



# APERIO

CLINICAL OUTCOMES

## Inspection Readiness and Management Services

### Introduction

Development programs for novel drugs and biologics represent huge investments for sponsors with a remarkably high risk of failure - 96% for development programs as a whole, with a 90% failure rate during clinical development. Unfortunately, failures sometimes occur because of significant findings of noncompliance during an FDA GCP inspection - despite the IP demonstrating clinical efficacy and safety. A rigorous program for Inspection Readiness and Management can be cost-effective insurance against the late-stage failure of a clinical development program for any reason other than shortcomings in the Investigational Product itself.

### Inspection Readiness Experience

Aperio Clinical Outcomes has extensive experience in managing inspections for regulatory submissions and addressing the requirements of multiple regulatory agencies, including FDA, EMA, MHRA, BfArM and DEA. Tony Bumarch, VP Global Quality Assurance, has held senior QA roles for both sponsors and CROs and has been a part of more than 10 agency inspections for regulatory submissions. Experience of the Aperio QA team with inspections for regulatory submissions includes:

- **Inspection Readiness Overview and Assessment**
- **Inspection Readiness Planning and Training**
- **Trial Master File Audits**
- **Conducting Mock Inspections**
- **Inspection Management**

### Inspection Readiness Services



#### ADVISORY SERVICES

Do you have effective processes? Do you understand the steps and timelines involved? Do you have the resources and structure required to host an inspection?



#### INSPECTION READINESS SERVICES

Do you have an Inspection Readiness Plan? Are you prepared for a TMF audit? Do you have a BIMO Checklist? Are your sites and vendors ready for an audit?



#### INSPECTION MANAGEMENT SERVICES

Are you ready to arrange the logistics of an inspection? Are you prepared to host and manage the ready-room during the inspection? Do you have a plan for efficient handling of inspection questions and document requests?

## Inspection Readiness Service Offerings

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### Advisory Services

The Aperio Inspection Readiness and Management team advises sponsors on:

- **Effective processes for assessing inspection readiness**
- **Steps required to ensure inspection readiness**
- **Appropriate timelines**
- **The resources, processes and operational structure required to host an FDA inspection**

### Inspection Readiness Services

Aperio offers comprehensive inspection readiness services, including:

- **Development of an Inspection Readiness Plan based on program/study status**
- **Trial Master File (TMF) audit**
- **Development and annotation of a Bioresearch Monitoring (BIMO) Checklist and reviewing and addressing gaps**
- **Inspection training for sites, CRO and key vendors**

### Inspection Management Services

In addition to ensuring inspection readiness, the Aperio Inspection Readiness and Management team assists sponsors with management of FDA inspections, with services that may include:

- **Facilitating the FDA inspection process**
- **Managing the Ready Room for preparing interviewees**
- **Managing and tracking FDA requests to ensure timely and accurate responses**
- **Developing daily debriefs for distribution to management**
- **Ensuring all inspection requests are optimally addressed before the FDA inspector leaves the site**

## About Aperio Clinical Outcomes

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Aperio Clinical Outcomes provides full, customizable CRO services across multiple therapeutic areas, as well as specialized services in Strategic Resourcing, Quality Assurance and practical application of the latest Clinical Trial Technology. Aperio's team has an average of 17 years of industry experience and is dedicated to providing our partners with transparency and quality. In an industry flooded with data, metrics and technology, Aperio remains steadfastly focused on the most important part of the process: people.

*"Sponsor needs for achieving inspection readiness vary greatly, and we tailor our services accordingly. We may do anything from advising about steps required for inspection readiness all the way through providing comprehensive inspection preparation and management."*

**Tony Bumarch**  
Aperio VP, Global Quality Assurance



### For Further Information

To learn more or to discuss whether your Clinical Development Program is Inspection Ready, contact us at [info@aperioclinical.com](mailto:info@aperioclinical.com) or 888.448.2969.