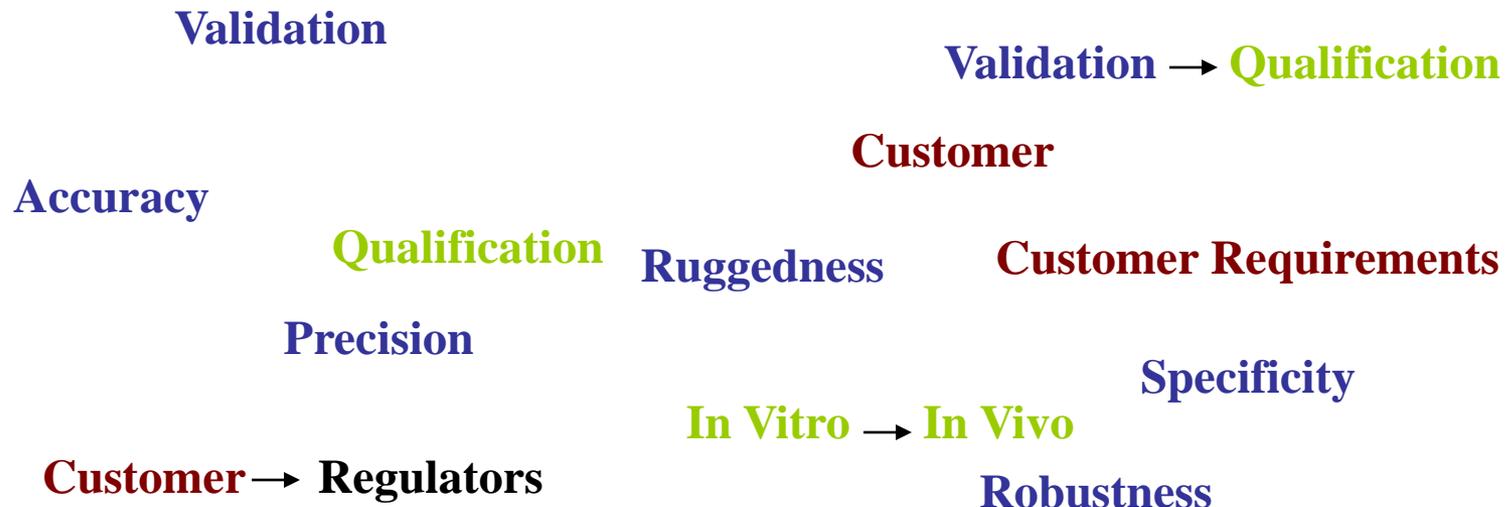


# Current Perspectives on Validation

- Working Definitions:
  - Validation is a documented evidence providing a high degree of assurance that a specific assay will consistently produce a result that meets its predetermined specifications
  - Qualification is a documented process that provides a high degree of assurance that the assay results support the intended use



# Current Perspectives on Validation

9:40-10:15 AM:

**Development and Validation of New Technologies for use in Drug Discovery and Toxicology**

*Christopher Austin, MD, NCATS/NIH*

10:15-10:35 AM:

**Break**

10:35-11:10 AM:

**Validation/Qualification Issues for Enabling Technologies for Drug Discovery**

*David Stresser, Ph.D., BD Biosciences*

11:10-11:50 AM:

**From Engineering Validation to Qualification of Biomarkers, an FDA Success Story**

*Federico Goodsaid, Ph.D., Vertex Pharmaceuticals*

11:50-12:50 PM:

**Reception-Lister Hill Lobby**