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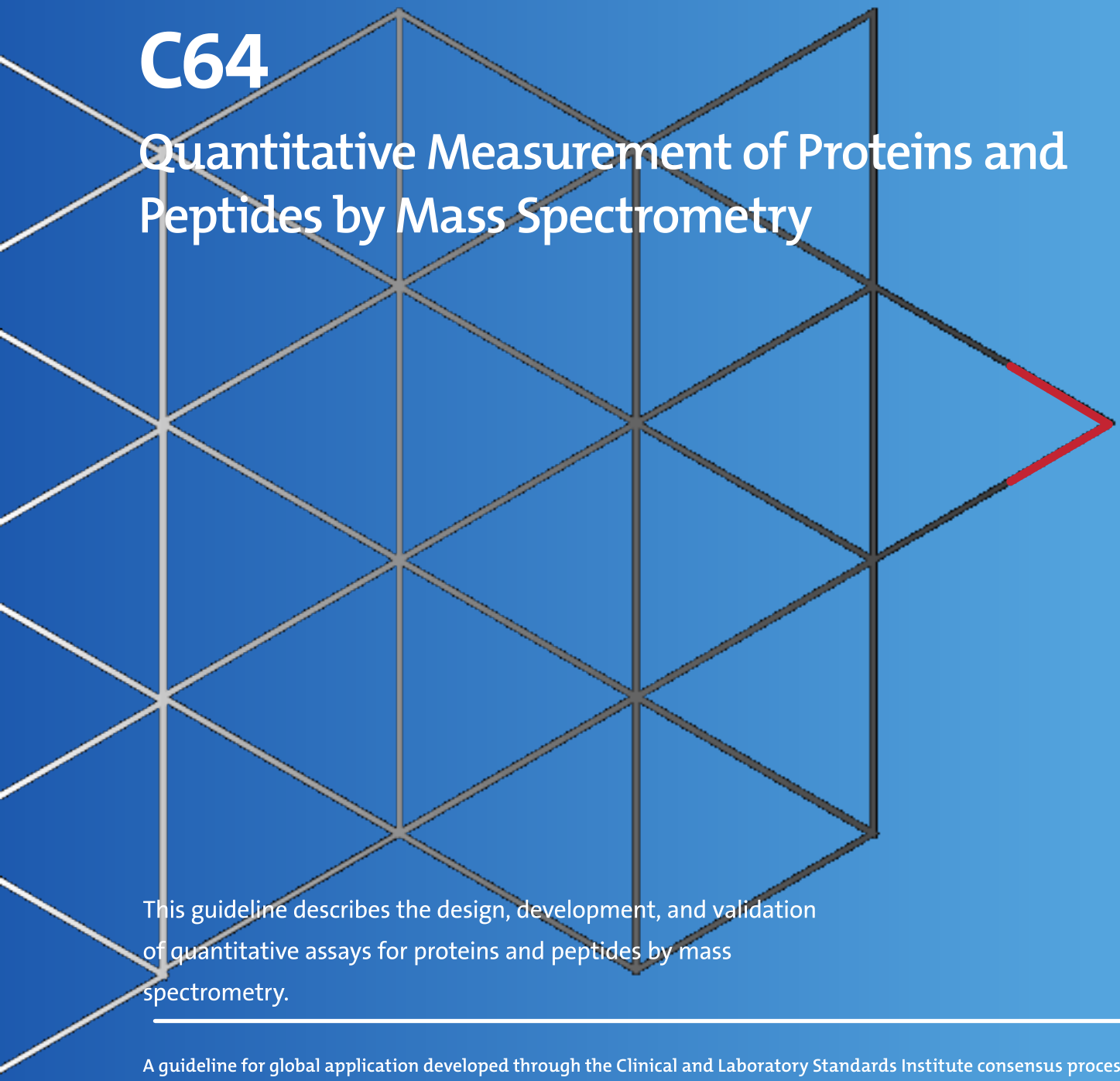
1st Edition

C64

Quantitative Measurement of Proteins and Peptides by Mass Spectrometry



This guideline describes the design, development, and validation of quantitative assays for proteins and peptides by mass spectrometry.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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Abstract

Clinical and Laboratory Standards Institute guideline C64—*Quantitative Measurement of Proteins and Peptides by Mass Spectrometry* provides a framework for developing clinical protein and peptide assays from conception to validation. This guideline is intended for those who have experience with traditional small-molecule liquid chromatography–mass spectrometry (LC-MS) but not with protein and peptide analysis. Although closely related to traditional small-molecule analysis by LC-MS, protein and peptide analysis involves unique challenges and necessitates complex workflows, which are covered in detail. To enhance translation of assays to clinical use, this guideline focuses on method development aligned with clinically appropriate analytical validation.

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Foreword

This guideline is intended to accompany CLSI documents C62[1] and EP19.[2] Many of the recommendations found in CLSI documents C62[1] and EP19[2] also apply to liquid chromatography–mass spectrometry (MS) protein measurements, and commonalities are highlighted. However, this guideline primarily concentrates on aspects that are unique to quantitative measurement of proteins and peptides by MS.

NOTE: The content of this guideline is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

KEY WORDS

Assay development
Bioanalysis
Liquid chromatography
Mass spectrometry
Peptide
Protein
Surrogate peptide
Validation

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