PLIANCED

REGULATORY COMPLIANCE
MASTER PROGRAMS

Masters Program in GMPS Across The Phases Of Development

MASTERS PROGRAM IN GMPS ACROSS THE PHASES OF DEVELOPMENT

Duration	: 4 weeks	Hours	: 9 hours
No of modules	: 4 modules	CEU	: 9
Course fees	:	Mode of delivery	: Online

Regulatory compliance is increasingly visible in healthcare compliance, clinical research compliance, and in quality and regulatory industries, including pharmaceutical, life sciences, food, and medical device industries.

Plianced brings Master programs, which allow learners to attend live classes, complete assignments at their convenience.

ABOUT THE PROGRAM:

Early clinical trials are conducted to establish the initial safety of a drug. The studies are generally in a small number of healthy subjects and use lower or ranging doses of the drug product. Therefore, only small amounts of investigational material are required. In-order to not undertake substantial costs and to reduce regulatory burden during these early stages, the FDA has established guidelines to allow early-stage investigational products to be manufactured under “phase 1 GMPs,” allowing flexibility in some of the rigorous, expensive, and time-consuming requirements. As clinical development progresses, evolving into “phase 2 GMPs” and into commercialization with a methodical and comprehensive planned approach can save substantial time and expense.

This master program will include a detailed review of the current regulations as must be followed for commercialization as well as guidance documents with the flexibility in the interpretation of the regulations for earlier stages of manufacturing in compliance with GMPs to support early clinical trials.

Regulatory strategies, logistical considerations, and GMP-staging plans, options and alternatives, including raw material selection and receipt, vendor selection and management, stability programs, packaging and labelling, SOPs, documentation requirements, and validation will be discussed and explored through interpretations and case study examples.

PROGRAM OBJECTIVES:

Employ strategies within your company to save time and money in advancing clinical development.

This master program will provide the information and tools that you need to understand different baseline GMP requirements for each stage of development; beginning with needs for IND submission and phase 1 studies, progressing to phase 2, phase 3, NDA/BLA submission, and commercialization.

Options to explore and considerations for each will be discussed so that you have tools to develop and implement strategies for your organization using a phase-specific staging program of GMP requirements.

LEARNING METHODOLOGY:

Topic	Delivery mode	Presented By	Date	Time	Duration
Module 1: Overall drug development and GMP timing	Live class	Plianced Expert	3rd June 2020	12.00 pm ET	2 hrs
Q&A Session					15 mins
Module 2: GMP regulations and interpretation for early stages Part 1 Q&A Session	Live class	Plianced Expert	10th June 2020	12.00 pm ET	2 hrs
Q&A Session					15 mins
Module 3: GMP regulations and interpretation for early stages Part 2	Live class	Plianced Expert	17th June 2020	12.00 pm ET	2 hrs
Q&A Session					15 mins
Module 4: Evolving processes to commercialization	Live class	Plianced Expert	24th June 2020	12.00 pm ET	2 hrs
Q&A Session					15 mins
Online Assessment Final assessment and certificate	Online test				30 mins

PROGRAM FEATURES:

- Online course delivery – Live instructor-led training delivered by top industry experts
- Question session after every session
- Unlimited access to learning videos in case you miss the live classroom session
- Softcopy of learning materials
- Assessment at the end of course with CCU Certificate.
- Lifetime access to the learning platform with hundreds of courses and 1-on-1 access to experts.

DETAIL COURSE CONTENT:

Module 1: Overall drug development and GMP timing	- Planning for the IND - Gaining feedback on GMP plans - Resource and product consideration in planning - Quality Unit and oversight - General GMP considerations for every stage/phase
Module 2: GMP regulations and interpretation for early stages Part 1	- Facility - Personnel - Equipment - SOPs - Documentation
Module 3: GMP regulations and interpretation for early stages Part 2	- Vendor selection, oversight, and management - Quality agreements and contracts - Auditing - Complaint handling - Change control - Investigations - SOPs internally and externally - Record review and batch release - Packaging and labeling - Updating the IND
Module 4: Evolving processes to commercialization	- Quality unit roles and responsibilities - Facility updates Change control - Preparing for the NDA/BLA - Validation plan - Master batch record - Electronic data collection - Packaging and labeling - Distribution - Instructions for use, storage, and handling
Online Assessment	Final assessment and CCU certificate

The following topics will be discussed to provide the foundation and basis for advancing drugs into clinical development from research and providing required information to the FDA regarding these products.

- Moving a Product out of R&D
- CMC Requirements for an IND Study and commercial
- Good Manufacturing Practices: Basics for Beginners
- Raw Material Management

Specifics topics include:

- Issues with research grade material used for laboratory and non-clinical testing
- Optimizing manufacturing processes
- Raw material requirements and process development
- Assessing scalability of manufacturing
- Planning the CMC for a potential IND
- Study Essential elements of the CMC section of an IND
- Characterization of the active ingredient and finished product
- Various kinds of products: drugs, biologics, botanicals, diagnostics, medical device
- Manufacturing facility personnel equipment and requirements
- Core principles of GMP regulatory requirements for all different products… drugs to medical devices
- Customizing regulatory compliance to a given product
- Role of discussions with the FDA
- Planning for the early stage with an eye toward large scale manufacturing
- Vendor management
- Raw material handling issues for early-stage products
- Manufacturing step development

The following topics will be discussed to provide the requirements for early-stage products of different types and for vendor selection and management.

- The scope of the FDA guidance documents
- Acceptable practices and tips
- GMP requirements for exploratory clinical studies
- Specific requirements for drugs, biologics, and combination products
- Specific issues for various kinds of combination products
- Combination products with one or more new components
- CMC issues for 505(b)(2) products
- GMP and QSR: which to follow for a combination product
- Introduction to process validation for early-stage manufacturers
- Step by step introductions for process validation
- Process validation reports and other documentation
- Developing SOPs based on validation processes
- Logistics of using contract manufacturing organizations for early-stage products
- Pilot scale manufacturing requirements GMP-grade and non-GMP grade manufacturing
- Benefits and challenges with using local and international vendors