



From Spectrum to **Validated Risk**, in a single, automated workflow

SpotMap MS now integrates directly with the BioPhorum HCP Data Platform. Every host cell protein identified by your LC-MS run is automatically cross-referenced against BioPhorum's expert-curated, peer-reviewed risk database. No tab-switching. No PubMed sprints. No spreadsheets to reconcile.

From *forty-five minutes to under three.*

Median time analysts spend cross-referencing a single host cell protein against the BioPhorum risk database.

BEFORE INTEGRATION

Manual PubMed, spreadsheets, copy-paste

~45 min

AFTER INTEGRATION

Single authenticated API call from inside SpotMap MS

< 3 min

~90%
TIME SAVED

Internal benchmarking, TotalLab 2025. Comparison based on average analyst workflow for a mid-complexity CHO mAb harvest sample (n=12 HCPs).

Two trusted tools. *One workflow.*

BEFORE

Five tools. Five tabs. No audit trail.

- 1 Run LC-MS analysis in SpotMap MS, export ID list to CSV.
- 2 Open BioPhorum portal. Look up each UniProt ID manually.
- 3 Copy-paste risk classifications and citation lists into Excel.
- 4 Chase down PubMed references for high-risk hits.
- 5 Reconcile spreadsheet back into a final scientific report.

PAIN POINTS

- Inconsistent risk calls between analysts
- Citation chains that fall apart at audit time
- No version control. No traceability.

AFTER

One window. Audit trail by default.

- 1 **Drop in raw spectra and FASTA.**
SpotMap MS handles identification, Hi3 quantification, and QC.
- 2 **Walk away.**
BioPhorum lookups happen automatically, every HCP, every run.
- 3 **Come back to a regulator-ready report.**
Quantitation, risk class, citation trail, audit log. Ready for IND / BLA.

WHAT YOU GAIN

- Consistent risk calls, every time, every analyst
- 21 CFR Part 11 audit trail logged automatically
- USP <1132.1> manual-inspection guidance operationalised

Available to active subscribers of both the BioPhorum HCP Data Platform and SpotMap MS.

~90%

LESS MANUAL LOOKUP

Cross-reference time per HCP cut from minutes of literature search to a single API call.

100%

PEER-REVIEWED

Every risk annotation traces back to BioPhorum's curated, expert-reviewed evidence base.

USP <1132.1>

ALIGNED BY DESIGN

Manual inspection guidance operationalised inside SpotMap MS's Protein Verification Loop.

1-click

FROM .RAW TO REPORT

Drop in raw files, FASTA, and credentials. Walk away. Come back to a regulator-ready output.

1 CONTEXT

Detection is solved. *Decision* is not.

LC-MS now routinely identifies hundreds of HCPs in a single bioprocess sample. The hard work has shifted downstream of the spectrum: deciding which proteins matter, why, and how to defend that call to a reviewer.

With USP General Chapter <1132.1> in effect since May 2025, regulatory expectations on MS-based HCP analysis are now explicit. Reviewers expect manual inspection, traceable rationale, and references that hold up to scrutiny.

2 THE FRICTION

Two trusted tools. *One messy* handoff.

Analysts already trust the BioPhorum HCP Data Platform for curated risk intelligence, and SpotMap MS for automated LC-MS analysis. But until now, getting from one to the other meant copy-paste, manual searches, and reconciliation spreadsheets.

THE HIDDEN COST

Hours per sample spent moving identifiers between systems. Inconsistent risk calls between analysts. Citation chains that fall apart at audit time.

3 THE INTEGRATION

Same window. Same report. *Same audit trail.*

SpotMap MS now connects directly to the BioPhorum HCP Data Platform via authenticated API. Risk classifications, impact categories, and peer-reviewed citations flow into the SpotMap MS analysis automatically.

- ✓ Real-time database lookup at analysis time
- ✓ High-risk HCPs flagged with category and citations
- ✓ Audit trail logged automatically (21 CFR Part 11)
- ✓ Available to active subscribers of both platforms

4 HOW THE INTEGRATION WORKS

From *raw spectra* to a regulator-ready, risk-annotated report.

SPOTMAP MS (TOTALLAB)
BIOPHORUM HCP DATA PLATFORM
COMBINED OUTPUT

1 SPOTMAP MS · INPUT

Raw LC-MS files in.

Drop a folder of .raw / .mzML spectra and a FASTA database into SpotMap MS. No proteomics expertise required.

VENDOR-NEUTRAL · CHO, HEK, E. COLI, SF9

2 SPOTMAP MS · ANALYSIS

Automated identification & Hi3 quantification.

The Protein Verification Loop performs the manual-inspection workflow USP <1132.1> expects, automatically. Every HCP gets a quality-checked quantitative call.

HI3 LABEL-FREE · XIC / MS / MS-MS QC

3 BIOPHORUM · LOOKUP

Real-time risk & citation lookup.

Each identified HCP is sent to the BioPhorum HCP Data Platform. Risk level, impact category, and peer-reviewed references are returned for every protein.

AUTHENTICATED API · SUBSCRIBER CREDENTIALS

4 COMBINED OUTPUT

Risk-annotated, regulator-ready report.

Quantitation, risk classification, and full citation trail in a single SpotMap MS report. Drop straight into IND / BLA documentation.

PDF · CSV · AUDIT LOG · 21 CFR PART 11

5 WHY THIS MATTERS

Three teams. *One* shared workflow.

For BioPhorum HCP Data Platform subscribers

Your subscription now lives inside the workflow your analysts run every day. Risk intelligence is no longer a separate destination, it's an annotation on every result. The ROI on your platform investment compounds with every sample analysed.

For SpotMap MS users

Stop second-guessing your calls. Every HCP gets a peer-reviewed evidence trail attached automatically: high-risk classifications, immunogenicity flags, biological-activity warnings, and full citation chains, ready for your scientific report.

For QC and regulatory teams

Submission-ready documentation. Risk decisions arrive pre-justified. References, classifications, and rationale travel with the data, ready to drop into IND and BLA packages.

USP General Chapter <1132.>, in effect since May 2025, sets a clear expectation: search-engine output for low-abundance HCPs must not be taken at face value, and manual peptide-level inspection of raw, MS, and MS/MS data should be routine. The integration operationalises that guidance.

PARAPHRASED FROM USP GENERAL CHAPTER <1132.1>

6 SAMPLE OUTPUT

What an analyst *actually* sees.

A composite extract from a SpotMap MS report on a CHO-derived mAb harvest, showing the new BioPhorum risk columns populated automatically alongside the standard quantitative output.

HCP (UNIPROT)	MW · PI	Hi3 (eRelQuant)	RISK	IMPACT CATEGORY	REFS
Phospholipase B-like 2 PLBL2 · G3HQ56	66.5 kDa 6.1	142	HIGH	Immunogenicity, formulation	12 refs
Cathepsin D CTSD · G3HZK1	44.6 kDa 6.1	38	HIGH	Product fragmentation	9 refs
Lipoprotein lipase LPL · G3I8R8	53.1 kDa 8.6	21		Polysorbate degradation	7 refs
Hexosaminidase B HEXB · G3IBN6	61.0 kDa 5.5	15		Product fragmentation	5 refs
Glyceraldehyde-3-PD GAPDH · G3HM39	35.8 kDa 8.0	9		None reported	2 refs
Pyruvate kinase M PKM · G3I7K4	57.9 kDa 7.9	6		None reported	1 ref

Illustrative output. Risk levels, impact categories, and reference counts sourced live from the BioPhorum HCP Data Platform.

7 SEE IT RUN

Book a live demo *at the booth.*

Bring a USB stick of your own LC-MS data, or use one of our sample sets. We'll run it through the integrated SpotMap MS × BioPhorum workflow live, end to end. Come away with a real, risk-annotated report from your own data.

ABOUT TOTALLAB

TotalLab Ltd builds analysis software trusted by biopharma scientists worldwide for HCP analysis, image analysis and assay automation. SpotMap MS is the company's purpose-built LC-MS HCP analysis platform, designed from the ground up for regulated biopharma workflows.

totallab.com

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ABOUT BIOPHORUM

BioPhorum is a global biopharmaceutical industry collaboration. The BioPhorum HCP Data Platform is an annual subscription resource curated by a Scientific Expert Review Committee, providing peer-reviewed risk and impact data for problematic host cell proteins.

biophorum.com

SELECTED REFERENCES

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