Different requirements for Phase I Investigational Drug Products (ntz)

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Organizer : NYMT

Venue :

Location : Four Points by Sheraton Boston Logan Airport Revere407 Squire RoadRevere, MA 02151United States,
Boston, MA, US, ZIP: 02128

Different requirements for Phase I Investigational Drug Products: which GMPs apply since most Phase I drugs are exempt from full GMP requirements and what IND data requirements are necessary as a result?

In January 2006, FDA issued a final rule which specified that most pharmaceutical products (including biologics) produced for use in Phase I clinical trial studies were exempted from complying with GMP requirements, as defined in 21 CFR Part 211 under 21 CFR 210.2(c). Section 501(a)(2)(B) of the FD&C Act requires drugs, including IND products, to comply with cGMPs or if they are not manufactured in compliance with cGMPs, they are deemed adulterated. Based on this statutory requirement for manufacturers to follow GMPs, FDA issued cGMP regulations for drug and biological products in the Code of Federal Regulations (in 21 CFR parts 210 and 211). There are certain requirements in 21 CFR Part 211 that are directed at the commercial manufacture of products typically characterized by large, repetitive, commercial batch production and requirements as a result, are not appropriate to the manufacture of most investigational drugs used for phase I clinical trials. Based on these issues, application of cGMPs to Phase I investigational drug products was exempted from 21 CFR 211. However, based on statutory requirements as given in Section 505(i) of the FD&C Act, FDA issued regulations

governing IND products in order to protect human subjects enrolled in clinical trials, specifically with regards to the chemistry, manufacturing and controls data submitted as part of IND applications for drugs or biological products.

Subsequent to FDAs final rule of January 2006, FDA released the Guidance for Industry, "INDs-Approaches to Complying with CGMP During Phase I". This document describes the CMC data necessary for inclusion in the IND. FDA reviews the IND to determine whether phase I investigational drugs to be used in the clinical trial to permit the trial to proceed, which is partially dependent on whether the product has the identity, strength, quality and purity and purported effect described in the IND application. FDA can chose to place the IND on clinical hold or could terminate the IND based on their review. If an IND is placed on clinical hold, the hold may be removed if the sponsor addresses the deficiencies, but clinical trials may not progress until the clinical hold is removed.

In July 2008, FDA issued an additional Guidance for Industry, "CGMP for Phase I Investigational Drugs", in order to provide guidance to sponsors regarding meeting GMPs appropriate for Phase I investigational drug products. In this seminar, the attendees will gain a complete understanding of all current good manufacturing practices that are applicable to the manufacture of Phase I investigational drug product, in addition to understanding which products were exempt and which were not. The attendees will gain an understanding of CMC data necessary for the preparation of an Investigational New Drug application, and have an understanding of the requirements of the document and therefore avoid clinical holds or termination of the IND. Additionally, based on the products that were exempted from GMPs as defined in 21 CFR part 211, several guidance documents were created to provide guidance regarding the content and format of the CMC information necessary for inclusion in the IND for the following products: for Phase I, studies of drugs, including well-characterized, therapeutic, biotechnology-derived products, for somatic cellular therapy and for human gene therapy INDs.

Why should you attend:

FDAs guidance document "Good Manufacturing Practice for Phase I Investigational Drug Products" applies to correct GMP requirements to drug products made for the purpose of using an investigational drug product on human subjects for the first time, during conduct of Phase I clinical trials, which can begin if your IND is not put on clinical hold in 30 days after receipt by the FDA. If they review your IND and the appropriate information is not available to ensure FDA of the quality of the product, the IND will be placed on clinical hold, preventing your clinical program from going forward. The necessary content of the IND will not be discussed in this webinar, but the specific GMPs for Phase I Investigational drugs will be understood by attendees, therefore allowing the applicant to apply only those GMPs which are applicable to the drug product at this stage of development, instead of trying to apply GMPs, as defined in 21 CFR Part 211, to Phase I Investigational drug products, which often leads to frustration and even errors, as the CFR definition was meant for commercial batches, which are large and repetitive, as well as different in other ways, making the application of some of the GMPs for finished drug products impossible.

Who will benefit:

- Quality Associates or Specialists
- Regulatory Management or Regulatory Specialists
- Compliance professionals
- Quality Auditors
- Validation Engineers
- R & D Scientists- chemists, geneticists, biochemistry specialists, formulation chemistry
- Laboratory Personnel
- Senior Quality Managers, Quality VPs

Day 1 Schedule

Lecture 1(90 Mins):

30 Minutes: brief overview of the objectives of the seminar, brief introduction of attendees, including their functions, type of products that they are working on (if applicable), and the function(s) they serve.

60 Minutes: an explanation of the statutory requirements, the changes that precipitated the products being exempt and the specific products exempt and those that were not exempt will be discussed.

Lecture 2(90 Mins):

Brief discussion of the product lifecycle, including when regulatory filings, such as the IND and NDA (or the equivalent, depending on region) are filed, description of differences in chemically-synthesized drug and biologic products and biotech products will be briefly discussed. Brief discussion of the Pharmaceutical Quality System, as per ICH Q10 (and the companion documents, ICH Q8, pharmaceutical development and ICH Q9, quality risk management, will be introduced.

Lecture 3(90 Mins):

15-30 Minutes: brief discussion of GMPs for APIs, specifically the information that addresses GMPs for products in clinical trials, ICH Q7. GMPs for phase I investigational drug products will be dsicussed, including guidance for complying with the statute, discussion of having appropriate QC procedures in effect during product development to ensure the quality and safety of the investigational drugs are maintained, as well as emphasis on following appropriate GMPs, as both of these actions will facilitate the manufacture of equivalent of comparable IND product for future clinical trials. Several different resources/technologies are suggested to facilitate conformance with cGMPs and to streamline product development.

Lecture 4(90 Mins):

Additional review of GMPs for phase I investigational drug products, including personnnel, QC function, facility and equipment, control of components, and containers and closures, manufacturing and records, laboratory controls, including testing and stabilit, packaging, labeling and distributing and recordkeeping will be addressed. If we do not get through all of the information just mentioned in this time period, the dicussion will continue the following day, along with the remaining content that needs to be understood for implementing GMPs for Phase I Products.

Day 2 Schedule

Lecture 1(90 Mins):

Continued discussion of GMPs for Phase I Investigational drug products, including content from previous day and the special manufacturing situations, such as multi-product facilities.

Lecture 2(90 Mins):

Continued discussion of GMPs for Phase I Investigational drug products to include considerations and adventitious agent control will be addressed in regards to biological and biotechnological products. Gene therapy and cellular therapy products will be addressed, as well as sterile products/aseptically processed products. The remaining time will introduce "INDs - Approaches to complying with CGMP during Phase I".

Lecture 3(90 Mins):

The IND Regulation(21 CFR 312.23(a)(7)(i)) will be reviewed, including the "sufficient CMC information to ensure the proper identification, quality, purity, and strength of the investigational drug." Each item (identification, quality, purity, and strength of the investigational drug) will be reviewed, including meaning of each, some of the requirements, such as strength and assays for drug substance and drug product, validation requirements of each, blend uniformity, uniformity of dosage units, container/closure, stability, etc. If additional time is left, will start review of CMC regulatory requirements.

Lecture 4(90 Mins):

The CMC regulatory requirements, including requirements for drug substance (APIs) and drug products. Potential safety concerns for an investigational drug product (and its' drug substance) will be discussed in order to help attendees avoid safety issues and clinical holds. Other potential hold issues will be addressed, including impurities, expiration dating, etc. will be

addressed. The ICH guidance documents specific for identity, stability, etc. will be provided to the attendees. Questions will be accepted throughout the seminar, but any questions that the attendees have and discussions are encouraged to ensure that all attendees have any questions answered.

Speaker

Stephanie Cooke

President/CEO, Cooke Consulting Inc.

Stephanie Cooke, is the President/CEO of Cooke Consulting, Inc. Stephanie uses her roughly 20 years of experience to provide global consulting services in various areas of Regulatory Affairs, Quality Assurance and validation for pharmaceutical, biological/biotech products, medical device, combination drug/device and nutraceutical firms. Her broad-based experience includes preparation of regulatory dossiers for human and animal pharmaceutical (chemical entities and biologically-based drugs), biotech products, drug/device combination products and medical devices in all stages of development (INDs, NDAs, BLAs, post-marketing supplements such as CBEs, Prior approval supplements, orphan drug designation and related submissions, 510ks, PMAs and HDEs). She also has extensive QA and validation experience, successfully hosting many regulatory audits conducted by FDA, ISO and other international regulatory bodies (Irish Medical Board and others), training personnel on hosting audits by global regulatory bodies, as well as establishing auditing programs to qualify contract manufacturers and vendors of raw materials, APIs, etc. and product release experience in manufacturing environments and for companies using contract manufacturers, responsibility for establishing and maintaining Quality systems for all product types, establishing stability programs, as well as preparation/performance of process validation(s), including sterilization validation(s) (EtO, steam, gamma), aseptic processing, qualification of cleanrooms/water systems and manufacturing process validation. Stephanie has been involved in the development of drugs, including biologics, biotech products and medical devices, from product concept through post-approval maintenance including requirements for submissions for various regions/countries, process validation requirements, etc. and has considerable project management experience. Ms. Cooke is experienced the development of APIs, drug products (including biological/biotech products and their associated manufacturing processes. In addition, she has had much experience working on CMC sections of the CTD for various countries/regions, establishing required preclinical and clinical testing necessary for regulatory filings, as well as preparing the information for regulatory submissions. Prior to beginning Cooke Consulting, Inc.about 9 years ago, Stephanie worked for Sciele - Pharma from 2005-2009 as the VP of Regulatory Affairs, Quality Assurance/Validation. She also

held various senior RA, QA and validation positions at Merial, Bayer (Visible Genetics), Cryolife, Theragenics and other pharmaceutical, biotech and medical device companies, after beginning in industry as a lab tech and working as a certified as a Microbiologist. She has a BS in Biology and an M.S. in Molecular Genetics and Biochemistry from Georgia State University.

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