Risk Based Approach to Scheduling External Facility Inspections

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Who Conducts Facility Inspections?

- Regulatory agencies
  - EPA
  - FDA
- Testing Facilities
- Sponsor companies

Why Conduct Facility Inspections?

- EPA and FDA
  - EPA GLP Standards 40 CFR Part 160.15 (a) and FDA GLP Standards FIFRA 21 CFR Part 58.15 (a)

    A testing facility shall permit an authorized employee or duly designated representative of EPA or FDA, at reasonable times and in a reasonable manner, to inspect the facility and to inspect (and in the case of records also to copy) all records and specimens required to be maintained regarding studies to which this part applies.

Why Conduct Facility Inspections (cont.)?

- Testing Facilities
  - EPA GLP Standards 40 CFR Part 160.35 and FDA GLP Standards FIFRA 21 CFR Part 58.35 (a)

    A testing facility shall have a QAU which shall be responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records and controls are in conformance with the regulations in this part.
- Sponsor companies
  - EPA GLP 40 CFR 160.12

    Sponsor must sign compliance statement
  - Business risks

What is a ‘Facility’?

- A physical location
  - Lab
  - Field site
  - Archives
- Records
  - Master schedule
  - SOPs
  - Training records
  - Organizational chart
  - Floor plans
- Systems
  - E-systems

What is the Scope of a Facility Inspections?

- Compliance of the facility as a whole
  - Personnel and staffing
  - Instruments/equipment
  - TCR substances, reagents, solutions
  - Test systems
  - Raw data generation/retention
  - Quality Assurance
  - SOPs
  - Electronic systems

Facility Inspection Program (pre-risk based)

- All facilities were treated equal
- Study Directors not invested

Steps toward Risk Based Implementation

- Awareness
- Alignment
- Action

Guidelines for Risk Assessment

- Q9 Quality Risk Management
  - ICH Guideline, *November 2005*
    - International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
    - FDA Guidance for Industry, *June 2006*

- Primarily designed for pharmaceutical product lifecycle.
  - Applicable and available to other industries

Define ‘Risk’

- ‘Risk’ is a combination of:
  - Probability of an occurrence of harm/failure
  - Severity of the harm/failure
  - Detectability of the harm/failure

Risk Based Implementation

- Identify facilities
- Identify/define risk assessment factors
- Score facilities
- Obtain Study Director/Monitor feedback
- Develop schedule
- Document

Assessment Criteria

- Facility inspection history
- Quality assessment
- ‘Profile’ of studies
- Compliance of studies

Risk Assessment Scoring

- Each facility was scored for each criteria
  - Low (1)
  - Medium (3)
  - High (9)
- Criteria scores were multiplied to give the Risk Priority Number (RPN)
- Relative RPNs determine risk

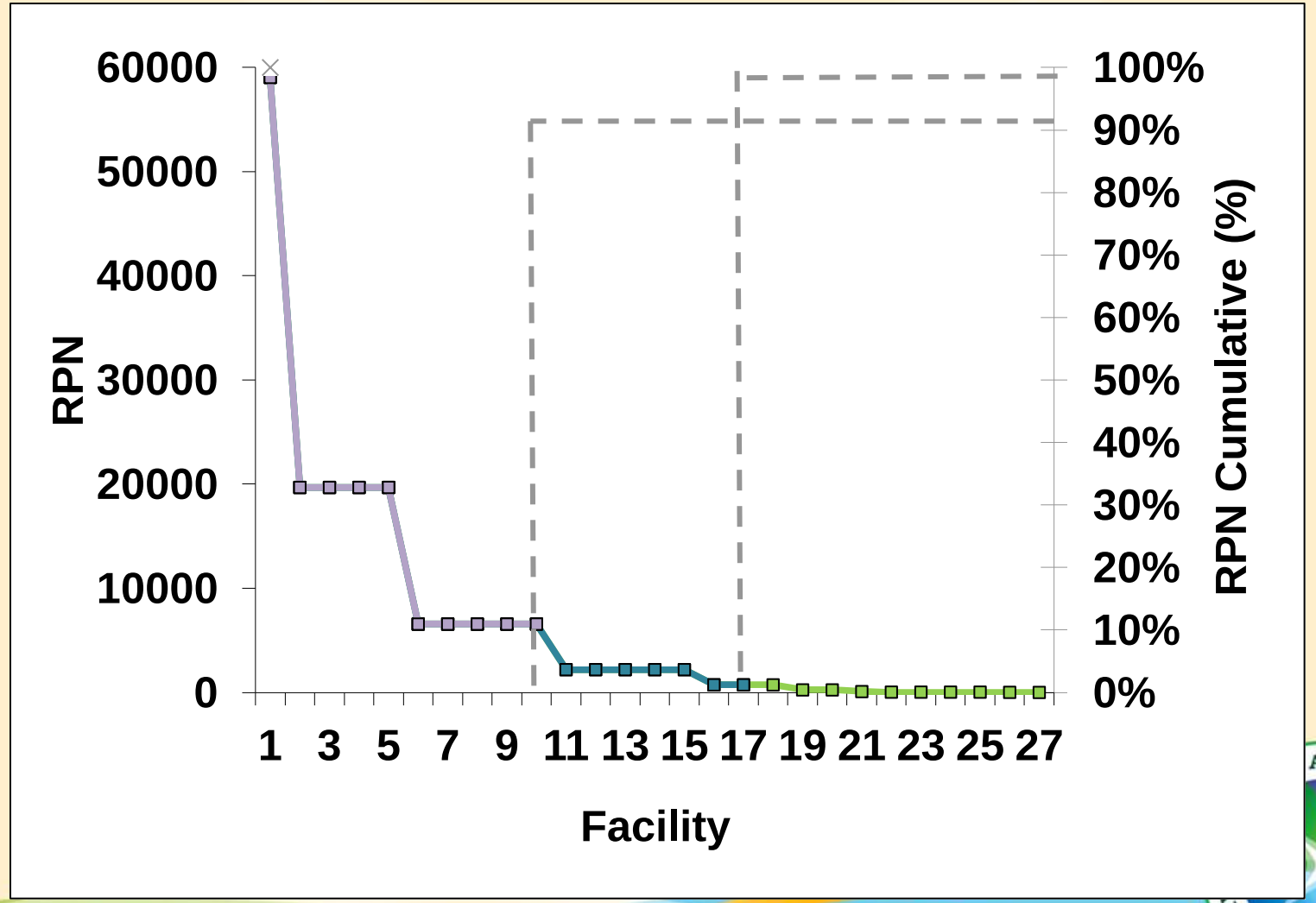
Example Scoring Sheet

Assessment Factors	Scoring	Determination of Scores
Inspection History	High (9)	Last Inspection: 3 years
	Medium (3)	Last Inspection: 2 years
	Low (1)	Last Inspection: 1 year
Quality Assessment History	High(9)	Last inspection had significant findings or QA concerns from data/report audits
	Medium (3)	GLP inspection with findings or Non-GLP inspection
	Low (1)	GLP inspection with no findings
Study Profile	High (9)	≥ 2studies and/or includes some non-routine and/or higher risk study type (e.g., Toxicology)
	Medium (3)	2 studies and/or routine and/or higher risk study type (e.g., Toxicology)
	Low (1)	1 study and/or routine and/or lower risk study type (e.g., method validation)
Compliance of Work	High (9)	GLP
	Medium (3)	N/A
	Low (1)	Non-GLP

Example Schedule

Facility Name	Risk Priority Number	Risk %
Joe Plumber, Inc.	65610	25.7%
Scientific Leaders, Inc.	65610	51.3%
Compliant Tech, Inc.	65610	77.0%
Acme, Inc.	21870	85.5%
Blues Brothers, LLC	810	97.4%
Good O' Boys, Inc.	810	97.7%
A Plus, Inc.	810	98.0%
Quality Results, Inc.	81	99.9%
Partner, LLC.	81	99.9%
CRO to the Sponsors, Inc.	3	100.0%

Example Risk Assessment Chart



Feedback

- Discuss risk assessment with Study Directors
- Identify Study Director concerns and/or business risks
- Move facilities up in risk when appropriate

Documentation

- SOP revisions
- Annual Risk Assessment Report
- Annual Inspection Schedule

Impact of Risk Based Scheduling

- Inspection frequency based on risk instead of on a routine basis
- Focused on higher risk facilities
- Enhanced communication with Study Directors/Monitors
  - Study Directors/Monitors more invested
  - Opportunity to travel with Study Directors/Monitors
    - Shared learnings
    - Reduced footprint at facility

Learnings

- Assessment criteria need ‘tweaking’
  - Inspection history
  - Study Profile

Other Applications

- Internal facility inspections
- Data audits

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Questions?

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