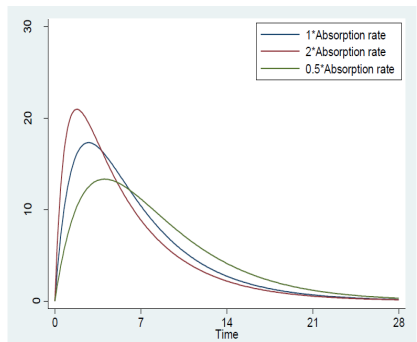
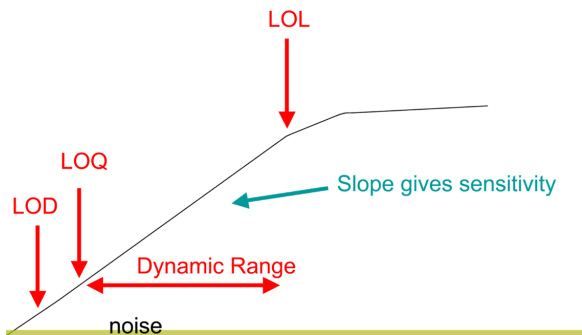
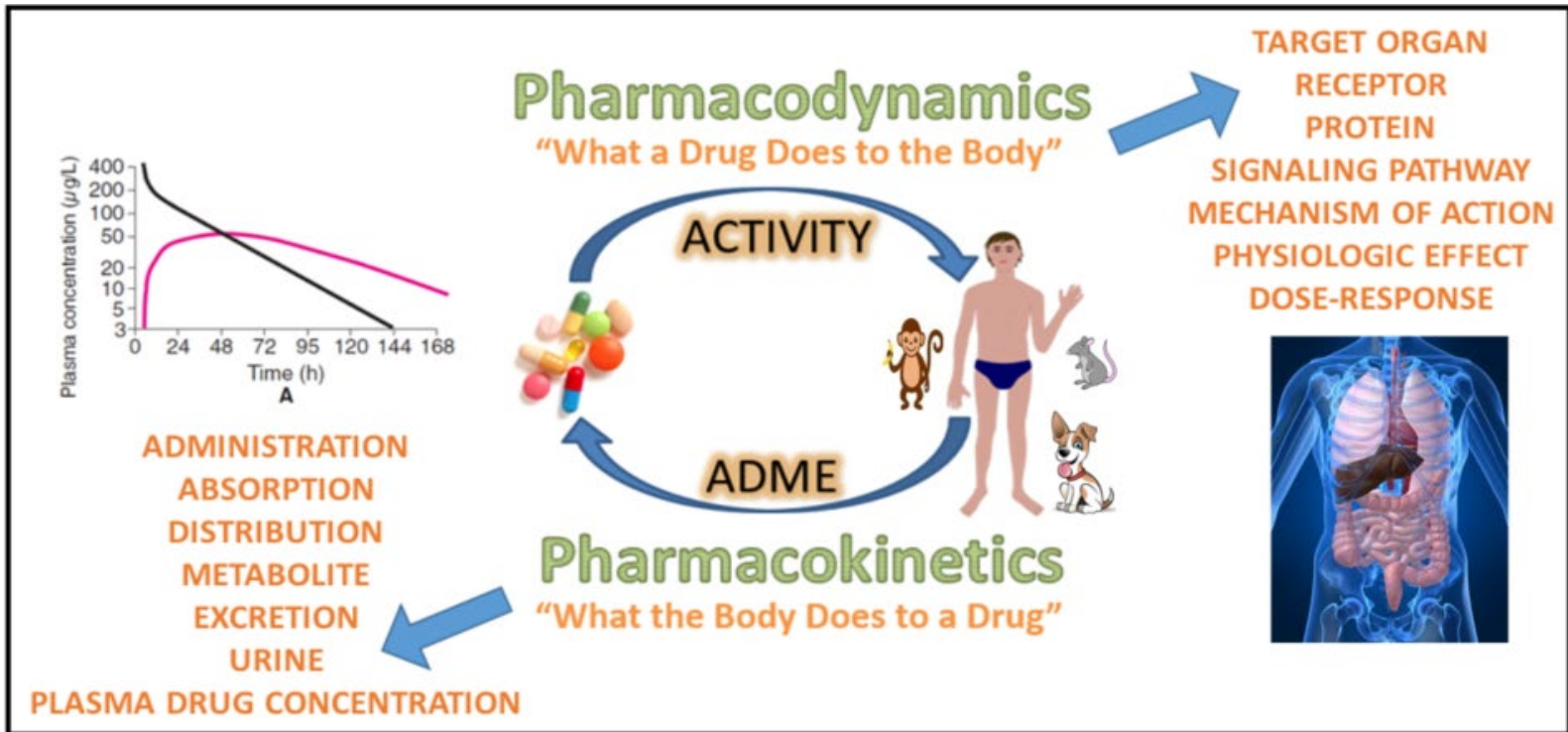
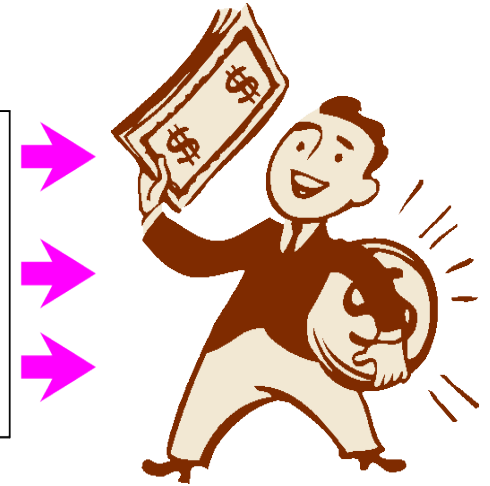
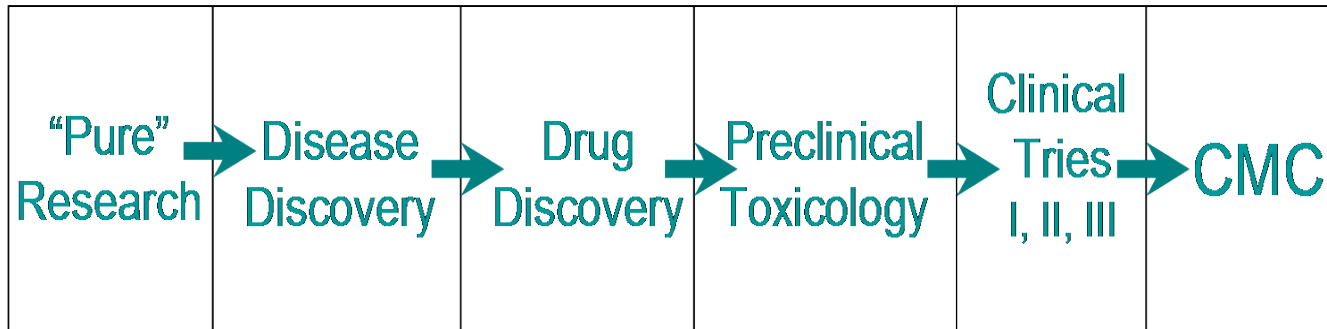


# Introduction to GLP Regulations and Bioanalytical Method Validation by LC-MS/MS



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



GLP    GCP    GMP

Not regulated

Regulated



Study based

Process based

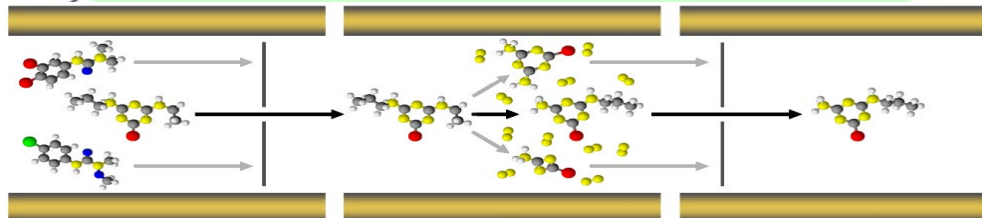
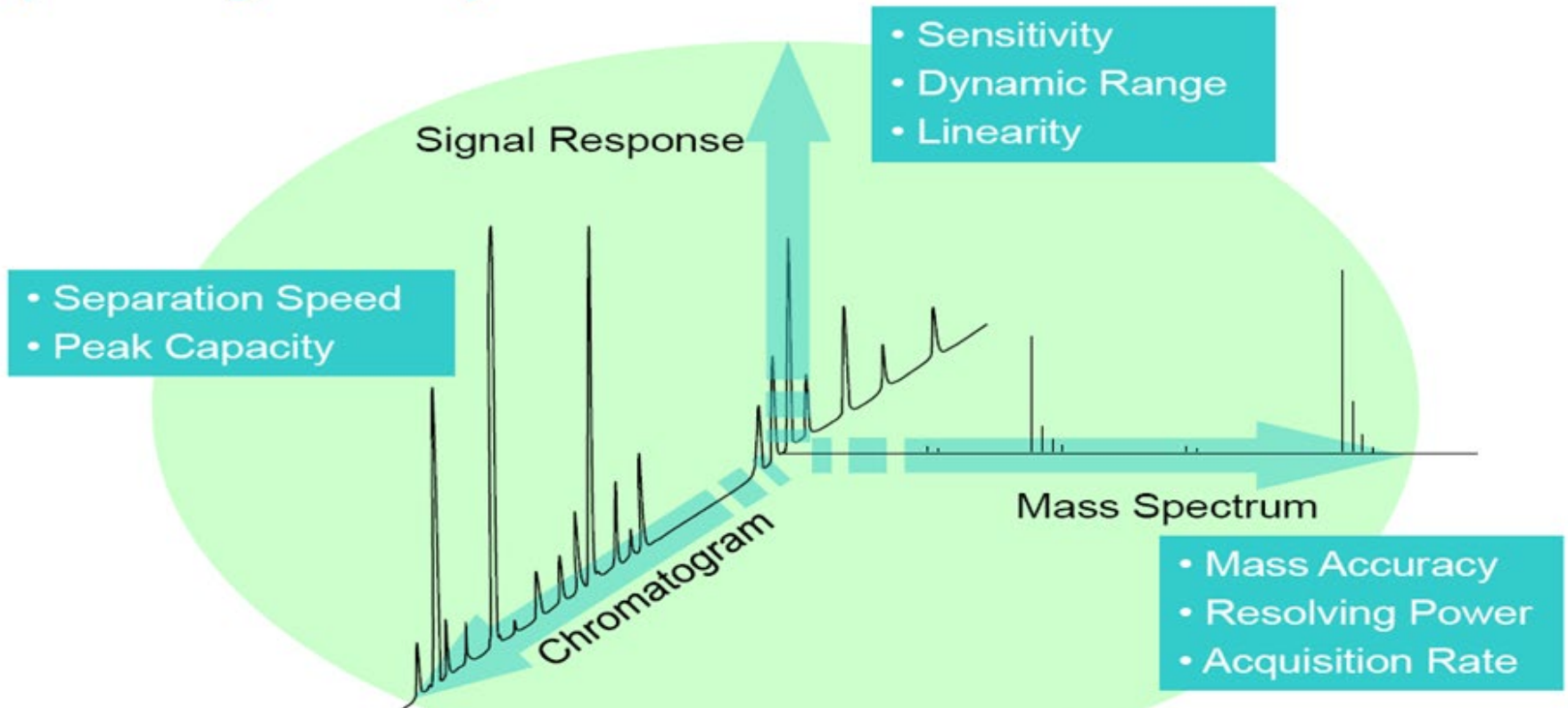
Good Regulatory Practices (GXP)

Good Regulatory Practices (GXP)

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

## Ultra High Definition

*Optimizing all Analytical Dimensions*



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

| 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