

CBF Feedback on “Protein Bioanalysis by LC/MS”

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On behalf of China Bioanalysis Forum
Steering Committee

Chinese Bioanalytical Community

CBF has become an official member association of Chinese Pharmaceutical Society. The celebration ceremony and a scientific symposium were held on September 18, 2020

Universities/Research Institutes

- Mainly support non-regulated bioanalysis
- A few BA labs affiliated with GLP Tox facilities

Hospital Based BA Labs

- Mainly support clinical research and sample analysis from Phase I unit



Bioanalysis Community in China



Contract Research Organization

- Support the majority of regulated bioanalysis in China

Pharma/Biotech BA Labs

- Mainly support in-house discovery bioanalysis

Newly Released Regulatory Guidelines From NMPA

-  **China Pharmacopeia 2020 Chapter 9012: Guidance for Bioanalytical Method Validation** 
-  **Guidance for Clinical Pharmacokinetic Studies of Therapeutic Proteins (Draft, August 2020)** 
-  **Guidance for Immunogenicity of Therapeutic Products (Draft, Sept 2020)** 
-  **Guidance on Drug-drug Interaction (Draft, Sept 2020)** 

Local Survey on Protein Bioanalysis Using LC/MS



Intact Analysis vs Surrogate Peptide



LC/MS/MS vs HRMS



Research/discovery vs Regulated Bioanalysis



Quantitative vs qualitative analysis

Survey Questionnaire

Q1: Do you have bioanalytical experience in Quantitation of Protein Biotherapeutic PK using LC-MS/MS (e.g. surrogate peptide approach) in Research/Drug Discovery?

Q2: Do you have bioanalytical experience in Quantitation of Protein Biotherapeutic PK using LC-MS/MS (e.g. surrogate peptide approach) supporting Regulated Studies?

Q3: Do you have bioanalytical experience in LC-MSMS Quantitation of Peptide Biotherapeutic using intact analysis approach (e.g. insulin analogues) supporting Regulated Studies?

Q4: Do you have bioanalytical experience in Quantitation of Protein/Peptide Biotherapeutic using High Resolution Mass Spectrometry (HRMS) in Research/Drug

Q5: Do you have bioanalytical experience in Quantitation of Protein/Peptide Biotherapeutic using High Resolution Mass Spectrometry (HRMS) supporting Regulated Studies?

Q6: Do you have bioanalytical experience in Protein Quantitation using Hybrid LCMS Approaches (e.g. coupled with immuno-enrichment) in Research/Discovery?

Q7: Do you have bioanalytical experience in Protein Quantitation using Hybrid LCMS Approaches (e.g. coupled with immunocapture) supporting Regulated Studies

Q8: Do you have experience in Protein Biomarker Quantitation using LCMS Approaches?

Q9: What is your acceptance criteria for Protein Bioanalysis using LCMS method?

Experience in Protein Bioanalysis Using LC/MS in China

Survey Results

Quantitation of Protein Biotherapeutic PK using LC-MS/MS (e.g. surrogate peptide approach)?	Research/Discovery √	Regulated Studies √
LC-MSMS Quantitation of Peptide Biotherapeutic using intact analysis approach (e.g. insulin analogues)?	Research/Discovery √	Regulated Studies √
Quantitation of Protein/Peptide Biotherapeutic using High Resolution Mass Spectrometry (HRMS)?	Research/Discovery √	Regulated Studies x
Protein Quantitation using Hybrid LCMS Approaches (e.g. coupled with immuno-enrichment)?	Research/Discovery √	Regulated Studies √
Protein Biomarker Quantitation using LCMS Approaches?	Research/Discovery √	
Acceptance criteria for Protein Bioanalysis using LCMS method?	2/3 of responders using 4-6-15%	1/3 of responders using 4-6-20%

Example of published manuscripts:

Y. Gao et al.,(2019) Two validated liquid chromatography-mass spectrometry methods with different pretreatments for the quantification of an anti-CD47 monoclonal antibody in rat and cynomolgus monkey serum compared with an electrochemiluminescence method. J Pharm Biomed Anal. 2019 Oct 25;175



THANK YOU