PHARMACEUTICAL COMPLIANCE
REGULATORY REQUIREMENTS
&
SUPPLY CHAIN SECURITY AUDITS
(Industry · Pharmacies · Licensees)

The MPM Group (MPM) offers expert regulatory, compliance and investigative services for all pharmaceutical industry issues concerning criminal, civil, diversion and regulatory matters relating to Title 21 of the United States Code (USC) as well as Title 21 of the Code of Federal Regulations (CFR). Additionally, MPM personnel can provide expert criminal investigative services, *Discovery* analysis and subject expert testimony in cases targeting licensed medical personnel accused of improperly prescribing (or most commonly, over-prescribing) certain Schedule II and Schedule III medications – usually, in violation of Title 21, USC and/or Title 21, CFR.

INDUSTRY

MPM provides a cadre of former Drug Enforcement Administration (DEA) Special Agents (Series 1811) and DEA Diversion Investigators (Series 1810) who are collectively; court adjudicated experts in compliance/regulatory audits, trademark and *counterfeit* drug violations, pre/post civil fine violations and invaluable with those occasional criminal prosecutions.

In addition to assisting in establishing an effective and compliant Standard Operating Procedure (SOP), MPM strongly urges their pharmaceutical industry Clients to be proactive rather than reactive to Food and Drug Administration (FDA) *483 Letters*. Notably, the FDA issued more than 3,500 *483 Letters* in both 2018 and 2019. Usually, the *483 Letter* simply serves as a "heads-up" that we urge our Clients to take full-advantage of – especially, by making appropriate corrective action and responding to the FDA in a timely matter. Succinctly, show the FDA and the DEA that they are capable and willing to be cooperative and compliant with industry requirements and standards.

Routine MPM proactive inspections usually uncover the following issues - as will most FDA inspections.

- **Lack of Written Procedures or Failure to Follow Written Procedures as well as a Lack of Training in Same** [See Title 21, CFR, §211.22(d)]

- **Failures in Laboratory Controls** [See Title 21, CFR, §211.160(b)]

- **Faulty Production Records & Reviews** [See Title 21, CFR, §211.192]

- **Absence of Written Procedures for Production and Process Controls** [See Title 21, CFR, §211.100(a)]

- **Improper Cleaning/Sanitizing/Maintenance of Facility & Work Areas** [See Title 21, CFR, §211.67(a)]

[MPM Clients based in the State of New Jersey are also directed to Form EB-08, *Board of Pharmacy Library Compliance Checklist* pursuant to N.J.S.A. 45:14-48a (10) and N.J.A.C. 13:39-5.8(a)1]

SUPPLY CHAIN SECURITY AUDITING

Select MPM personnel are experienced in assisting their Clients with Supply Chain Security Audits (**SCSA**) at their primary facility, any satellite facilities, or as part of the Client's Third-Party Risk Management (**TPRM**) review process anywhere throughout the free-world. MPM Audit Programs not only include the scheduling and execution of audits, but more importantly, **CAPA** life-cycle management. Any **SCSA** can be accomplished in-person and/or virtually, depending on the specific situation at any given facility. Specifics of any Security Audit will be discussed and agreed upon beforehand on a case-by-case basis.

PHARMACIES

MPM Diversion personnel emphasize the following for licensed pharmacies and will assist Pharmacy Clients in establishing an effective compliance program:

- Establish an SOP for receiving and maintaining ***DOCUMENTATION***, which is a core component of pharmacy compliance. In fact, an inability to produce records to confirm their compliance can have serious consequences for any licensed independent or corporate pharmacy owner.

- Maintain a constant "vigil" on regulation changes and/or amendments. Make sure you are current on the ever-changing policies and make sure your reference material is up-to-date as well.

- Make sure your employees are properly trained in the current regulations as well. Ensure they are up-to-date on changes and provide them with access to up-to-date reference material as well as educational websites at the FDA and the DEA. MPM recommends mandatory and regularly scheduled "In-Service" training seminars for all pharmacy staff members.

- MPM recommends that our pharmacy Clients establish and maintain a "shared resource" of up-to-date regulations that authorized staff members can refer to via office computers or gain access through a cloud-based program that offers real-time file sharing. An up-to-date file-sharing database will help keep senior management, as well as support staff, more efficient and complaint in their day-to-day activities.

LICENSEES

Licensed medical practitioners, such as physicians, nurse practitioners, and, in some cases, physician assistants ("*Licensee*") are authorized under the Controlled Substance Act (CSA) to prescribe controlled substances if they are properly registered with the Attorney General of the United States. [See Title 21, USC, §822(b) and Title 21, CFR, §1306.03]

However, of late, hardly a day passes by that the public doesn't read about a *Licensee* being arrested for illegal distribution (usually, via illegal prescriptions) of Schedule II opioid based pain medication, most common being Oxycodone, or a derivative thereof. Subsequent to their arrest, the *Licensee* will soon learn that the government is mostly unforgiving in these matters and the punishment for their offense is usually staggering depending on the type and number of pills dispensed.

MPM litigation support investigators have had the unique opportunity to prepare criminal cases and testify as subject experts on both sides of the isle in federal and/or state courtrooms. Succinctly, as extremely experienced, albeit objective, criminal investigators, with a unique expertise in these types of "pill factory" investigations, MPM investigators are well-known for consistently extracting either incriminating or exculpatory evidence from any case that they are engaged to examine. Consequently, depending on case specifics, MPM subject experts have been retained by both the prosecution and/or defense counsel to offer their considerable expertise in these types of criminal matters.

WHY MPM?

The MPM Group's expertise in this complex industry is uniquely positioned to offer and provide our clients with the most experienced and competent support available.

In sum, MPM offers a *one-stop* industry resource for those clients seeking to be compliant with federal and state pharmaceutical regulations and want to do so in an effective, proven and cost-efficient manner.

For more information on specific programs and MPM's myriad capabilities, please feel free to contact us at **pharma@thempmgroup.com.**