DTPM

256-979-1533
888-516-0345
sales@DTPM.com
www.DTPM.com

YOUR CLIA / COLA CONSULTANTS - FOR THERMO FISHER CUSTOMERS ONLY

ASSURING YOUR LABORATORY'S SUCCESS IN TODAY'S REGULATORY ENVIRONMENT

CLIA, the Clinical Laboratory Improvement Amendments, and COLA, the laboratory accreditation program, enable laboratories to meet the high standards of today's regulatory requirements.

At DTPM, we offer experienced consultants and fast, dependable methods to bring your lab into compliance with CLIA and COLA. We keep you on track with proven protocols and procedures, including ongoing equipment calibration.

Our consultants are available to work side-by-side with your team to assure success in meeting quality standards for methods development, proficiency testing, quality control, patient test management, personnel qualifications, and more.

Contact us for more information on how we can help your lab with all of its regulatory compliance needs.

APPLICATION PROCESSING

We will file your CLIA application for you and assure that it is done correctly. Mistakes at this level can contribute to months of wasted time which translates into lost revenue.

LAB DIRECTORS

Our team of recruiters maintain a list of qualified laboratory directors for your lab. Finding qualified directors is vital toward getting your CLIA application filed and lab running.

POLICIES & PROCEDURES

We will provide you with your own personalized set of professional bound policies and procedures for your laboratory. We will assure that you are in complete compliance.

VALIDATION

DTPM consultants can assist you with validation of your chemistry analyzer and LCMS. We will assure that your lab director has reviewed and approved the validations and that they are available in your laboratory.

TECHNICAL SUPERVISORS

When you lab needs or is required to have an ongoing technical supervisor we will make sure you have the person you need. We will work with you on a monthly basis to assure that you are in compliance.

MOCK INSPECTION

Prior to your inspection we will be in your laboratory to perform a MOCK INSPECTION. We will assure you are ready and then will stand by your side during the official inspection process.

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9/2020

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DTPM OFFERS PACKAGES FOR HIGH AND MODERATE COMPLEXITY

HIGH COMPLEXITY PACKAGES

CLIA TURNKEY PACKAGE:

High Complexity Lab Director.

High Complexity Technical Supervisor to Perform Data Review.

Filing CLIA application and assistance with CLIA compliance and COLA accreditation.

CLIA Laboratory Audit Support.

Assistance with Proficiency Testing for regulated and non-regulated analytes.

Creation and maintenance of validation manuals.

Verification of Performance Specifications for all Test Methods (Accuracy, Precision, Specificity).

Annual Safety Training & Competency Training with personnel required by CLIA and COLA.

Providing DTPM Representative On-site During all Inspections.

Ongoing monitoring of quality assurance (QA) and quality control (QC).

24/7 Technical support.

Description:	Quantity:	Cost:
CLIA Turnkey Package	Monthly	$2,500

INITIAL START UP PACKAGE:

Filing CLIA application and assistance with COLA accreditation.

Document Specificity of all analytes, Linearity of Calibration, Reportable Ranges, and Defining Limit of Detection.

Verification of Performance Specifications for all Test Methods (Accuracy, Precision, Specificity).

General Laboratory Procedures, Lab Equipment Procedures, Operational Procedures, and Quality Assurance / Quality Control Procedures.

Written Personnel Policies with Job Descriptions.

Description:	Quantity:	Cost:
Initial Start Up Package	One Time	$1,500

MODERATE

COMPLEXITY ADJUSTMENT PACKAGE:

File an adjustment to your current CLIA from High Complexity to Moderate Complexity.

Adjust Policy and Procedures as needed.

Technical Consultant to Perform Data Review.

BENEFITS OF MODERATE COMPLEXITY:

The physician or other qualified personnel with an M.S. or B.S. can potentially become the Laboratory Director of the laboratory with the correct criteria.

The Testing Personnel can potentially be an existing employee with a high school diploma or equivalent with proper documentation of training.

Description:	Quantity:	Cost:
Complexity Adjustment Package	One Time	$1,500

Description:	Quantity:	Cost:
Ongoing Coverage	Monthly	$500

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