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COURSE BROCHURE

# Biologics Comparability After Process Changes Training Course

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# Biologics Comparability After Process Changes Training Course

Biologics Comparability After Process Changes is a 1-week training course for biopharmaceutical CMC, quality and process development staff, in which each participant drafts a Comparability Protocol and Assessment Report for a realistic manufacturing change. Cell line updates, site transfers and scale-up now arrive faster across a product's life, and each one must show that quality, safety and efficacy are unaffected. Biologics comparability after process changes is taught by Jupiter Prime Training.

## Why Biologics Comparability After Process Changes Matters Now

Three forces shape comparability work today: more frequent post-approval changes as manufacturers chase yield and capacity, more sensitive analytical platforms that reveal small shifts in glycosylation or charge variants, and health authority reviewers who expect a clear risk rationale behind every study. A well-argued package lets a change proceed with analytical data alone and keeps supply uninterrupted. A weak one triggers requests for extra non-clinical or clinical bridging, delays launch at a new site and can leave older and newer lots treated as different products. The course rests on quality risk management and quality by design principles.

## Who Gains Most from Biologics Comparability After Process Changes

- CMC leads who author change packages and defend them in health authority submissions
- Process development scientists who design and execute pre- and post-change runs
- Analytical scientists who select characterisation methods and interpret orthogonal results
- Quality assurance staff who own change control and approve comparability conclusions
- Manufacturing science staff who prepare technology transfers and scale-up

Product teams gain most when CMC, analytical and quality members attend together.

## Biologics Comparability After Process Changes Capabilities

Participants learn to turn a proposed process change into a defensible evidence chain, from risk ranking to final conclusion.

- Assess the impact of a manufacturing change on critical quality attributes — study scope approval
- Design a comparability study with suitable lot numbers and sampling — process development planning
- Specify an orthogonal analytical characterisation panel — analytical laboratory resourcing
- Apply statistical equivalence and quality range methods — acceptance criteria sign-off
- Weigh stability and forced degradation evidence — shelf life and release decisions

- Build change documentation that links data to conclusion — quality assurance and reviewers

## Key Biologics Comparability After Process Changes Terms

- Comparability — evidence that pre- and post-change product are highly similar, with no adverse impact on safety or efficacy.
- Critical quality attribute — a physical, chemical or biological property that must stay within limits to protect product performance.
- Orthogonal method — an analytical technique using a different principle to confirm a result from another method.
- Equivalence testing — a statistical approach that shows a difference between groups lies inside a predefined margin.
- Forced degradation — exposing product to heat, light, oxidation or agitation to compare degradation pathways.
- Comparability protocol — a prospective document setting out the studies and acceptance criteria for a planned change.

## Biologics Comparability After Process Changes Day by Day

## Day 1: Change Drivers and Comparability Principles

- Lifecycle Change Types — Cell Line, Scale, Site and Raw Material Shifts
- Comparability Concept and Evidence Hierarchy — When Analytics Alone Suffice
- Product Knowledge Map — Linking Structure to Function and Safety
- Critical Quality Attribute Inventory — Ranking Attributes by Clinical Relevance
- Historical Lot Database — Defining the Pre-Change Reference Baseline

## Day 2: Risk Assessment and Study Design

- Change Impact Risk Assessment — Scoring Attribute Sensitivity to Each Change
- Study Design Options — Side-by-Side, Retrospective and Prospective Lots
- Lot Selection and Sample Size — Balancing Statistical Power and Cost
- Process Intermediate Testing — Detecting Shifts Before Drug Substance
- Comparability Protocol Drafting — Prospective Acceptance Criteria Agreement

## Day 3: Analytical Characterisation and Statistics

- Primary Structure and Peptide Mapping — Sequence and Modification Confirmation
- Glycan, Charge Variant and Aggregate Profiling — Orthogonal Method Selection
- Potency and Biological Activity Assays — Functional Equivalence Evidence
- Equivalence Testing and Tolerance Intervals — Setting Statistical Acceptance Limits
- Quality Range and Min-Max Approaches — Choosing Methods for Small Lot Numbers

## Day 4: Stability, Release Data and Conclusions

- Real-Time and Accelerated Stability Comparison — Degradation Rate Slopes
- Forced Degradation Studies — Revealing Hidden Pathway Differences
- Release and In-Process Specification Trending — Batch History Signals
- Handling Out-of-Range Results — Root Cause and Scientific Justification
- Bridging Study Triggers — Deciding on Non-Clinical or Clinical Follow-Up

## Day 5: Practising the Comparability Protocol and Assessment Report

- Applying the Risk Assessment to a Case Site Transfer — Study Scope
- Applying Statistical Methods to Case Lot Data — Acceptance Verdict
- Applying Stability Evidence to the Case — Shelf Life Position
- Change Control Record and Submission Narrative — Linking Data to Conclusion
- Completing the Comparability Protocol and Assessment Report — Peer Challenge

## Applying Biologics Comparability After Process Changes After the Course

- Run a change impact risk assessment on the next planned process change and agree attribute rankings with analytical and quality leads.
- Re-examine the statistical acceptance limits in a current comparability protocol against historical lot variability.

## Biologics Comparability After Process Changes Questions FAQ

### What is biologics comparability after process changes and why does it matter now?

It is the evidence that a biologic made after a manufacturing change is highly similar to the product made before it. Faster lifecycle changes and more sensitive analytics make a sound comparability case essential for continued supply.

### Which roles gain most from biologics comparability after process changes training?

CMC leads, process development and analytical scientists gain most, together with quality assurance staff who approve change control and manufacturing science staff preparing transfers.

### How does a biologics comparability after process changes course differ from a biosimilar development course?

It compares one manufacturer's own product before and after a change, using its historical lot data. A biosimilar course compares a new product with another company's reference product and needs a wider clinical evidence package.

## What do you bring back from biologics comparability after process changes training?

You bring back a drafted protocol and assessment for a case change, covering risk ranking, study design, analytical panel, statistical limits, stability evidence and documentation.

## Biologics Comparability After Process Changes: The Way Forward

The Comparability Protocol and Assessment Report first informs whether a proposed change can be supported by analytical data alone. CMC leads use it to agree study scope with quality assurance, and analytical scientists use it to plan testing. After its first use, revisit the attribute risk rankings and statistical margins as real post-change lots accumulate.