

# GAMP 5 Quality Risk Management

Perform initial **Risk Assessment**  
and Determine System Impact

1

2

Identify Functions with  
**Impact** on:

- Patient Safety
- Product Quality
- Data Integrity

Perform Functional  
**Risk Assessments** and  
Identify Controls

3

4

Implement and  
Verify **Appropriate Controls**

Review Risks and  
**Monitor Controls**

5

# Gamp 5 A Quality Risk Management Approach To Computer

**Kathleen Armour**



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