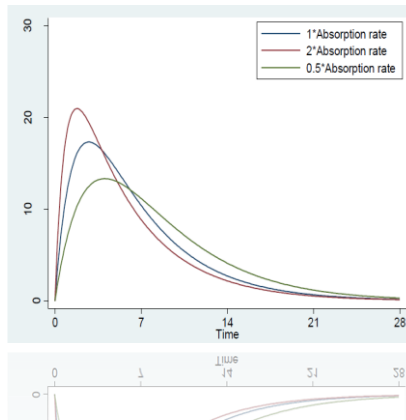
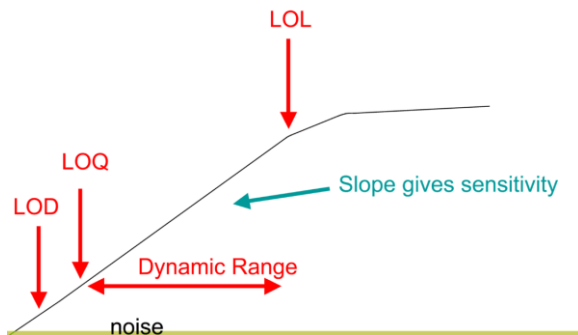


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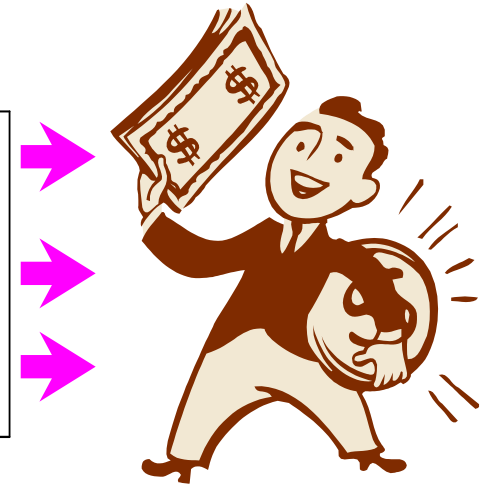
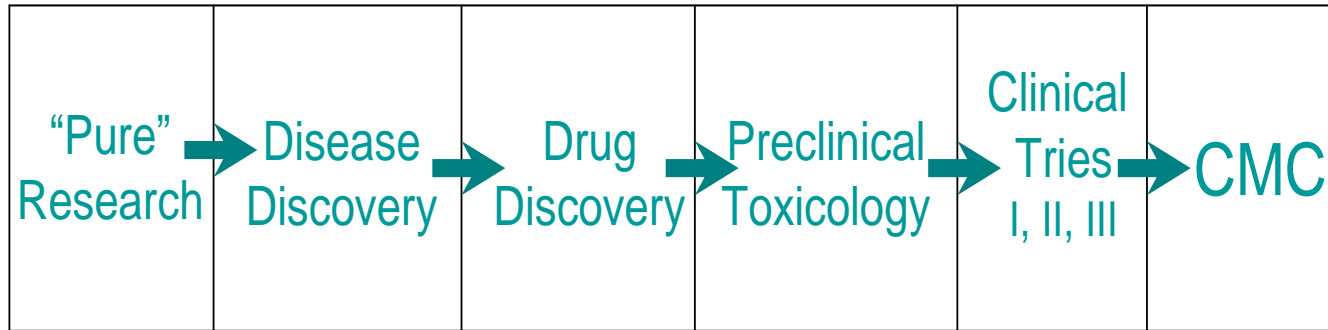
Federal Food, Drug, and Cosmetic Act

Good Laboratory Practice

Guidance for Industry Bioanalytical Method Validation



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GLP GCP GMP

Not regulated

Regulated



Study based

Process based

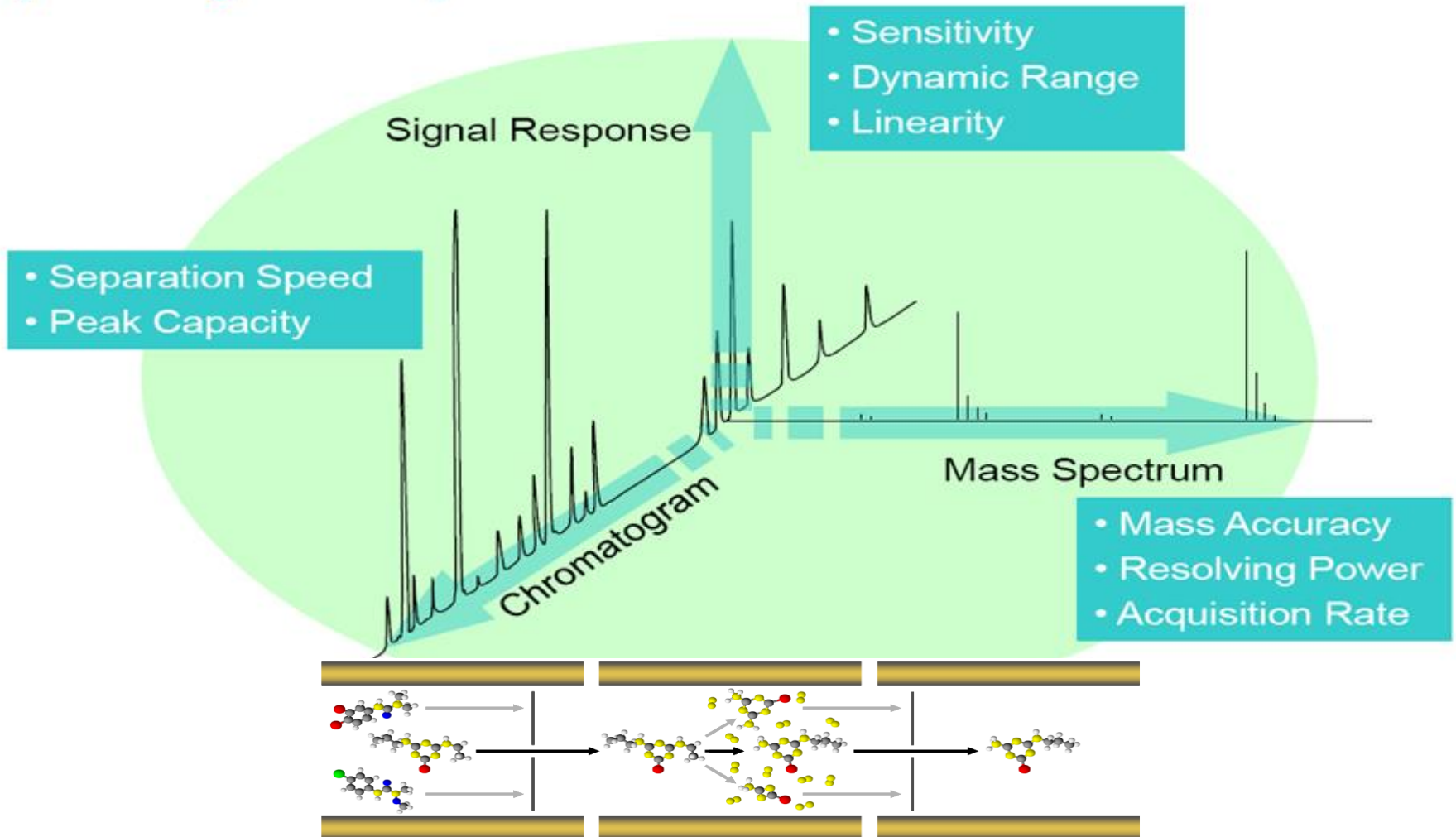
Good Regulatory Practices (GXP)

Good Regulatory Practices (GXP)

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Ultra High Definition

Optimizing all Analytical Dimensions



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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