

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

Scott C. Dulebohn



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