

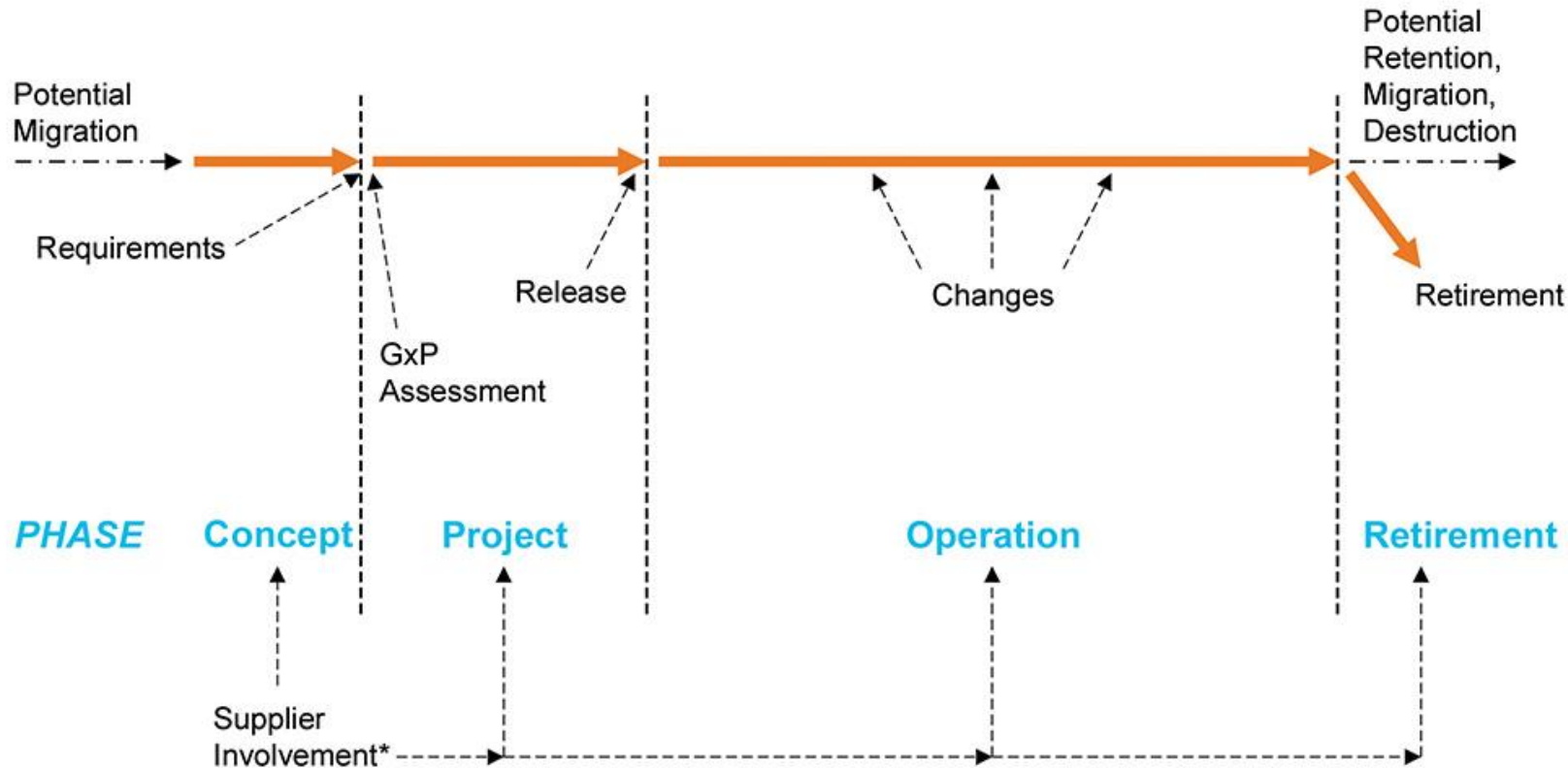
ASPECTOS CLAVE EN LOS PROYECTOS DE IMPLANTACION DE SISTEMAS EN ENTORNO FARMACÉUTICO



Juan Pedro Gallardo



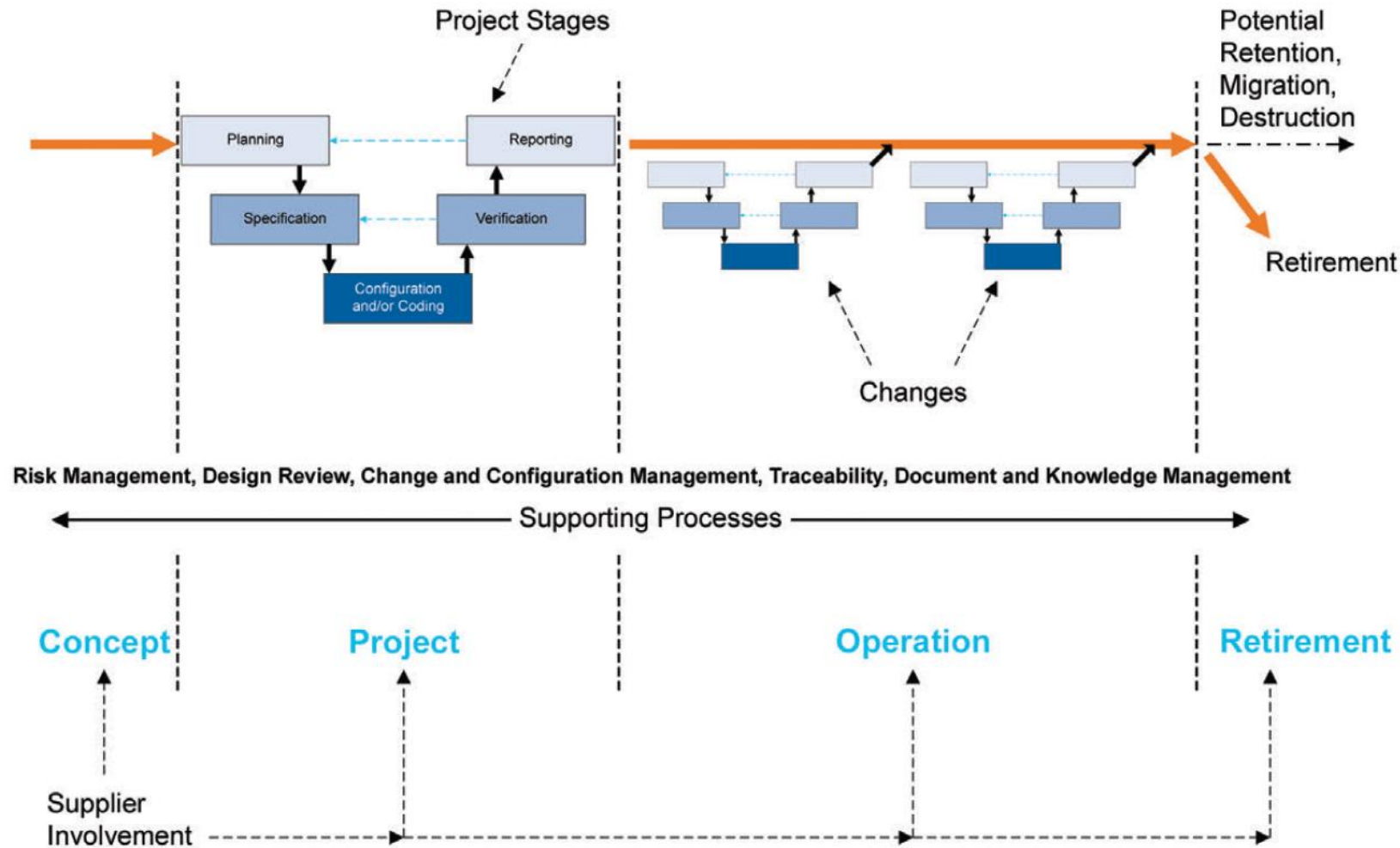
Ciclo de vida de los sistemas en Farma



- * - This could be a complex supply chain.
- Supplier may provide knowledge, experience, documentation, and services throughout life cycle.

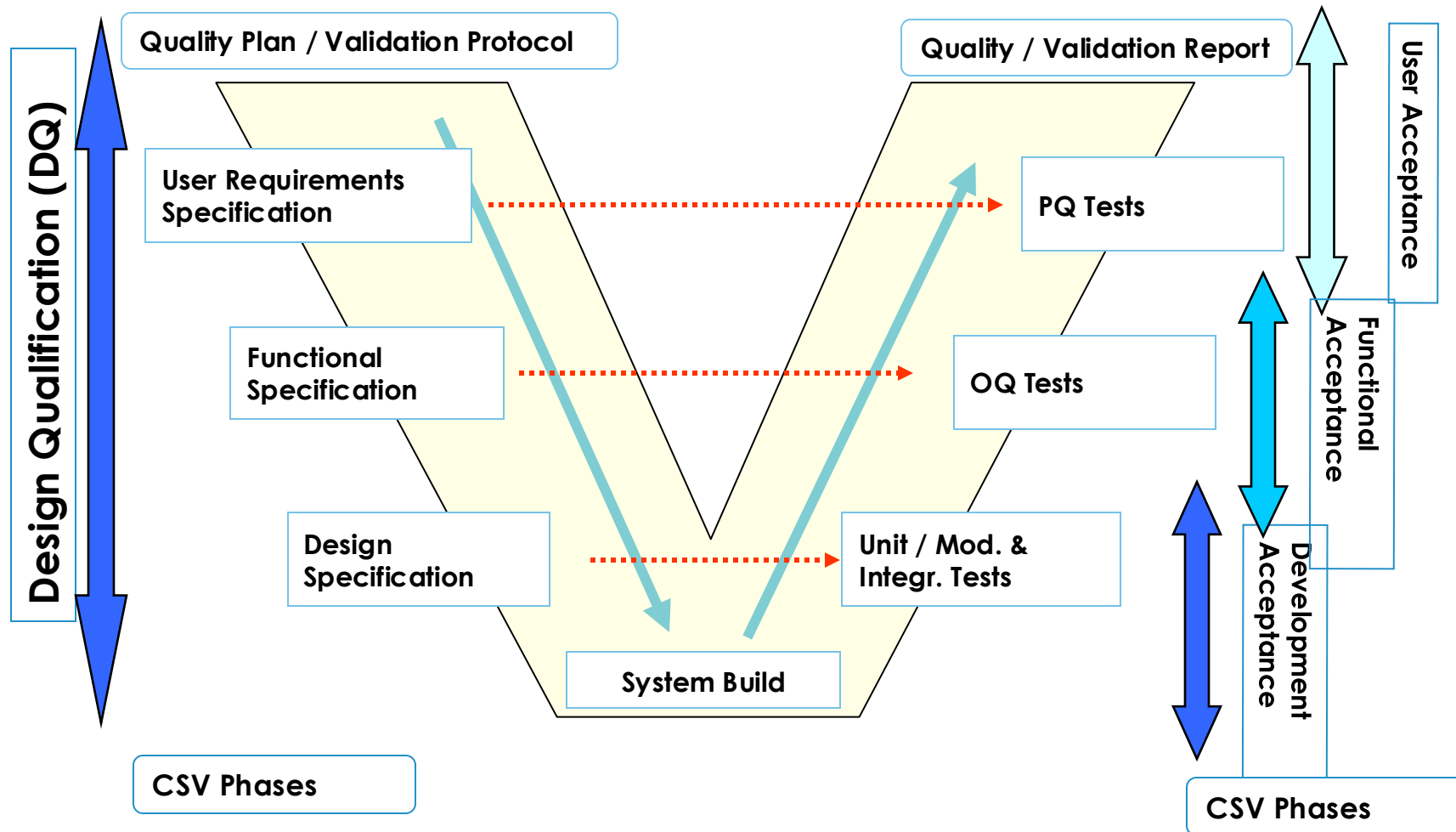
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Ciclo de vida de los sistemas en Farma



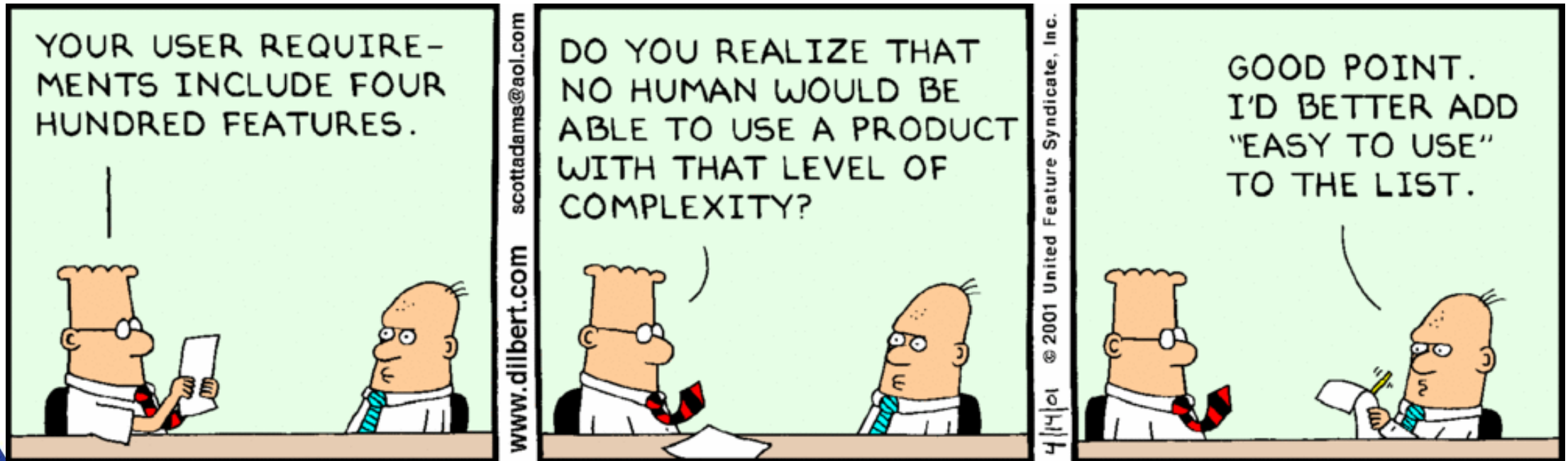
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Project Phase: VModel



User Requirements Specifications

Describen **qué debe hacer** el sistema



User Requirements Specifications

Describen **qué debe hacer** el sistema

Deben ser correctos

- Sin ambigüedades
- Completos
- Trazables

Deben ser coherentes

- No se deben contradecir entre ellos

Testeables

- Debe ser posible asegurar su cumplimiento

Completos

- Deben ser autoexplicativos

Deben estar priorizados

- Clasificación entre esenciales, opcionales y deseables

Compliance

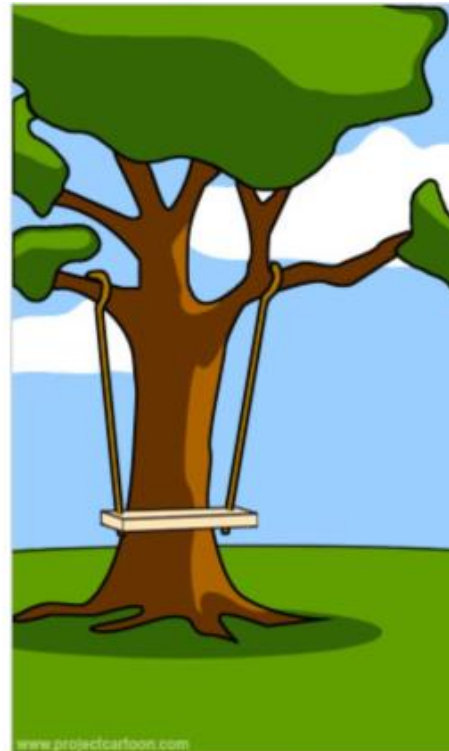
- Deben cumplir con el marco regulatorio

Especificaciones de diseño

Describen **cómo funcionará** el sistema



How it was explained



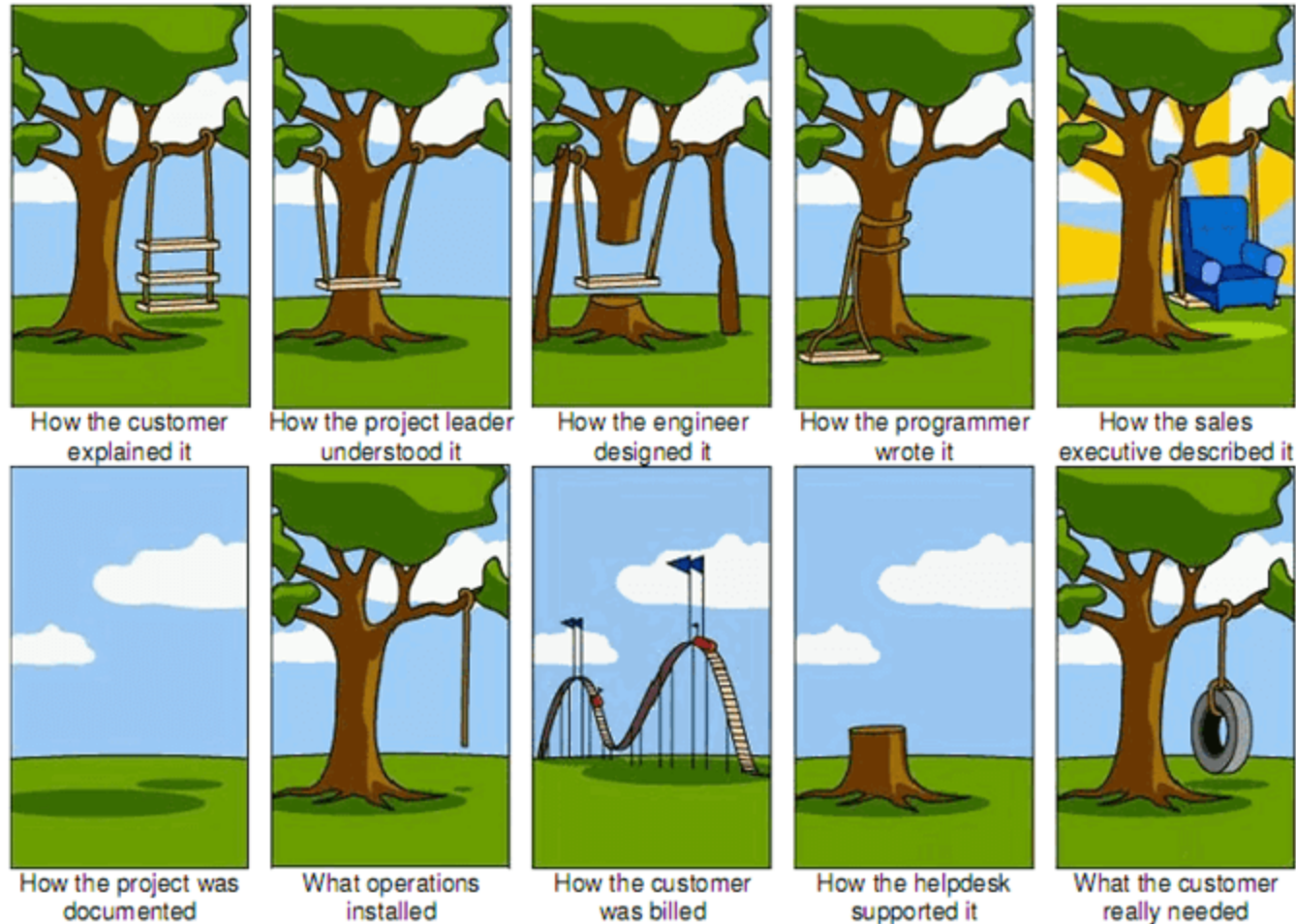
How it was designed



What was needed

Especificaciones de diseño

Describen **cómo funcionará** el sistema







Especificaciones de diseño

Describen **cómo funcionará** el sistema



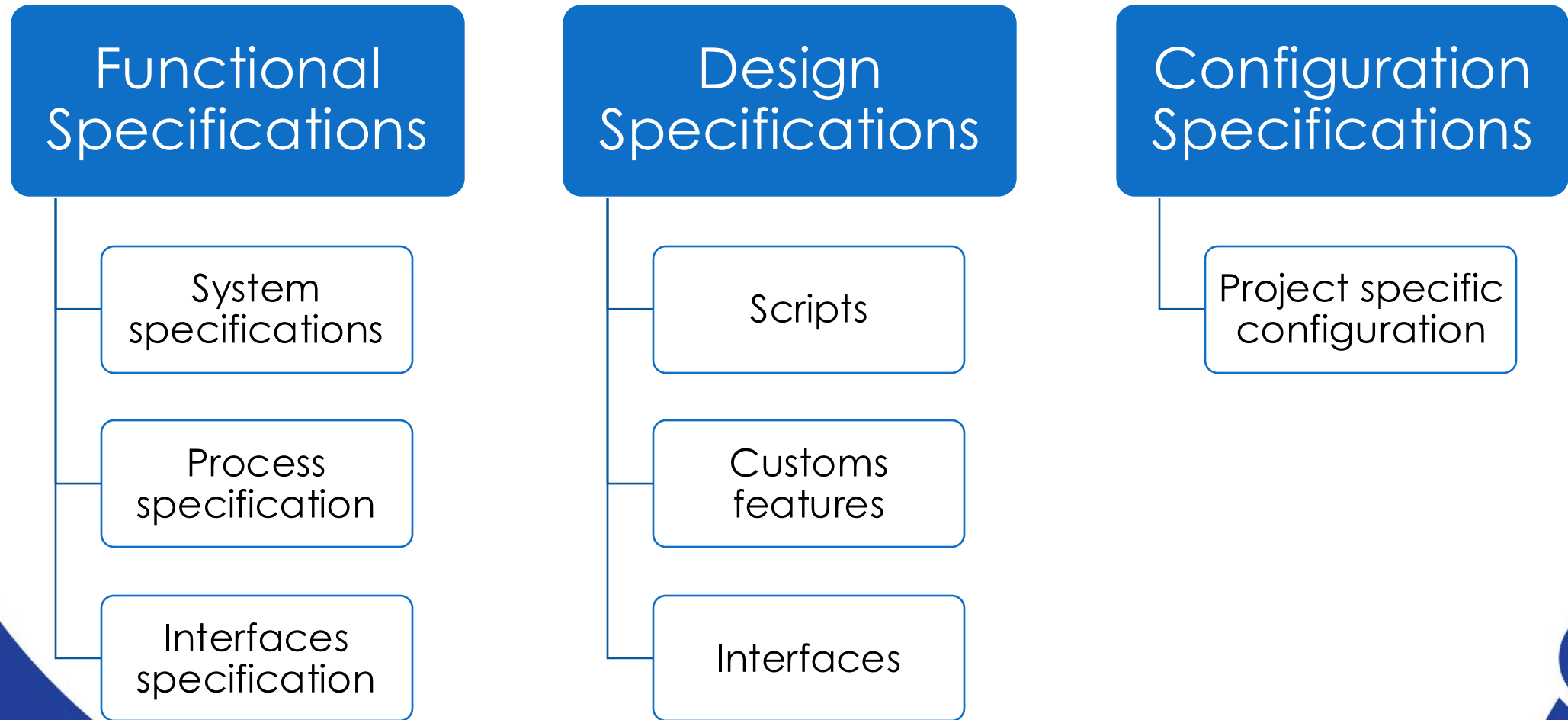
Especificaciones de diseño

Describen **cómo funcionará** el sistema

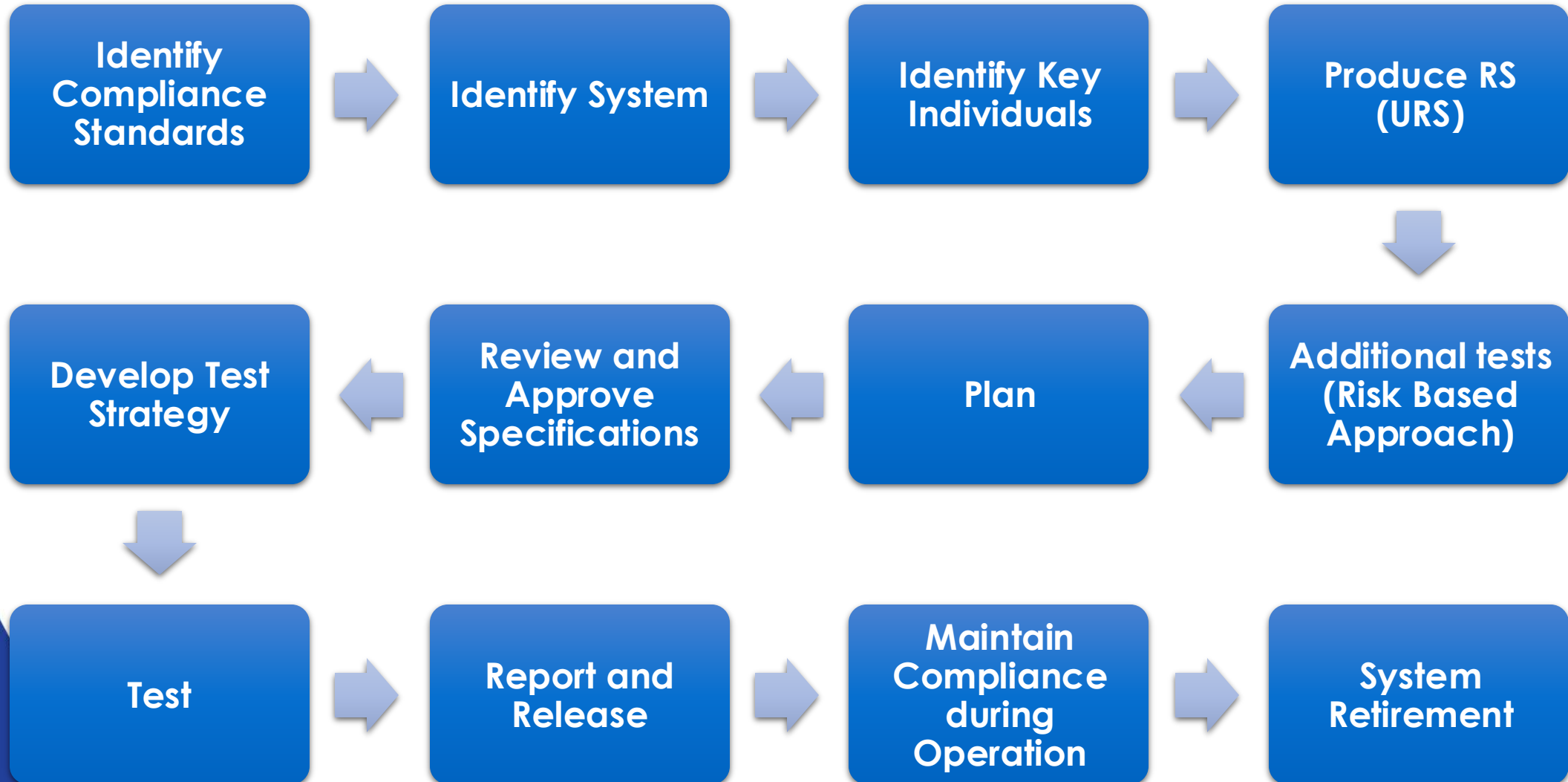


Especificaciones de diseño

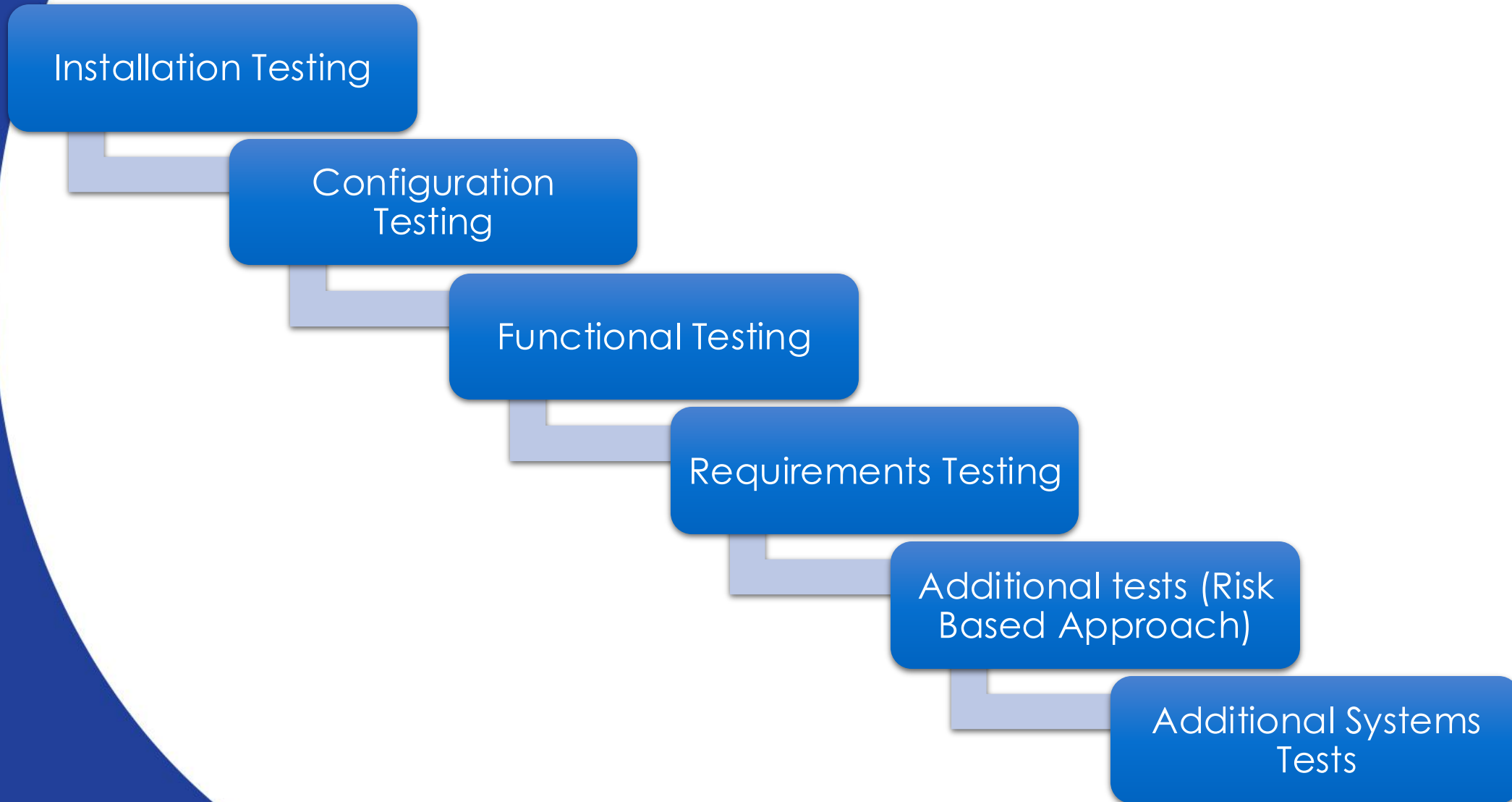
Describen **cómo funcionará** el sistema



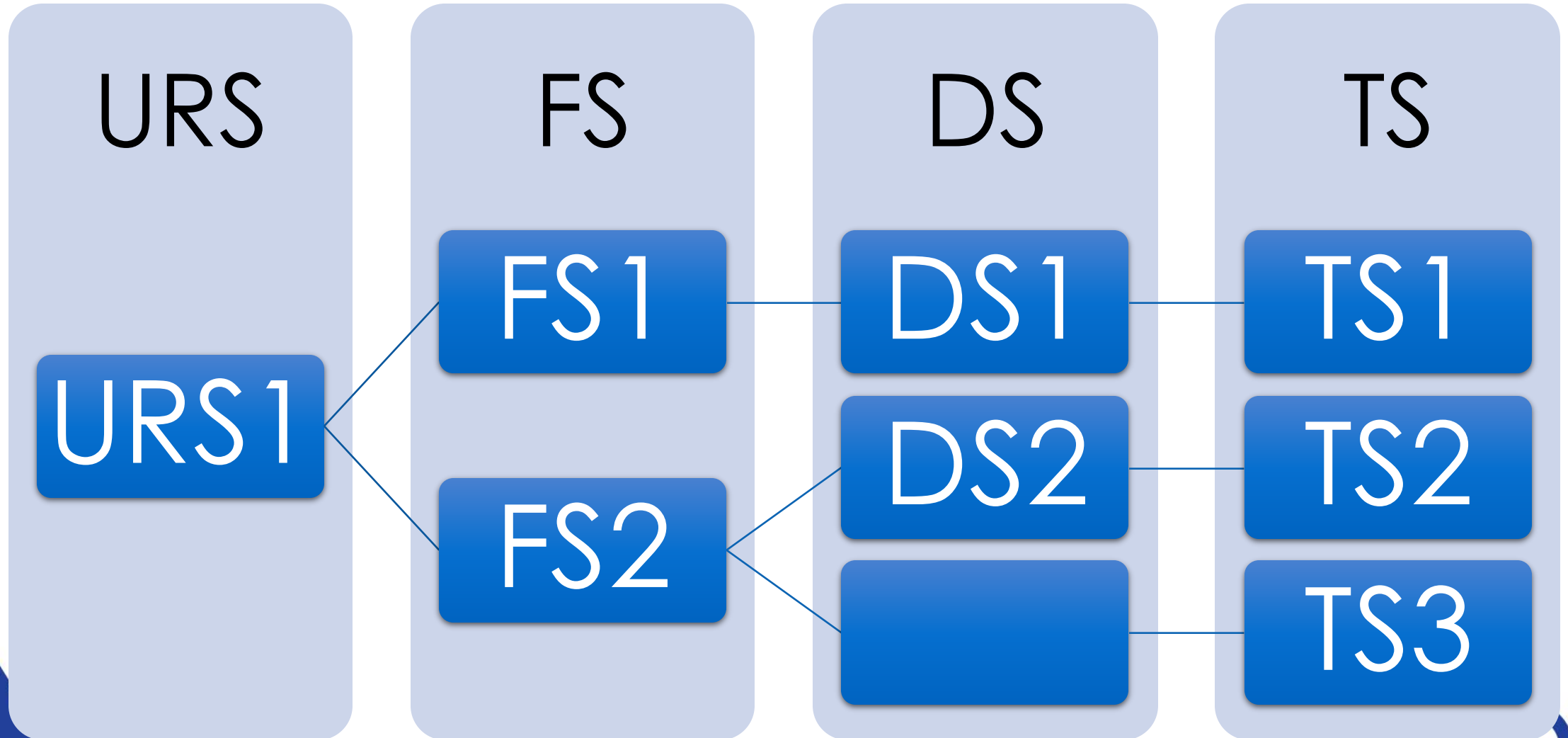
Estrategia de Verificación (según GAMP 5 Second Ed.)



Proceso de Verificación (según GAMP 5 Second Ed.)



Asegurar la Trazabilidad



Go-Live

Go-Live Preparation

- Document review (SOP's, Support agreement, ...)
- Backups and systems support
- Interfaces and Master Data
- Training
- Security



Post Go-Live support

- Business continuity
- 24x7 support service
- Continuous Improvement



Review by Exception (RBE)

Electronic Control Recipe

- Raw Materials
- Weigh and Dispense
- In-Process Inspections
- Operator Work Instructions
- Environment Monitoring and Control
- Process Monitoring and Control
- Product Inspection

Real Time Quality Assurance

- Occurs during Manufacturing Operations
- E-Monitoring EPR Data and Events
- Deviation Identification and Investigation
- Alarm Monitoring
- Event Monitoring
- In-Process QC Monitoring

E-Records



Review By
Exception



Real Time
Release



¿QUESTIONS?