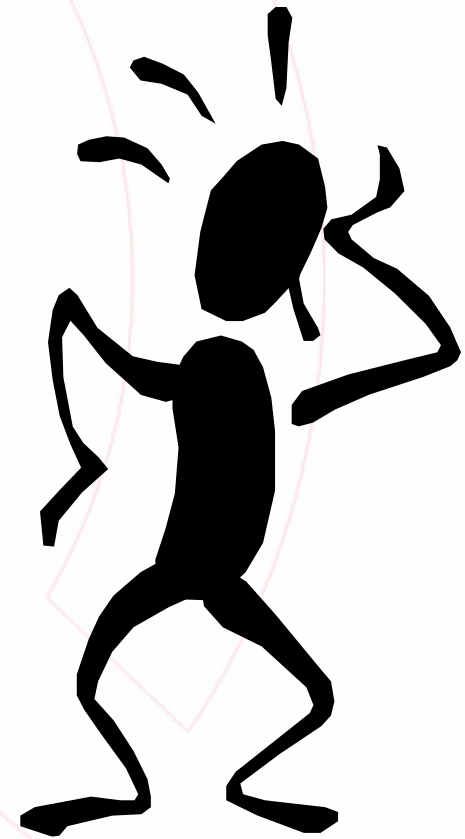




QUALITY SOURCE
by Blood Systems

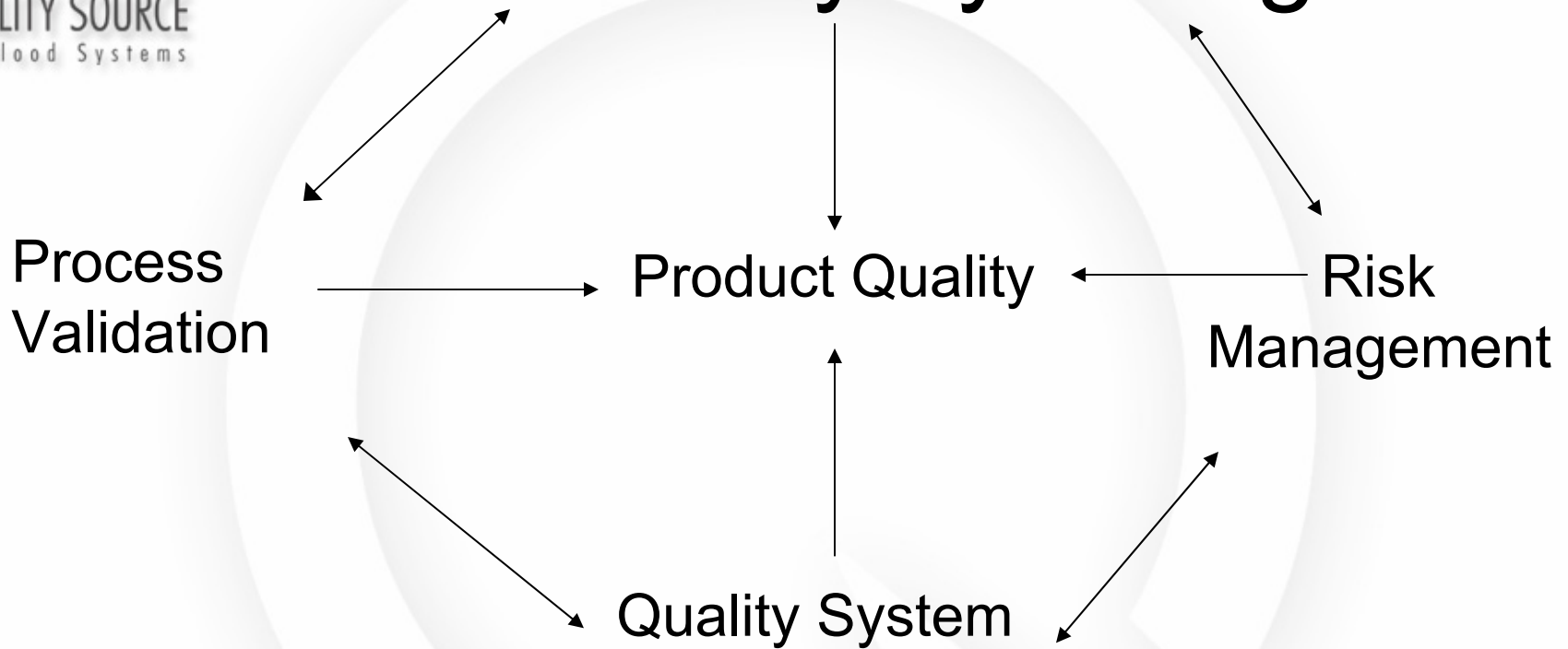
Process Control Validation



On Q – The Source for Quality Training



Quality by Design





Objectives

- Define Validation and the terms used in validation process
- Describe the elements of validation
- Differentiate between validation and verification/qualification.
- Define Prospective and Retrospective Validation
- Develop a Validation Plan



Why Validate?

- Required
- Ability to evaluate worst case scenarios
- Reduce errors
 - Decrease in cost, waste, recalls, rework, retesting, returned goods

Key Activity: Define Everything

- Define intended use
- Define system which achieves the intended use
- Identify risks and hazards associated with the use of the system
- Define test plan and test cases
- Functional requirements/specifications
- System requirements/spec



System Validation Protocols

- Minimum should include
 - ▶ description of function
 - ▶ steps to perform
 - ▶ equipment to use
 - ▶ methods to use
 - ▶ inputs from all sources
 - ▶ expected outputs and acceptance criteria