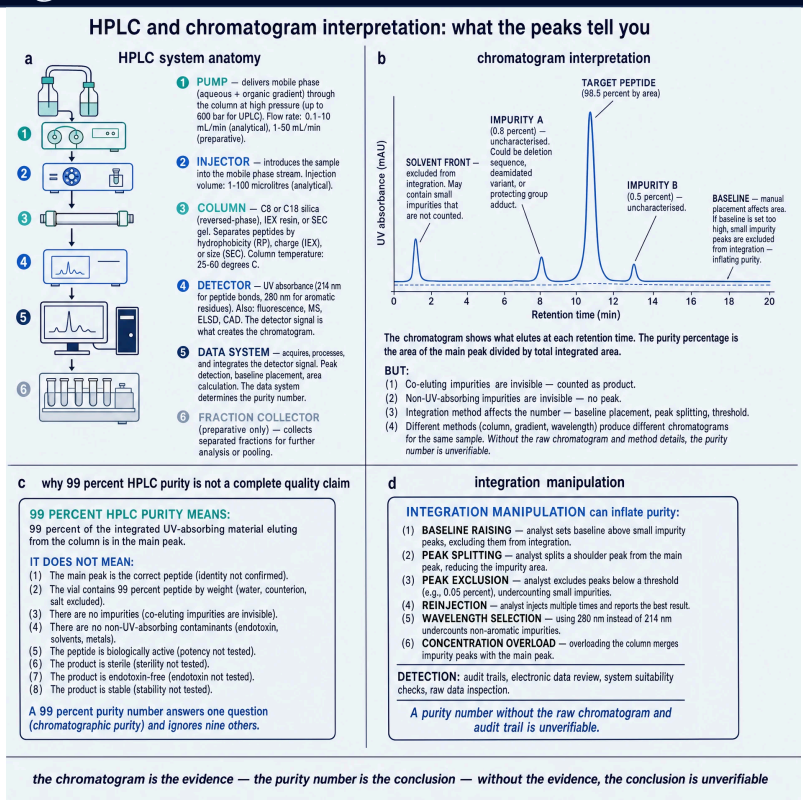

FIGURE 5 **HPLC and chromatogram interpretation.** HPLC/UPLC system anatomy, chromatogram integration choices, why a headline purity percentage is incomplete, and how baseline and peak decisions alter reported area percent. Commissioned plate.

Reversed-phase HPLC and UPLC dominate peptide-related purity claims because they separate species by hydrophobicity under gradient elution with UV detection, commonly near 214 nm for the peptide bond. Ion-exchange, size-exclusion and capillary electrophoresis supply orthogonal views by charge or size. System suitability, column chemistry, gradient design, sample concentration, detector response, relative response factors, peak thresholds, and integration events all shape the number that later appears as “98.7%”. Known impurities, unknown impurities, limits of detection and quantitation, and reporting/identification/qualification thresholds belong to impurity-control strategy, not to marketing adjectives.[2220]

SECTION 09

Why “99% HPLC purity” is not a complete quality claim

Area percent is not mass percent. Water and counterions are usually invisible to the UV chromatogram that generates the purity number. Non-UV-absorbing contaminants are invisible for the same reason. Co-eluting species can hide under the main peak. Impurities can respond differently at the chosen wavelength. Integration can be manipulated; peaks can be excluded without documentation; unresolved shoulders can be absorbed into the main peak by baseline choice. Methods differ; sample preparation differs; repeat injections vary. API purity is not finished-vial quality.

Compare 98% and 99% rigorously. If both numbers are honest area-percent results from the same validated method, moving from 2% to 1% impurity area is a nominal fifty-percent reduction in reported impurity burden. That arithmetic is real and sometimes meaningful. It is still secondary to whether the impurities are identified, whether the method can see the relevant related peptides, and whether the vial’s water, salt, assay, microbiology and potency have been addressed at all. A 99% chromatogram of an unrepresentative sample remains a precise answer to the wrong question.

SECTION 10

Assay and peptide content

Assay asks how much of the peptide is present relative to a qualified reference standard, typically by a specific chromatographic method. Net peptide content asks what fraction of the gross solid is peptide rather than water, counterions and other non-peptide mass, often via quantitative amino-acid analysis, nitrogen determination or an explicit mass-balance design. Concentration after reconstitution depends on fill and diluent volume. Label claim sits on top of all of that and can be wrong even when purity and mass look excellent.

Illustrative logic — not a fabricated commercial result — makes the trap obvious. A lyophilized vial can show high chromatographic purity and the expected molecular mass, yet contain substantially less peptide than the labelled milligram quantity because acetate or trifluoroacetate and residual moisture occupy mass. Industry analytical practice routinely treats NPC in the broad range far below 100% of gross solids for lyophilized peptides; the exact value is product- and salt-form-specific and must be measured, not assumed (see the net-peptide mass-balance figure in Part Three).[18]

SECTION 11

Sequence confirmation

Tandem mass-spectrometric fragmentation, enzymatic peptide mapping, fragment-ion interpretation, classical sequencing where applicable, NMR, chiral analysis, disulfide mapping and modification-site confirmation are the usual toolkit. Short peptides may be fully accessible to MS/MS or NMR; cyclic,

branched, lipidated and stapled peptides raise fragmentation and digestion barriers; pyroglutamate, amidation, D-amino acids, gamma-linkages and noncanonical residues break naive software assumptions. Sequence confirmation is a coverage argument, not a checkbox.

SECTION 12

Biological potency and activity

Receptor-binding, ligand-displacement, cell-based functional, second-messenger, reporter-gene, enzyme, proliferation and inhibition assays each measure a biological response relative to a reference. Relative potency, assay variability, system suitability and matrix effects dominate interpretation. Chemical identity does not automatically prove biological potency; biological response does not prove chemical purity; research assays are not automatically validated release assays. Mechanism-appropriate design is not optional.[111O]

SECTION 13

API testing framework

For peptide API or lyophilized bulk, the usual core includes appearance, identity, chromatographic purity/related peptides, assay, water, and risk-based residual solvents and elemental impurities; counterions and NPC appear when salt form and dosing accuracy matter; bioburden and endotoxin often appear when the API feeds a parenteral product; sterility is usually not the API claim unless a sterile API is explicitly justified. Characterisation is broader than routine release. See Apparatus matrices for the tabular form.

SECTION 14

Finished sterile dosage-form framework

Finished sterile injectables add fill/content uniformity, appearance, pH, osmolality, particulate testing, endotoxin, sterility, and often container-closure integrity, plus in-use and reconstitution stability where relevant. Chemistry that was adequate for bulk does not retire microbiology. Microbiology that passes on sampled units does not retire chemistry.

PART THREE

Safety-adjacent and physical claims

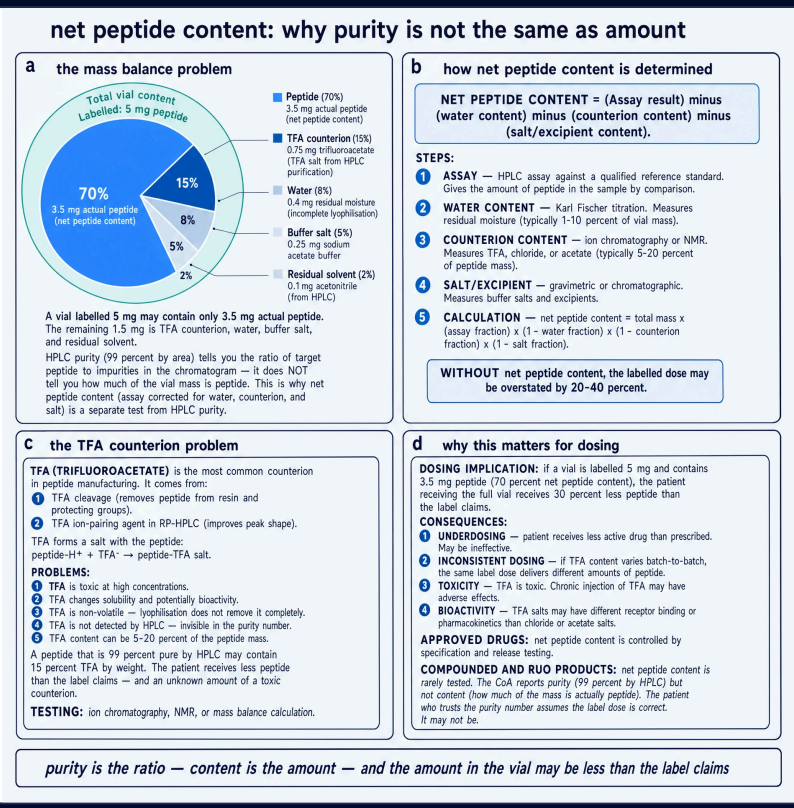

FIGURE 6 **Net peptide content: why purity is not the same as amount.** Illustrative mass-balance of peptide versus counterion, water, salt and residual solvent; how net peptide content is constructed; and why labelled milligrams can overstate peptide mass. Illustrative fractions are pedagogical, not a commercial vial result. Commissioned plate.

SECTION 15

Endotoxin testing

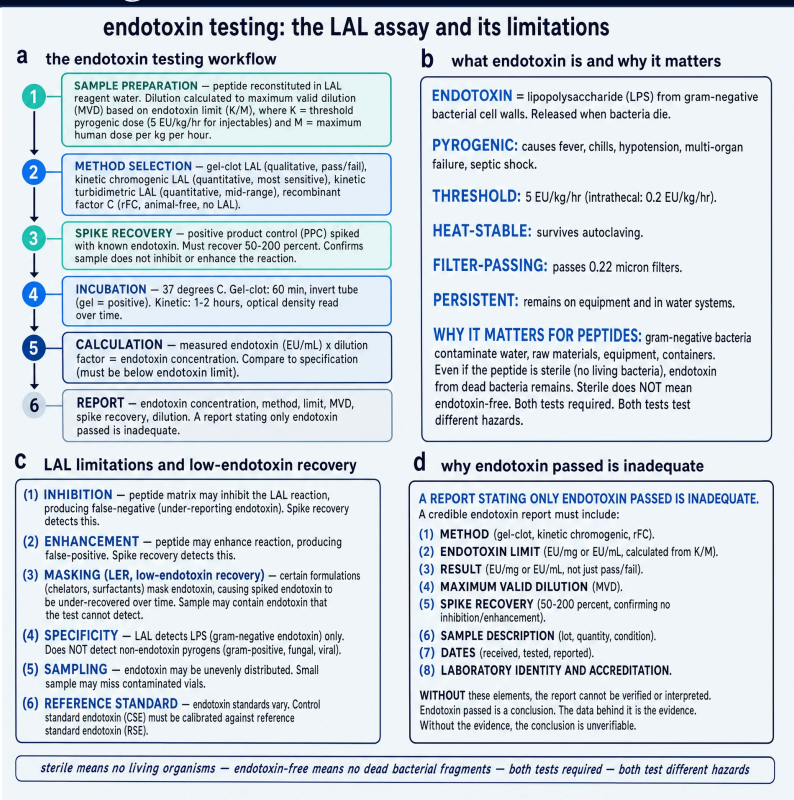

FIGURE 7 **Endotoxin testing: the LAL assay and its limitations.** Endotoxin workflow including suitability, MVD and spike recovery; what endotoxin is; LAL/rFC failure modes including LER; and why “endotoxin passed” without method detail is inadequate. Commissioned plate.

Bacterial endotoxin testing asks a pyrogen-risk question that chemistry cannot answer. Gel-clot LAL remains the classical limit test. Kinetic chromogenic and kinetic turbidimetric LAL methods provide quantitative readouts. Recombinant Factor C and recombinant cascade reagents reduce dependence on horseshoe-crab lysate while still requiring product-specific suitability. Reference endotoxin standards and control standard endotoxin anchor calibration. Results are reported in endotoxin units against a product-specific limit, often approached through maximum valid dilution mathematics.

Method suitability is not paperwork. Inhibition and enhancement studies, spike recovery, attention to endotoxin masking and low-endotoxin recovery, depyrogenated labware, and invalid-run rules decide whether a number is interpretable. Sample handling can create false comfort or false alarm. A report stating only “endotoxin passed” without method, limit, units, dilution, recovery and sample information is analytically inadequate. Retesting rules exist because invalid runs happen; retesting without investigation discipline can also manufacture comfort.[1019]

SECTION 16

Sterility testing and microbiology

Membrane filtration and direct inoculation are the main pharmacopeial approaches, each requiring growth-promotion testing and bacteriostasis/fungistasis method suitability. Incubation media, conditions and periods are defined to detect aerobic and anaerobic bacteria and fungi. Sample quantity and sampling plans bound the claim. False positives from laboratory contamination and false negatives from unsuitable methods both occur; organism identification and investigation of positives are part of the science, not optional theatre. Bioburden and tests for specified organisms answer different questions from sterility. Environmental monitoring and, where relevant, mycoplasma testing belong to manufacturing control rather than to a single vial COA.

The inference limit is non-negotiable: a single-vial sterility test does not prove batch sterility. Sterility assurance is a process property; sterility testing is a sample property.

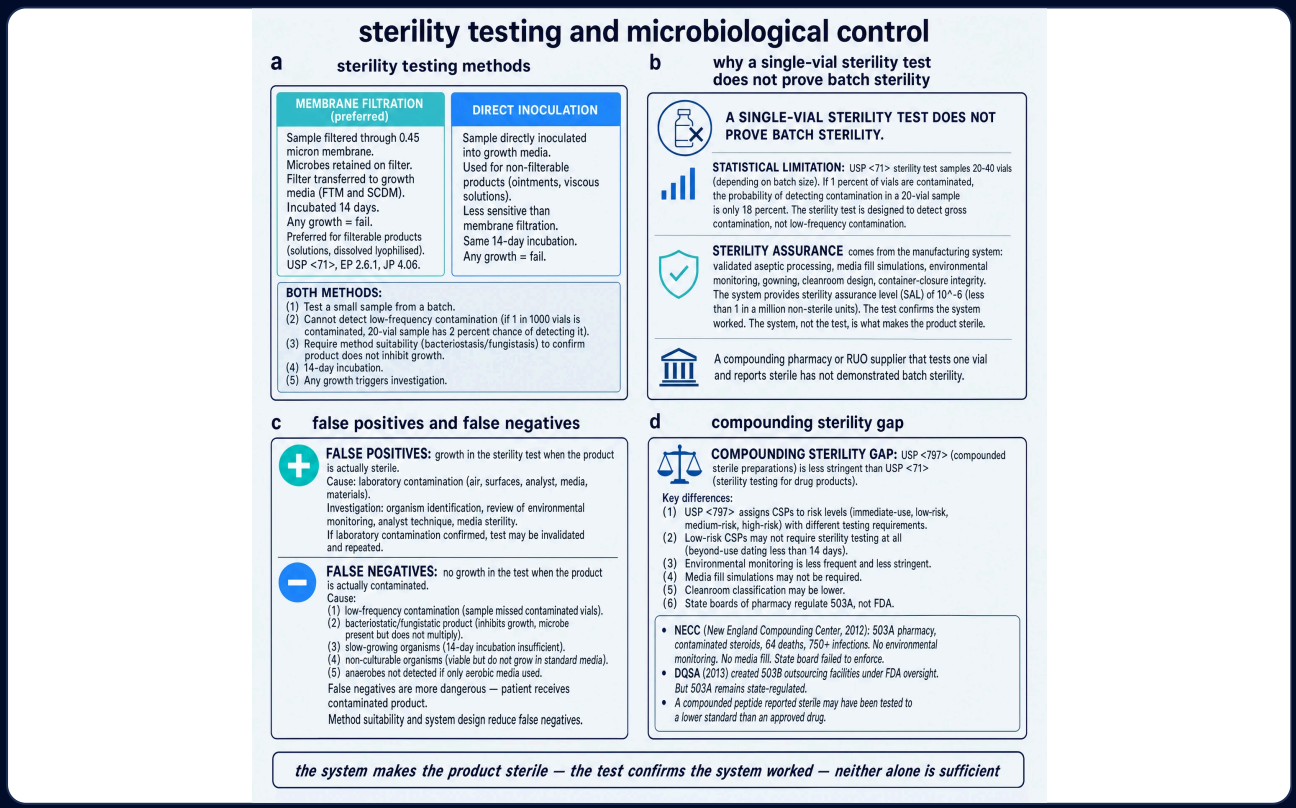

FIGURE 8 **Sterility testing and microbiological control.** Membrane filtration versus direct inoculation, why a negative test on sampled units is not batch sterility assurance, false positive/negative pathways, and the distinction between sterility testing and sterility assurance. Commissioned plate.

SECTION 17

Heavy metals and elemental impurities

ICP-MS and ICP-OES dominate modern elemental impurity control, with digestion, calibration, internal standards, blanks, interference correction, and detection/quantitation limits as the competence stack. ICH Q3D supplies a risk-based elemental framework. Lead, arsenic, cadmium and mercury remain toxicological priorities, but nickel, palladium, platinum, cobalt, chromium, copper, iron and product-specific catalysts or equipment-derived metals may dominate actual process risk. A generic four-metal panel can be inadequate for a synthesis that used palladium coupling chemistry or metal-contact equipment. Recovery studies and route-specific limits matter.

SECTION 18

Residual solvents and volatile impurities

Headspace gas chromatography with flame-ionization or mass-spectrometric detection is the usual tool. Solvent classes, product-specific panels, calibration, matrix effects and reporting limits define the claim. Water-soluble and organic solvents behave differently in sample preparation. Residual cleavage reagents and scavengers can be missed by a panel that only lists common ICH Q3C solvents. Process knowledge should drive the panel.

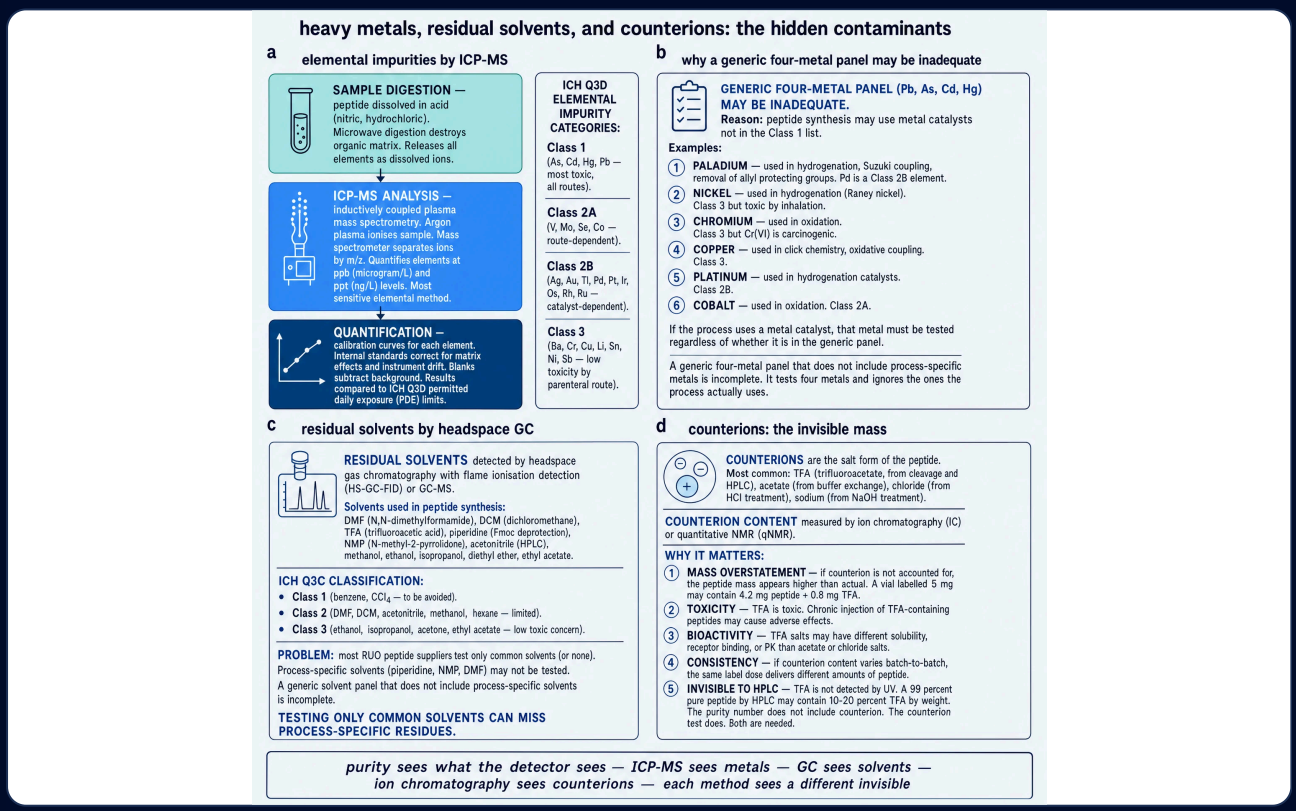

FIGURE 9 **Heavy metals, residual solvents, and counterions.** ICP-MS elemental risk framing beyond a four-metal panel, headspace GC residual-solvent logic, and why counterion burden matters for reported mass and net peptide content. Commissioned plate.

SECTION 19

Counterions and water

Trifluoroacetate, acetate, chloride, sodium and other counterions change reported molecular weight, formulation behaviour and net peptide content. Ion chromatography and NMR are common measurement routes; mass balance closes the argument. Counterion exchange can alter the salt form without changing the peptide sequence. Karl Fischer titration is preferred for residual moisture in many lyophilized peptides; loss on drying and thermogravimetric approaches are not automatic substitutes. Hygroscopicity makes sample handling part of the method. Ignoring water and counterions overstates peptide mass.

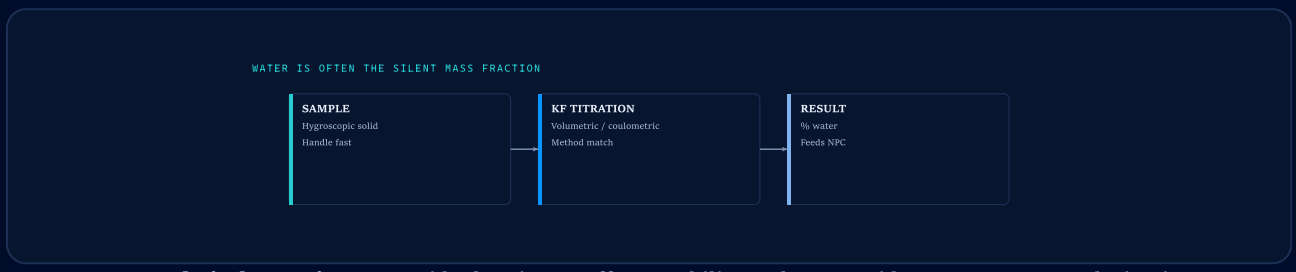

FIGURE 10 **Karl Fischer moisture.** Residual moisture affects stability and net peptide content. Loss on drying is not always equivalent.

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SECTION 20

Aggregates and particles

Size-exclusion chromatography, dynamic light scattering, analytical ultracentrifugation, light obscuration, flow imaging and microscopy address overlapping but non-identical populations: soluble oligomers, fibrils, insoluble aggregates, visible particles and subvisible particles. Immunogenicity concerns attach especially to aggregates and particles in parenteral products. Silicone oil, glass, rubber and fibres are container-derived confounders, not peptide HMW species.



FIGURE 11 **SEC aggregate analysis.** SE-HPLC watches soluble higher-molecular-weight species. Insoluble particles need other methods.



FIGURE 12 **Particle-analysis methods.** Visible inspection and subvisible counting answer different questions; container-derived particles complicate interpretation.

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SECTION 21

Structural and conformational analysis

Circular dichroism, NMR, FTIR, selected fluorescence methods and disulfide mapping probe higher-order structure and folding. For short, flexible peptides, classical protein HOS expectations may be overstated; the right question is often whether the relevant disulfide connectivity or conformational ensemble required for activity is present. Misfolding remains a live risk for multi-disulfide peptides.[3]

SECTION 22

Stability testing

Real-time, accelerated, stress, forced-degradation, freeze-thaw, photostability, agitation, oxidation, hydrolysis, deamidation, aggregation, adsorption, reconstitution, in-use, shipping-simulation and temperature-excursion studies answer time-dependent questions. Stability-indicating methods must actually move when the relevant degradants form. Shelf-life and beyond-use dating are regulatory or institutional decisions built on those data; a release snapshot is not a stability argument.[7][8]

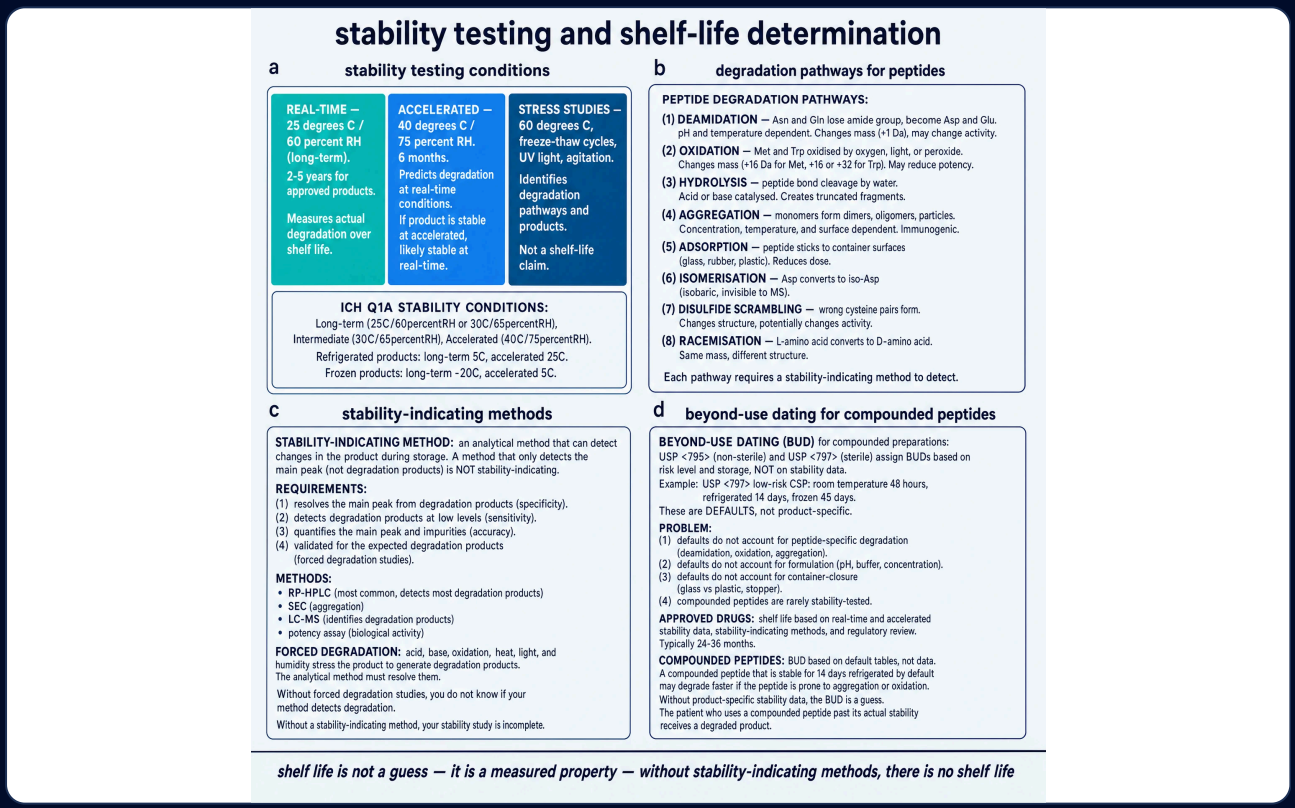

FIGURE 13 **Stability testing and beyond-use dating.** Real-time, accelerated and stress conditions; peptide degradation pathways; stability-indicating method requirements; and why a release snapshot is not a shelf-life argument. Commissioned plate.

PART FOUR

Evidence objects: sampling, certificates, raw data, validation

SECTION 23

Sampling and chain of custody

A laboratory result is a statement about a sample path. Random sampling, representative sampling, sample size, lot and batch definition, vial-level variation, stratified designs, top-middle-bottom bulk sampling, retain samples, sealed kits, tamper evidence, custody forms, courier tracking, receipt condition, photographs, weight records, blinded samples, splits, duplicates, reserves and independent procurement are the machinery that makes broader inference defensible. Without them, the honest claim is narrower: *this is what we found in the material that arrived.*

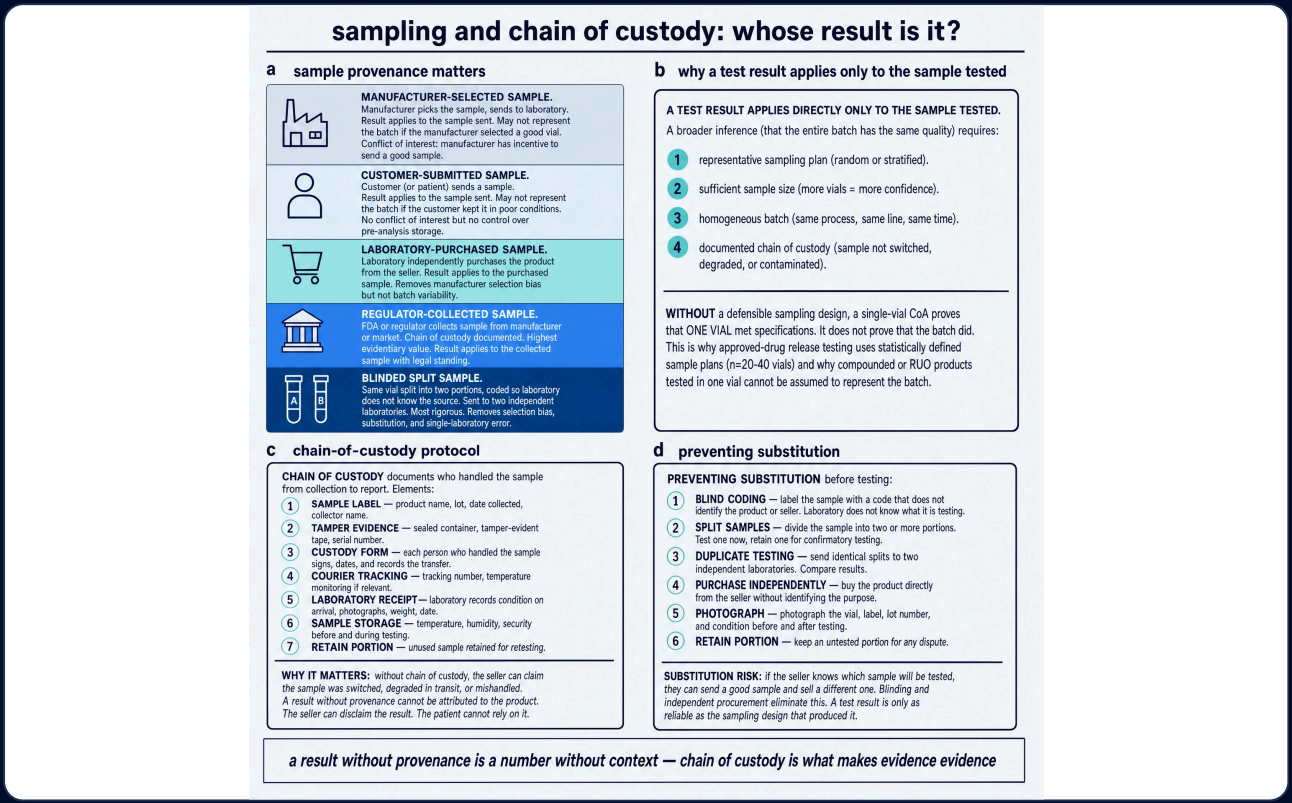

FIGURE 14 **Sampling, provenance, and chain of custody.** Five sample-origin classes, the rule that a result applies to the sample tested, chain-of-custody elements, and substitution-prevention measures. Commissioned plate.

Manufacturer-selected, customer-submitted, laboratory-purchased, regulator-collected and blinded split samples support different inferences. Customer-submitted units carry substitution risk before the laboratory door. Manufacturer-selected units can be the best of a lot. Laboratory-purchased units speak to what that procurement obtained. Regulator-collected units speak inside an official custody system. Blinded splits exist to adjudicate disagreements. Preventing substitution before testing is part of science, not paranoia.

SECTION 24

Anatomy of a credible COA

A credible certificate names the laboratory's legal identity and contacts; carries a unique report number; identifies sample, lot, product and reported sequence; states sample condition and quantity; records dates received, tested and reported; identifies methods and method IDs; states specifications, results, units and relevant detection or quantitation limits; records pass/fail logic; includes uncertainty where relevant; identifies analyst or authorised reviewer; carries electronic signature, page numbering and revision status; shows accreditation marks only with scope relevance; references chromatograms, spectra or raw data; discloses deviations and subcontracted tests; and preserves custody information.[618]

SECTION 25

COA red flags

Missing contacts, report numbers, lots, dates, methods, units, specifications or raw data are disqualifying for serious use. Generic reusable templates, identical chromatograms across lots, inconsistent typography, altered PDF metadata, copied signatures, impossible precision, unexplained rounding, mismatched molecular mass, missing sequence, inconsistent sample names, accreditation logos outside scope, laboratory denial of issuance, seller-controlled QR codes, unverifiable verification links, purity without chromatogram, purity confused with peptide content, and sterility inferred from HPLC or mass spectrometry are investigation triggers. Red flags do not automatically equal fraud; they block naive acceptance.

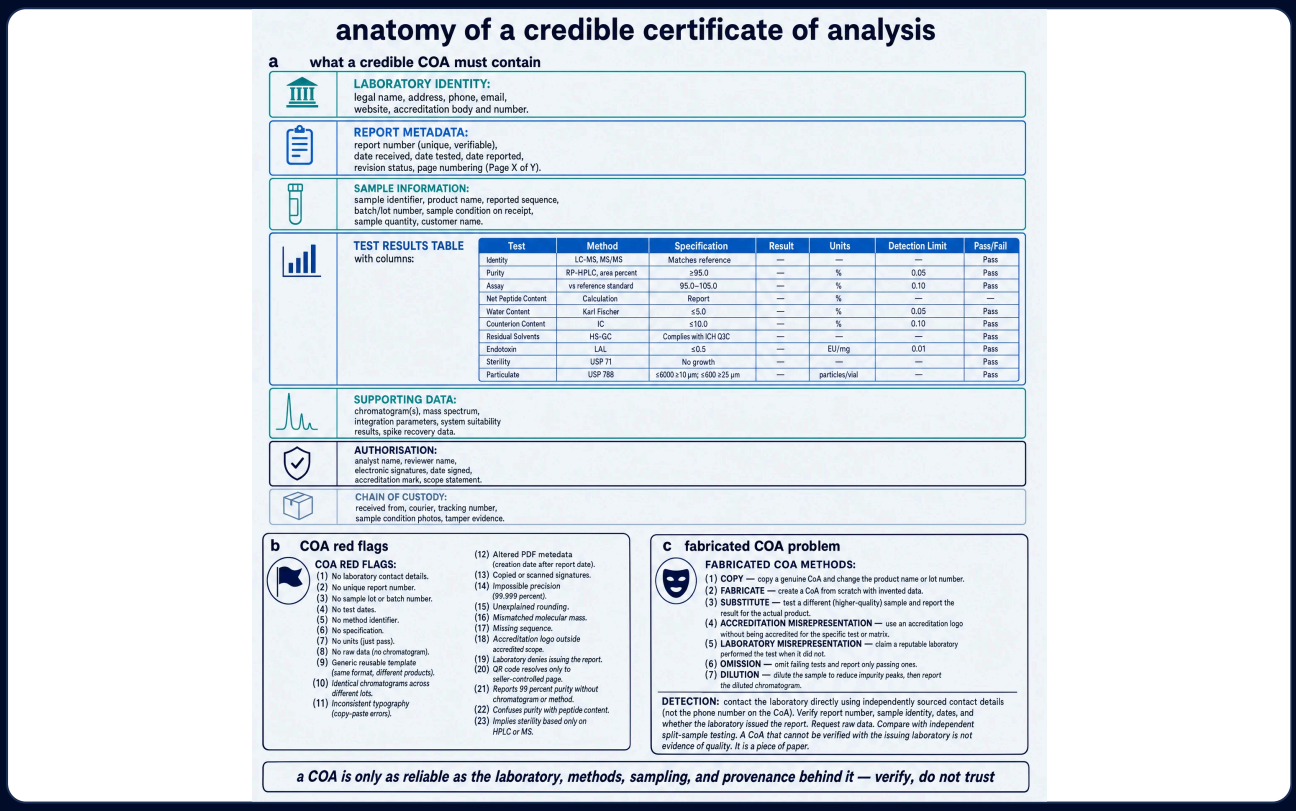

FIGURE 15 **Anatomy of a credible Certificate of Analysis.** Annotated COA elements, red-flag patterns, and fabrication modes that convert a tidy PDF into an unverifiable claim. Commissioned plate.

SECTION 26

COA verification process

At a non-operational auditing level: (1) obtain the complete unedited report; (2) verify the laboratory independently; (3) contact the laboratory using independently sourced details; (4) verify report number and sample identity; (5) confirm issuance; (6) confirm internal versus subcontracted testing; (7) verify accreditation and scope; (8) review methods and specifications; (9) inspect chromatograms and spectra; (10) inspect chain of custody; (11) compare dates and lots; (12) review signatures and revision history; (13) request raw data when justified; (14) compare with an independent split-sample result; (15) document discrepancies. Seller-hosted confirmation pages are not independent verification.

SECTION 27

Raw-data review

Chromatograms, peak tables, integration events, baselines, system-suitability injections, blanks, standards, calibration curves, quality-control samples, mass spectra, isotope patterns, fragmentation spectra, recoveries, sterility records, endotoxin kinetic data, ICP-MS calibrations, GC headspace data, audit trails, metadata and instrument sequence files are the evidentiary layer beneath a PDF summary. An image pasted into a certificate is not authenticated raw data. Data-integrity expectations (audit trails, attributable actions, contemporaneous recording) are part of laboratory competence, not optional polish.

SECTION 28

Method validation

Specificity/selectivity, accuracy, precision (repeatability, intermediate precision, reproducibility), linearity, range, detection and quantitation limits, robustness, system suitability, recovery, matrix effects, carryover, solution stability, reference-standard qualification and measurement uncertainty are the ICH Q2 grammar. Compendial, validated, verified, qualified research, screening, in-house, transferred and modified compendial methods are different claim classes. A screening HPLC used for informal market checks is not automatically a pharmaceutical release method.

SECTION 29

From sample to inference

The chain closes here. Methods create numbers; validation bounds their reliability; sampling bounds their scope; custody bounds their authenticity; laboratory competence bounds their trustworthiness; the COA is only the messenger. A result that survives all of those filters still answers only the question the method was designed to ask.

PART FIVE

Laboratories, packages, conflicts, and the standing constraint

SECTION 30

Laboratory accreditation and qualification

ISO/IEC 17025 is the international competence standard for testing and calibration laboratories. Accreditation is meaningful when an independent accreditation body has assessed the laboratory and published a scope that lists the relevant methods and matrices. A wall certificate without a matching scope line for peptide HPLC purity, LC-MS identity, endotoxin or sterility is not evidence of competence for those tests. Pharmaceutical GMP laboratories operate inside drug quality systems with additional expectations for data integrity, change control, reference standards and regulatory inspection. CLIA qualifies clinical diagnostic testing of human specimens; it is generally not the relevant frame for pharmaceutical product-release testing of peptide APIs or finished drug products.

Proficiency testing, instrument qualification, calibration, preventive maintenance, analyst training, sample security, subcontracting transparency, confidentiality, conflict-of-interest protections and inspection history complete the qualification picture. Willingness to verify reports through independently sourced contacts is itself a competence signal.

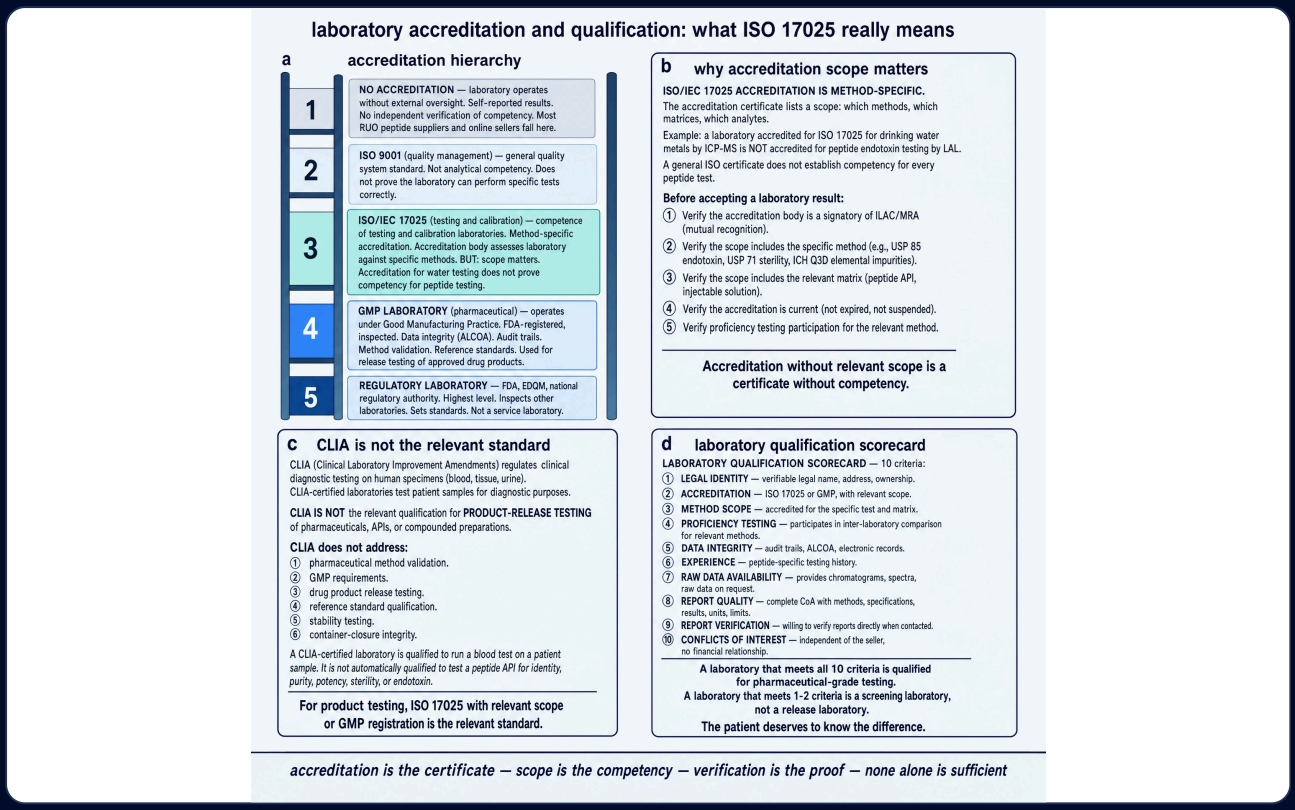

FIGURE 16 **Laboratory accreditation and qualification framework.** Accreditation hierarchy (including ISO/IEC 17025 and GMP context), why scope and matrix matter, why CLIA is generally not product-release qualification, and a laboratory scorecard. Commissioned plate.

SECTION 31

Global laboratory landscape

Laboratory capabilities, ownership claims, accreditation marks and service menus below were reviewed from public sources through **5 August 2026**. Entries mix laboratory claims, accreditation-directory practice, regulatory context and author inference; those layers are separated in the Apparatus laboratory appendix. Inclusion is not endorsement.

Large pharmaceutical analytical networks. Eurofins BioPharma Product Testing publicly offers peptide modality testing including LC/MS sequencing, amino-acid analysis, disulfide linkage work, LC/UV or LC/MS purity and strength, residual solvents and residual metals, with network statements referencing GMP authorisation and ISO 17025 accreditation at network level — scope must still be verified site-by-site. SGS, Intertek, Charles River Laboratories, Nelson Laboratories, Alcami, Pace Life Sciences, Element Materials Technology and WuXi AppTec analytical operations likewise present broad pharmaceutical or medical-device testing menus spanning chemistry, microbiology, endotoxin, sterility, elemental impurities and, to varying degrees, biologics characterisation. For full development and release programmes, these networks are the usual first shortlist because they can host validated methods, stability programmes and regulatory audit posture. They are not automatically the best choice for a consumer mailing a single research vial.

Independent research-market screening labs. Janoshik Analytical (Czech Republic) is widely used for HPLC purity and mass-spectrometric identity screening with a public verification portal; community and trade reviews commonly report that it does not hold ISO/IEC 17025 accreditation for peptide assays. MZ Biolabs (Arizona) appears frequently on vendor COAs; public accreditation signals for peptide matrices are inconsistent across secondary directories and require direct verification. Other named screening labs appear and disappear in marketplace directories; each must be re-verified

rather than inherited from popularity lists. University or institutional core laboratories can provide excellent characterisation science, yet may lack pharmaceutical release quality systems or custody designs suited to contested samples.

Specialist microbiology and endotoxin houses. Nelson Laboratories and Charles River are frequently positioned for sterility, bioburden and endotoxin work in medical-device and pharmaceutical contexts. Capability still depends on method suitability for the peptide matrix, because peptides can inhibit LAL or disturb sterility method suitability.

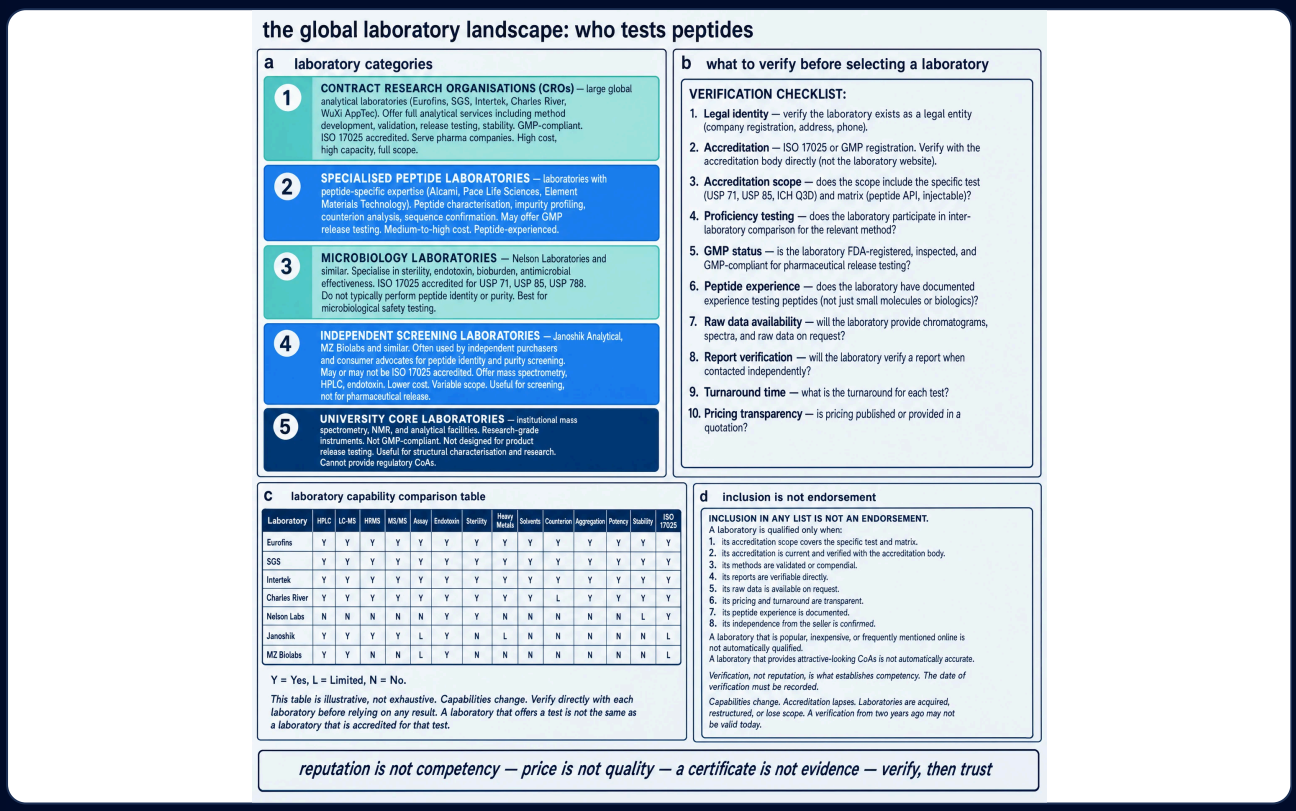

FIGURE 17 **Global laboratory landscape for peptide testing.** Laboratory categories, verification checklist, capability comparison themes, and the standing rule that inclusion is not endorsement. Landscape reviewed through 5 August 2026. Commissioned plate.

SECTION 32

Category-specific rankings

These are fit-for-purpose comparative assessments as of 5 August 2026, not “best laboratory” awards. Laboratories in different categories are often not directly comparable.

1. **Full pharmaceutical development and release testing:** Eurofins BPT network; Charles River; WuXi AppTec analytical; SGS / Intertek pharma labs — subject to site scope and peptide experience confirmation.
2. **Peptide identity and impurity characterisation:** Eurofins peptide modality teams; WuXi; specialist CDMO analytical groups with HRMS/mapping; selected university cores for research characterisation.
3. **Small-company or custom-peptide verification:** Mid-size GMP contract labs (Alcami, Pace, Element where peptide scope exists) plus characterisation-capable CDMO labs under contract.
4. **Independent consumer-submitted screening:** Janoshik (portal-verifiable screening; not ISO 17025 per common public reports); other screening labs only after independent contact and method review — never by vendor PDF alone.

5. **Sterility and microbiological testing:** Nelson; Charles River; Eurofins micro labs — matrix suitability required.
6. **Endotoxin testing:** Charles River; Eurofins; Nelson; in-house GMP micro labs with documented LER/suitability programmes.
7. **Elemental impurities and residual solvents:** Large network elemental/GC labs (Eurofins, SGS, Intertek, Element) with ICH Q3D/Q3C panels matched to process risk.
8. **Biological potency:** Charles River; Eurofins bioassay groups; specialised cell-assay CROs — mechanism fit dominates brand name.
9. **Litigation, regulatory or forensic custody work:** Laboratories with documented custody, accredited scopes, raw-data retention and willingness to testify; often large GMP networks or forensic-oriented labs rather than marketplace screening services.
10. **Overall value where evidence permits:** Not globally rankable. Value is panel-specific: a cheap HPLC screen can be good value for identity/purity screening and poor value for release; a full GMP suite is poor value for a question that needed only intact mass.

Before labelling any laboratory recommended, leading, qualified or best for a use case: verify current operations, capability, accreditation, scope, customer-type access, matrix fit and limitations; cite evidence; record the verification date.

SECTION 33

Testing packages

Basic research-peptide identity screening — intact mass, chromatographic purity, gross vial or sample mass. Can support a narrow identity/purity screen of the submitted material. Cannot establish NPC, potency, sterility, endotoxin, elementals or batch representativeness.

Strong independent API verification — identity, HRMS, sequence confirmation, orthogonal purity, assay, water, counterion, residual solvents, elemental impurities. Establishes a much stronger chemical dossier on the sample. Still does not, by itself, prove finished sterile product quality.

Finished injectable quality assessment — identity, purity, assay, fill volume/content uniformity, appearance, pH, osmolality, particulates, endotoxin, sterility, CCI as relevant, residuals/elementals and stability where relevant. Requires multiple vials because several tests are destructive.

Pharmaceutical-development package — full structural characterisation, impurity identification, validated assay, biological potency, formulation characterisation, microbiology, stability, method validation, reference-standard qualification and batch comparability. This is a programme, not a coupon panel.

Approximate costs and turnaround vary by geography, rush fees, method development, sample count and whether GMP documentation is required; published marketplace screening prices are not interchangeable with GMP release quotations. Where current formal quotations were not obtained for this monograph, numeric price claims are withheld rather than invented.

SECTION 34

Conflicting test results

Classic conflicts include 98% versus 99.5% purity across labs; correct mass with low assay; sterility pass with endotoxin fail (or the reverse); high content with poor purity; correct identity with unexpected biological activity; disagreeing masses; vial-to-vial content differences; disagreeing

elemental findings; failed replicate agreement. Causes include heterogeneity, different batches, different methods or standards, degradation in transit, integration differences, laboratory error, transcription error, fraud, interference, insufficient sample and retest bias.

Adjudication framework: preserve retains; verify both laboratories and reports; confirm whether the same claim lane was measured; compare methods, SST and reference standards; run blinded splits with orthogonal methods where needed; document disposition. Do not “average” incompatible methods into a false peace.

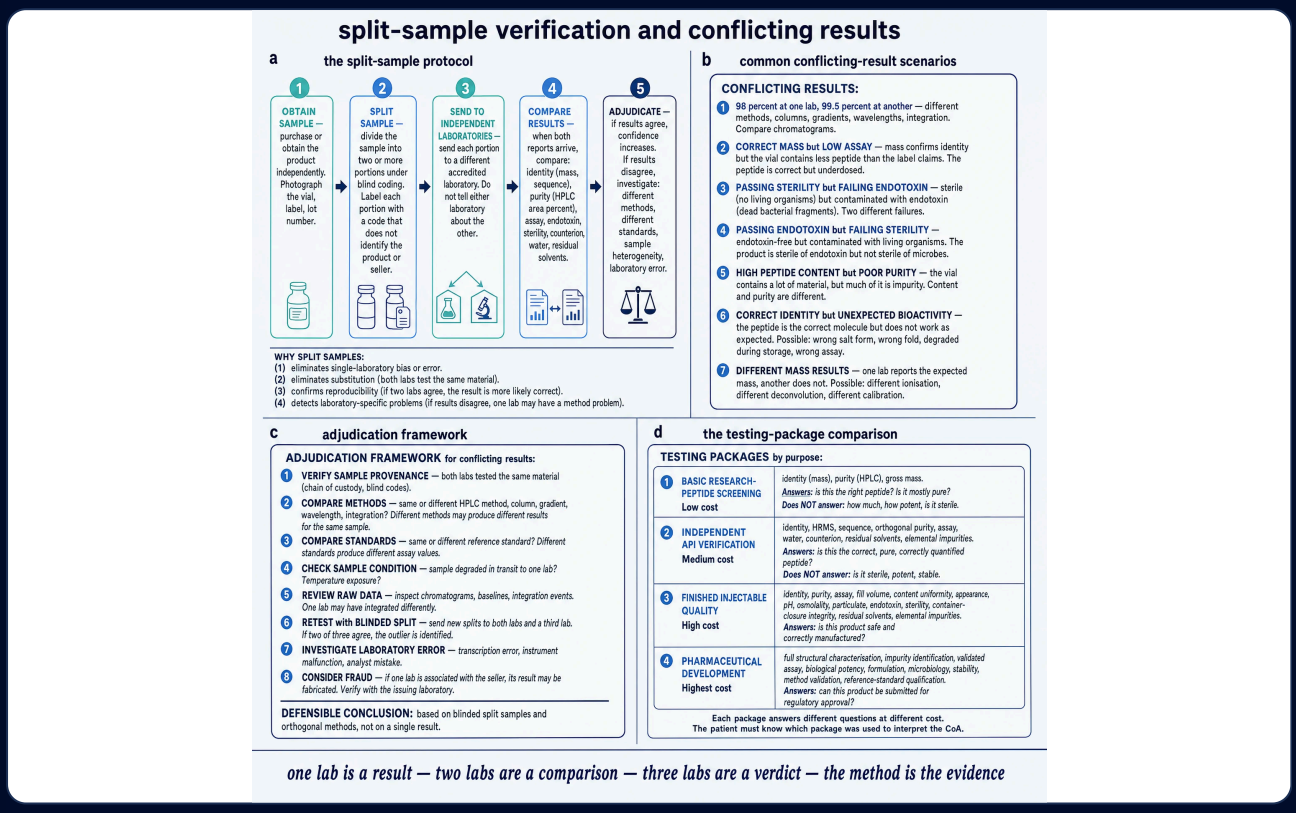

FIGURE 18 **Split-sample verification and conflicting results.** Blinded split-sample protocol, common conflict scenarios, adjudication steps, and testing-package comparison by purpose. Commissioned plate.

SECTION 35

Cost and turnaround factors

Drivers include method development versus compendial execution, GMP versus non-GMP documentation, number of analytes, stability pulls, microbiology incubation time, customs for cross-border shipments, rush surcharges and whether raw data packages are included. Sterility incubations impose calendar minimums that no courier can erase. Price transparency is itself a laboratory quality signal; opaque invoices complicate scientific comparison.

SECTION 36

Standing research-use constraint

Nothing in this monograph authorises human use of any peptide, or specifies a dose, route or schedule. Analytical literacy is not clinical advice. Research-use-only materials remain outside approved drug labelling even when their COAs look pharmaceutical. The ethical and legal boundary is part of the quality story, not a footnote after it.

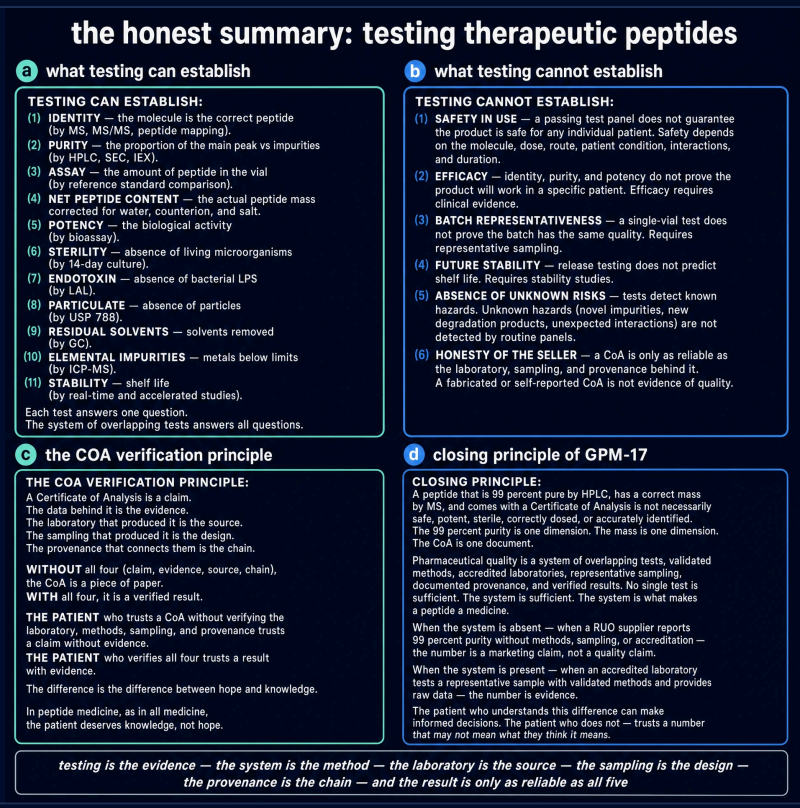

FIGURE 19 **What testing can and cannot establish.** Closing synthesis: what a competent testing system can establish; what it cannot; the claim–evidence–laboratory–sampling–provenance chain behind a COA; and the principle that no single test is sufficient. Commissioned plate.

APPARATUS

Tables, frameworks, glossary, audits and references

A1

Glossary

Assay — quantitative determination of peptide amount relative to a reference standard. **COA** — certificate of analysis. **CQA** — critical quality attribute. **LER** — low-endotoxin recovery. **MVD** — maximum valid dilution. **NPC** — net peptide content. **Orthogonal methods** — techniques that separate or detect by different physicochemical principles. **SST** — system suitability test. **Scope** — the accredited method/matrix list under ISO/IEC 17025.

A2

Abbreviations

AAA, AUC, CCI, CE, CSE, DLS, FID, FTIR, GC, GMP, HMW, HPLC, HRMS, HS-GC, ICH, ICP-MS, IEX, KF, LAL, LC-MS, LO, LOD, LOQ, MS/MS, NPC, rFC, RP, RUO, SEC, UPLC/UHPLC, USP.

A3

Quality-attribute taxonomy

See `notes/QUALITY_ATTRIBUTE_TAXONOMY.md` in the project dossier for the full attribute table. Working rule: no result stands in for an attribute it does not test.

A4

Method-to-question matrix

See `notes/METHOD_TO_QUESTION_MATRIX.md`. Primary versus orthogonal roles are marked there for identity, purity, NPC, potency, endotoxin, sterility, elementals, solvents, water/counterions, aggregates and particles.

A5

API and finished-product matrices

See `notes/API_TESTING_MATRIX.md` and `notes/FINISHED_PRODUCT_TESTING_MATRIX.md`.

A6

Regulatory and pharmacopeial brief

ICH Q6B (identity/purity/potency/quantity grammar for biotechnological products); ICH Q2(R2) (analytical validation); ICH Q3C/Q3D (solvents/elementals); EMA Guideline on the Development and Manufacture of Synthetic Peptides (EMA/CHMP/CVMP/QWP/367182/2025; effective 1 June 2026); USP general chapters commonly referenced in practice include chromatography (<621>), sterility (<71>), bacterial endotoxins (<85>), particulates (<787>/<788>), water (<921>) and elemental impurities (<232>/<233>) — chapter text not reproduced. FDA synthetic-peptide ANDA guidance history should be checked live because documents have been withdrawn and revised.[617]

A7

Method-validation appendix

Validation parameters follow ICH Q2. Distinguish compendial verification from full validation of noncompendial methods. Screening methods used for informal market checks should be labelled as screening methods.

A8

Laboratory-verification appendix

Verification date: **5 August 2026**. Layers recorded separately: laboratory claim; accreditation record/scope; method scope; verified performance (when available); customer/community report; regulatory finding; author inference. Public sources used for landscape context include laboratory websites (e.g. Eurofins peptide testing pages; Janoshik verification portal) and secondary directories; accreditation scopes must be confirmed on accreditation-body directories before operational reliance. Missing for this edition: complete paid accreditation-scope PDFs for every named lab, private proficiency-testing records, confidential inspection files and formal price quotations — requested where needed and not invented.

A9

Assumptions and limitations

Local JATS sweep identifies topic engagement, not automatic truth of every sentence in 1,561 reading-tier articles. Pharmacopeial numeric tables are not harvested as copyrighted text. Laboratory rankings use public evidence through the stated date and will age. No commercial vial results were fabricated.

Sampling/custody and independent-verification families are thin in open literature relative to HPLC method papers; frameworks there are principle-based.

A10

Contradictory-evidence register

Community reputation versus ISO 17025: marketplace screening labs may be widely used and portal-verifiable yet lack accredited peptide scopes; GMP networks may be accredited broadly yet weak on a specific peptide matrix until scoped. “99% pure” culture versus impurity-identification expectations in EMA/Ph. Eur. peptide control. Sterility test negatives versus sterility assurance. These are structured tensions, not errors to erase.

A11

Adversarial analytical review

Hostile readings anticipated: that the monograph over-weights formal accreditation against useful screening data; that it under-specifies operational lab SOPs; that category rankings will be misquoted as endorsements; that COA literacy will be weaponised for marketing. Mitigations: explicit non-endorsement language; refusal to publish sterile-suite recipes; dated verification notes; attribute-separation rule repeated at decision points.

A12

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