

Managing PAI and BIMO Inspection Readiness

This client is a biopharmaceutical company focused on discovering, acquiring, developing, and commercializing therapeutic medicines designed to alleviate patient suffering from debilitating diseases with significant unmet medical need.

In early 2020, the company was preparing for FDA PAI and BIMO inspections for their first commercial product. To support this initiative, the organization engaged Clarkston to provide project management services for inspection readiness activities. For Clarkston, this involved managing multiples action items lists to ensure all readiness activities were identified and completed in a timely manner.

Clarkston assisted in identifying the logistical processes to be used for remote inspections, and managed several mock inspections done by consultants. Additionally, Clarkston assisted in identifying all remediation activities from these inspections and monitored completion to ensure readiness for potential FDA inspections.

Life Sciences Case Study

PROJECT OVERVIEW

COMPANY:



A biopharmaceutical company

SERVICES:



Discovering and commercializing therapeutic medicines for patients with debilitating diseases

PRIMARY OBJECTIVES:

- Identify inspection readiness actions needed
- Manage timely completion of all inspection readiness activities
- Manage multiple fully remote mock inspections during the COVID 19 pandemic
- Provide back room support during the mock inspections
- Manage timelines and completion of all remediation activities from the mock inspections

RESOLUTION:

- Consolidated and summarized multiple Bioresearch Monitoring (BIMO) and Pre-Approval Inspections (PAI) action items lists to ensure all inspection readiness action items were included and completed in a timely manner.
- Worked with BIMO and PAI teams to identify and generate appropriate story boards and documentation for inspection readiness.
- Provided support during multiple practice runs and mock inspections to ensure that logistics for a fully remote inspection were identified and appropriate for use.

KEY BENEFITS:

- Over 500 inspection readiness activities were identified and completed in a timely manner
- Inspection support teams for both BIMO and PAI were trained and familiarized with logistics to be used during a fully remote inspection
- Provided back room and logistical support during the mock inspections, including documentation of finding and observations, and preparation of daily summaries for management.
- All identified remediation activities after mock inspections were tracked and completed prior to window for FDA inspections.

CLARKSTON

CONSULTING



Inspection readiness activities identified and completed in a timely manner.



Inspection support teams trained and familiarized with logistics to be used during a fully remote inspection.



All identified remediation activities tracked and completed prior to window for FDA inspections.

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