Introduction to GLP Regulations and Bioanalytical Method Validation by LC-MS/MS

This guidance provides assistance to sponsors of investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologic license applications (BLAs), and supplements in developing bioanalytical method validation information used in human clinical pharmacology, bioavailability (BA), and bioequivalence (BE) studies that require pharmacokinetic (PK) or biomarker concentration evaluation. This guidance also applies to bioanalytical methods used for nonclinical pharmacology/toxicology studies. For studies related to the veterinary drug approval process (Investigational New Animal Drug Applications (INADs), New Animal Drug Applications (NADAs), and Abbreviated New Animal Drug Applications (ANADAs)), this guidance may apply to blood and urine BA, BE, and PK studies.

2013 Guidance (draft)

This guidance provides assistance to sponsors of investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), and supplements in developing bioanalytical method validation information used in human clinical pharmacology, bioavailability (BA), and bioequivalence (BE) studies requiring pharmacokinetic (PK) evaluation. This guidance also applies to bioanalytical methods used for non-human pharmacology/toxicology studies and preclinical studies. For studies related to the veterinary drug approval process, this guidance applies only to blood and urine BA, BE, and PK studies.

2001 Guidance

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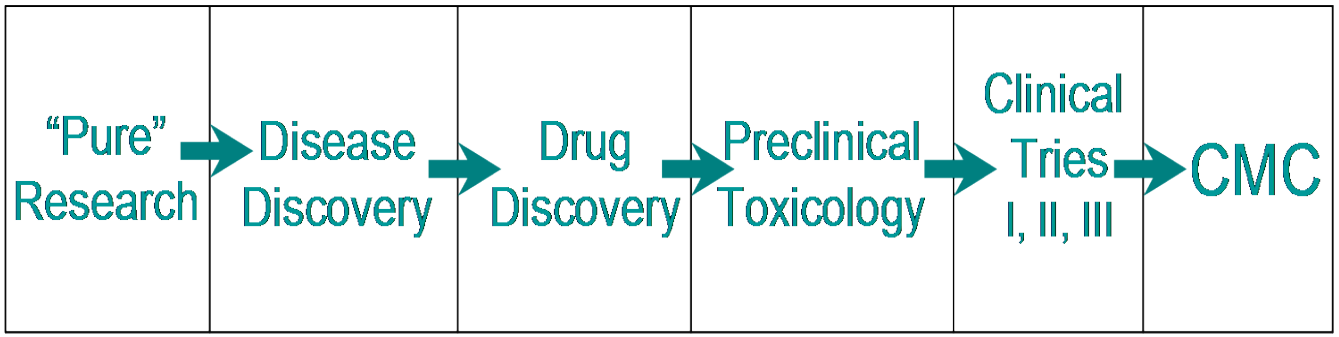
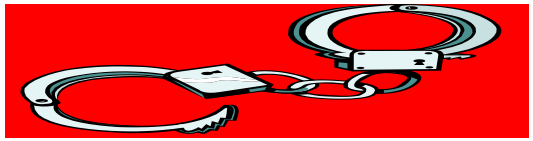


GLP GCP GMP

Not regulated

Regulated



Study based

Process based

Good Regulatory Practices (GXP)

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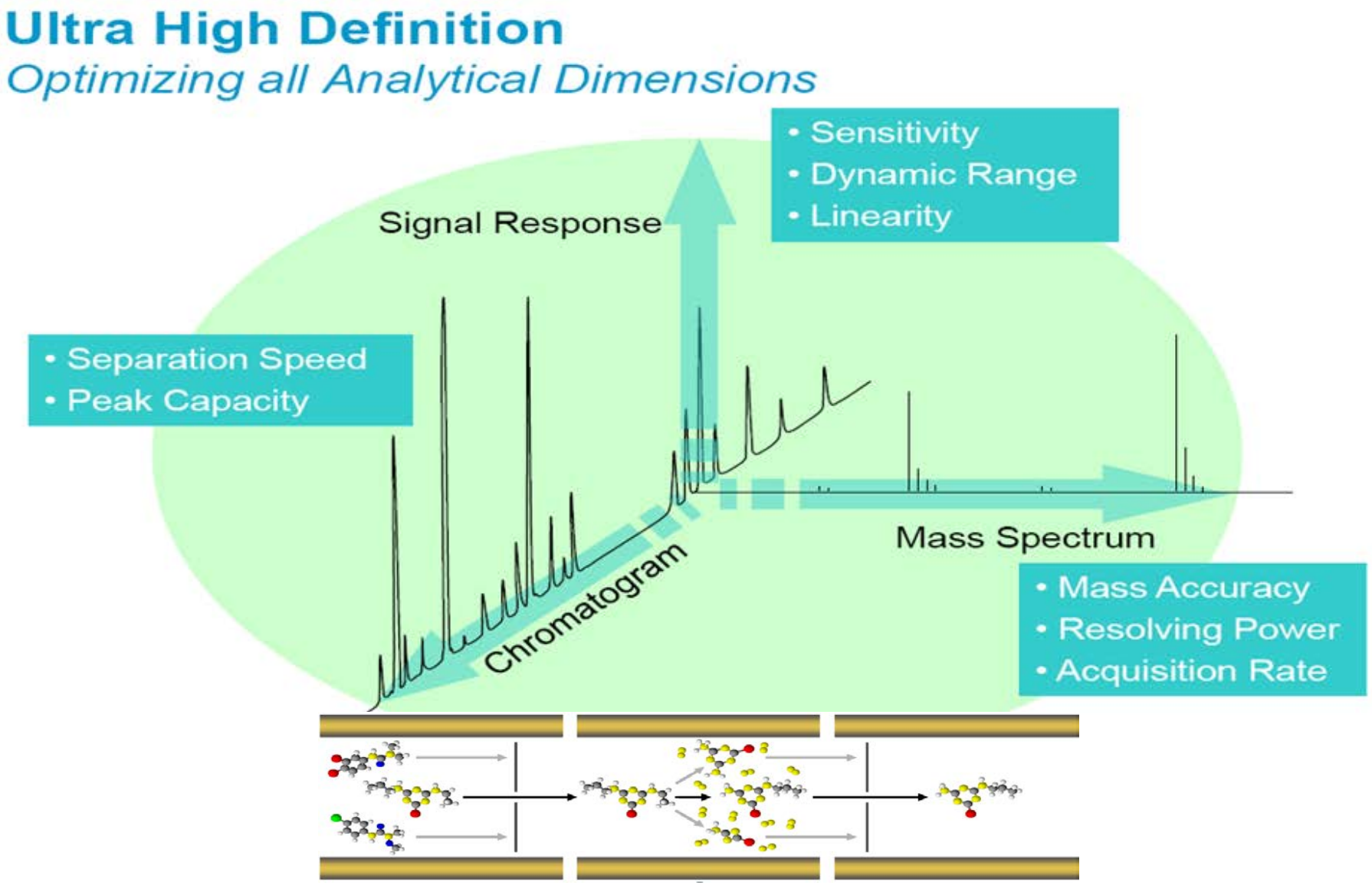

Calibration Standards		Quality Control Samples		Other Validation Samples	
Name	Replicate	Name	Replicate	Name	Replicate
Level 1	1	Level 1	6	pooled blank matrix	1
Level 2	1	Level 2	6	Zero Standard	1
Level 3	1	Level 3	6	Reference Samples	2
Level 4	1			LLOQ Evaluation Sample*	6
Level 5	1			ULOQ Evaluation Sample**	6
Level 6	1				
Level 7	1				
Level 8	1				
Level 9	1				

Bioanalytical Method Validation design