RISK-BASED TMF FOR LARGE AND SCALING BIOPHARMAS

Angela Faircloth, Lauren Garson, and Frank Lin
Veeva Vault Clinical Strategy

Determining How to Assess Risk

Embracing Risk-Based TMF Management

Standardize activities and drive efficiencies

Focus on activities most likely to reduce inspection findings

Factors Beyond Classification to Assess Risk Level

- **Regulatory trends**: Assess changing regulatory focus, such as increased scrutiny of audit trails
- **Trial phase:** Consider study phase → later phase studies likely have more critical documents
- **Study events:** Monitor for certain study events, like serious adverse events
- **Submission documents:** Assess submission records, as they are likely to be scrutinized more carefully
- **Quality issues:** Monitor for increase in quality issues from a certain study partner or region

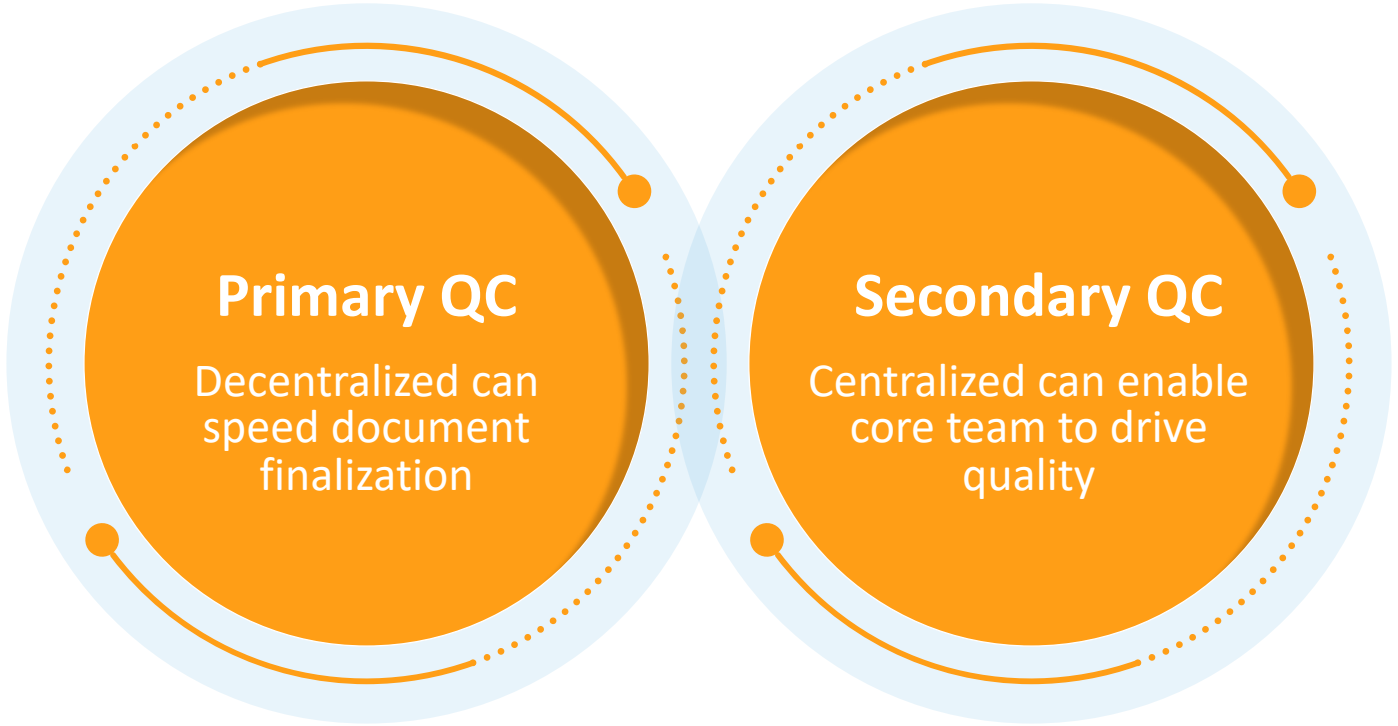
Group Discussion

- Do you currently use a risk-based approach? Why or why not? What challenges have you encountered?
- What criteria do you use to assess risk? Do you focus on classification, or do you incorporate other criteria?
- How do you measure/assess if your current risk-based approach is effective?
- What lessons have you learned in this process so far?
- What support do you want from your technology partners?

Deciding How to Approach QC Reviews

Trends in Document Processing and QC

Trends in Document Processing and QC



No clear standard operating model for primary and secondary QC

Group Discussion

- How do you define primary and secondary QC?
- Who owns each process at your organizations? How did you decide ownership?
- How do you approach risk in primary QC reviews?
- How do you approach risk in secondary QC reviews?
- What lessons or tips can you share from your experience?
- What support do you want from your technology partners?