VENDOR QUALIFICATION

Fran Rabe
Manager Quality Assurance
University of Minnesota
Molecular and Cellular Therapeutics

Molecular&Cellular Therapeutics
University of Minnesota

Vendor Qualification - Why

- Provides security to ensure product and service consistently meet requirements
- Required by FDA to ensure raw materials are of acceptable identity, quality and purity

Vendor Qualification – How?

- Define how, per your Standard Operating Procedures (SOPs)

Vendor Selection Preparation

- Determine material requirements (specifications)
- Evaluate regulatory requirements of manufacturer of the supply

  - Is FDA licensure of this type of vendor required?
- Define fee restrictions
- Determine service requirements
- Soft requirements

  - Use “green” manufacturing processes

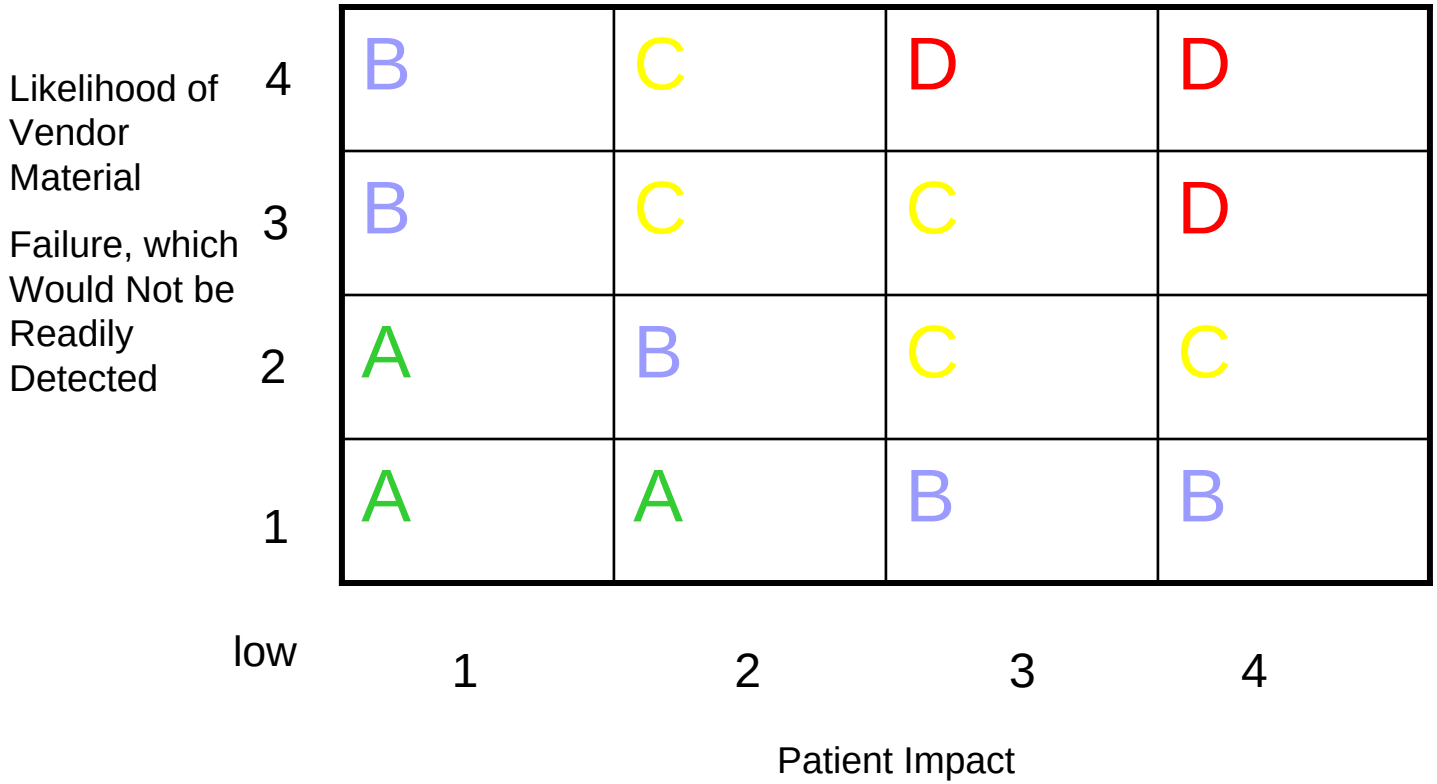
  - Good steward of the community

Vendor Qualification- How Thorough?

If the material fails:

- How would you quantify the risk to the patient?
  - low
  - medium
  - high
- How likely is the material supplied by this vendor to fail?
  - low
  - medium
  - high
- How likely are you to detect a material failure prior to use and after use?

Risk Matrix



A= Very good situation

B = Good situation

C = Critical situation

D = Catastrophic situation

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Risk Matrix

Patient risk grading is fairly straightforward

- Failure scale (one product/patient versus many)
- Detection of failure

Likelihood of Vendor Material Failure More Complex- Factors to Consider:

- Material's complexity
- Vendor longevity
- Vendor size
- Material is vendor's core business
- Word-of-mouth within the industry related to vendor performance
- Implemented quality systems
- ISO certified
- Good standing with FDA
- Supply historical integrity issues, not specific to this vendor, but across all vendors

Vendor Qualification Options

- On site audit
- Qualification by checklist
- Qualification by past performance

  - retrospective qualification
- No audit or checklist - Minimal impact material

Application of Risk Assessment

Define in your SOPs:

- D grade: require on-site vendor audit
- C grade: vendor checklist (comprehensive)
- B grade: vendor checklist
- A grade: no audit or vendor checklist

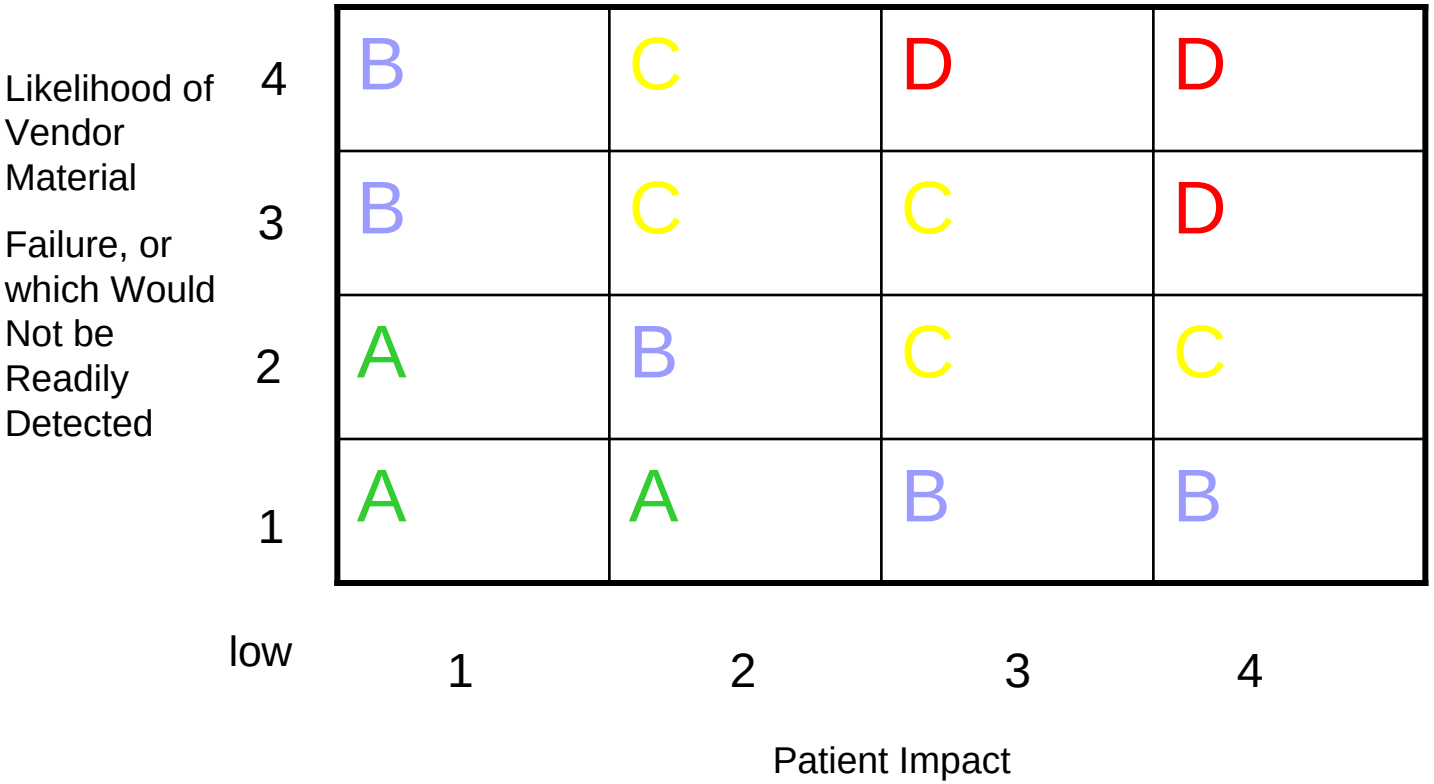
Define frequency within your SOP; (e.g., initially perform prior to vendor agreement and periodically)

Vendor Qualification – Case Scenario 1

Case Scenario 1 – Media Supplier

- Started using Media XYZ in 1999
- Manufacturing regulated our industry in 2005. Need documentation of vendor qualification
- Risk to patient is high if material fails
- Ability to detect failure is high
  - perform lot endotoxin and sterility before release of materials
- Retrospective qualification shows risk of material failure is low
  - Used this supplier for 6 years
  - Product quality and service record are flawless
  - Industry colleagues report favorable experiences

Risk Matrix



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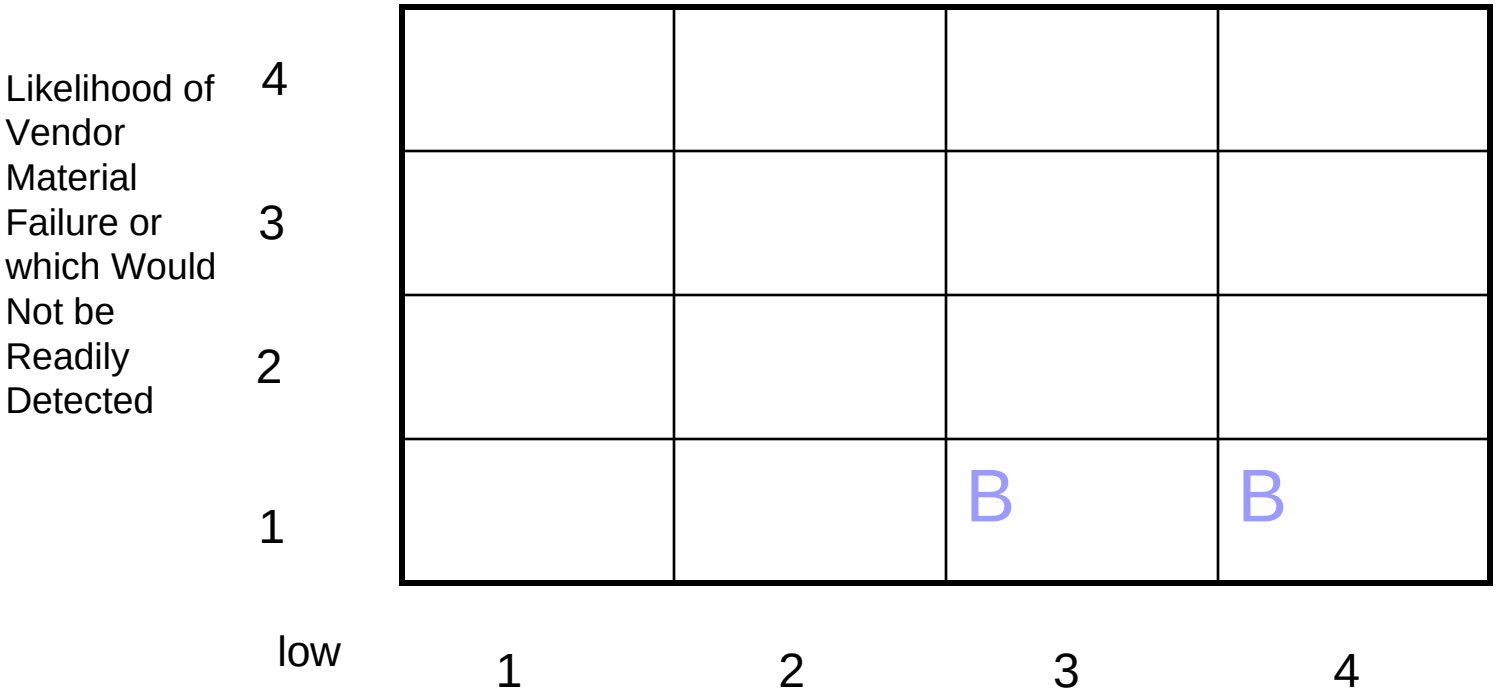
Risk Matrix- Scenario 1



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Case Scenario 1 Conclusion

Conclusion: This falls into B category

- B grade: vendor checklist

Provide continuity between products. If other similar medias fall into B, you may want guide your decision in this manner

Vendor Qualification – Case Scenario 2

Current vendor that performs donor infectious testing is doubling your fee. You are going to switch to another vendor 7/1/2009

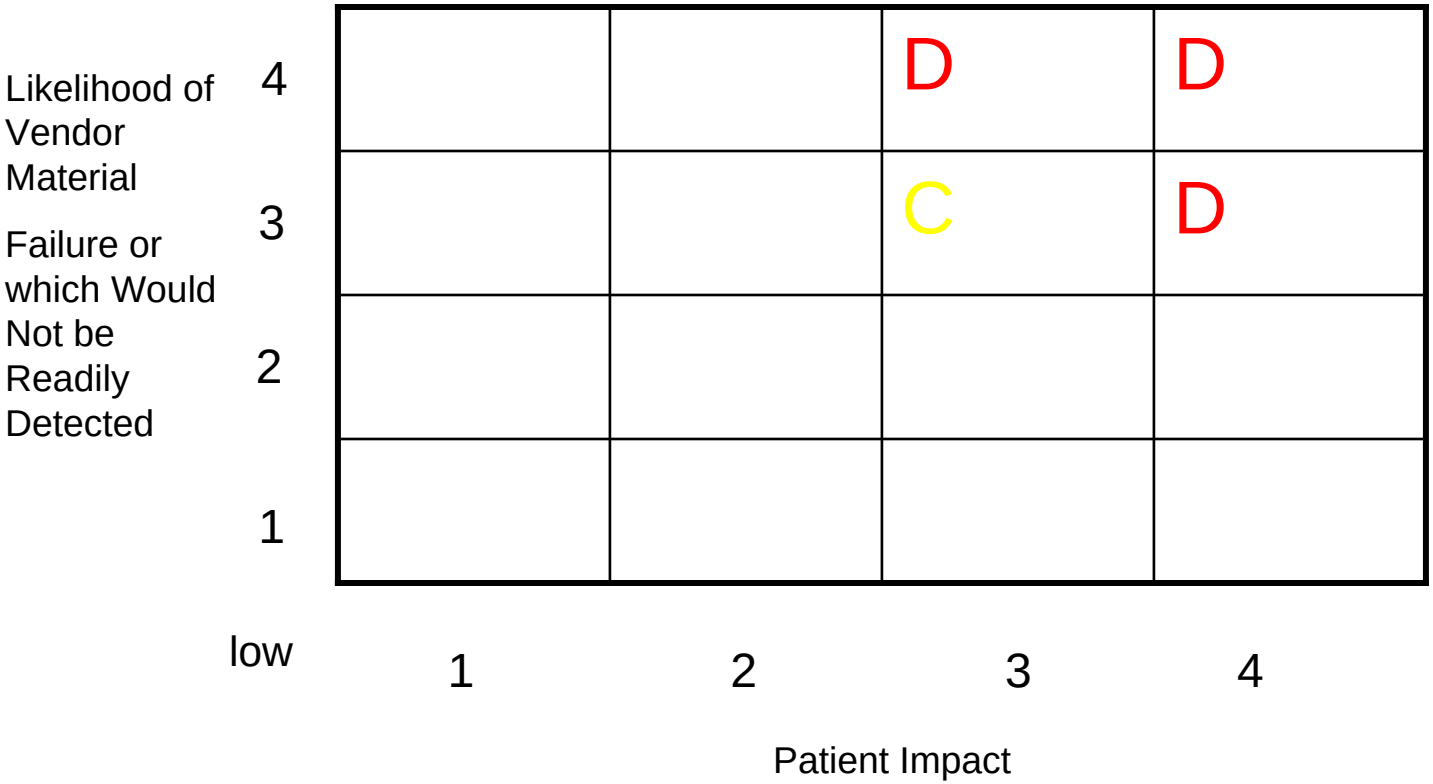
How are you going to qualify the new vendor?

Vendor Qualification – Case Scenario 2

Criteria to consider:

- Vendor failure can have negative patient impact (across many products). Failure could be “catastrophic”; category D
- Vendor failure would be difficult to detect (could go years before a patient infectious disease transmission is detected and reported)
- Failure could negatively impact my organizations’ reputation
- Failure could jeopardize standing with FDA
- Vendor has a good track record by word-of-mouth

Risk Matrix – Scenario 2



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Case Scenario 2 Conclusion

Conclusion: This falls into D or C category

- D grade: require on-site vendor audit
- C grade: vendor checklist (comprehensive)

On-Site Audit

Audit against your user product specifications our “user requirements”

In this case, the FDA regulations specifically state the requirements for this vendor

On-Site Infectious Disease Testing Facility

Audit against user/regulatory requirements

- CLIA certified or meets CMS requirements
- Registered as a FDA establishment (FDA Form 3356)
- Screening tests used, which have been cleared/approved by the FDA. Not diagnostic tests
- Time constraints of sample testing maintained
- Temperature constraints of samples maintained
- Pooled versus singlet used where appropriate

Audit against our service requirements

- Reports meet requirements
- Results provided in timely fashion