

Good Clinical Practice Certification

The development of OSCE is credited to Ronald Harden... 85d1702410
== Current models == 85d1702410 AACE is now the world's largest organization representing clinical endocrinologists and endocrine care teams. With more than 6,500 members in the United States and 91 other countries around the globe, the organization has developed a robust network of professional associates and political allies. 85d1702410 Job profile acceptable in CDM: clinical researcher, clinical research associate, clinical research coordinator etc. 85d1702410

Good manufacturing practice These guidelines provide minimum requirements that a manufacturer must meet to assure that their products are consistently high in quality, from batch to batch, for their intended use. system (QMS). Good manufacturing practice, along with good agricultural practice, good laboratory practice and good clinical practice, are overseen by Current good manufacturing practices (cGMP) are those conforming to the guidelines recommended by relevant agencies. Those agencies control the authorization and licensing of the manufacture and sale of food and beverages, cosmetics, pharmaceutical products, dietary supplements, and medical devices 85d1702410

Good practice They are used in quality guidelines and regulations, including the pharmaceutical and food industries, for example good agricultural practice (GAP) (see more examples below). practice, or GCCP Good clinical data management practice, or GCDMP Good clinical laboratory practice, or GCLP Good clinical practice, or GCP Good documentation A good practice is a procedure or set of procedures that are prescribed or accepted as being suitable or effective within a given professional or commercial setting 85d1702410

Clinical trial These authorities are responsible for vetting the risk/benefit ratio of the trial—their approval does not mean the therapy is "safe" or effective, only that the trial may be conducted. They are conducted only after they have received health authority/ethics committee approval in the country where approval of the therapy is sought. The International Conference Clinical trials are prospective biomedical or behavioral research studies on human participants designed to answer specific questions about biomedical or behavioral

interventions, including new treatments (such as novel vaccines, drugs, dietary choices, dietary supplements, and medical devices) and known interventions that warrant further study and comparison. Clinical trials generate data on dosage, safety and efficacy. before they can conduct clinical trials. They must understand the federal patient privacy (HIPAA) law and good clinical practice 85d1702410

In addition to partnerships with the American Diabetes Association, American Thyroid Association and others in the... 85d1702410
Depending on product type and development stage, investigators initially enroll volunteers or patients into small pilot studies, and subsequently conduct progressively larger scale comparative studies. Clinical trials can vary in size and cost, and they can involve a single research center or multiple centers, in one country or in multiple countries. Clinical study design aims to ensure the scientific validity and reproducibility of the results... 85d1702410

Maintenance of certification Some physicians disagree that the programs as implemented in reality uphold this ideal well enough to be a net positive to the profession rather than a net negative. Maintenance of certification (MOC) is a process of physician certification maintenance through one of the 24 approved medical specialty boards of the Maintenance of certification (MOC) is a process of physician certification maintenance through one of the 24 approved medical specialty boards of the American Board of Medical Specialties (ABMS) and the 18 approved medical specialty boards of the American Osteopathic Association (AOA). Variously implemented between 1990 and 2000 in response to quality concerns in the healthcare system, the MOC process is a voluntary certification process and is controversial within the medical community. The ideal behind it is that physicians formally measure and demonstrate that they are doing adequate continuing medical education to stay current in their fields as the state of the art in each field continually advances beyond what it was when each person was initially educated and trained 85d1702410

The utility of clinical diagnostic testing relies squarely on the validity of test methodology. To this end, much of the work done by medical laboratory scientists involves ensuring specimen quality, interpreting test results, data-logging, testing control products, performing calibration, maintenance, validation, and troubleshooting of instrumentation as well as performing statistical analyses to verify the accuracy and repeatability of testing. Medical laboratory scientists may also assist healthcare providers with test selection and specimen collection and are responsible for prompt verbal delivery of critical lab

results. Medical laboratory scientists... 85d1702410

American Association of Clinical Endocrinology AACE's mission is elevating clinical endocrinology to improve global health. ACE programs include the Endocrine Certification in Neck Ultrasound (ECNU) program and the The American Association of Clinical Endocrinology (AACE) is a professional community of physicians specializing in endocrinology, diabetes, and metabolism. The association is headquartered in Jacksonville, Florida, US. translation of scientific advances into clinical practice 85d1702410

Objective structured clinical examination In an OSCE, candidates rotate through a series of timed stations and complete predefined clinical tasks, such as history taking, physical examination, communication, interpretation of investigations, clinical reasoning, or practical procedures. licensing, certification and formative assessment contexts. Although the format is intended to improve standardisation and sampling of clinical skills, its An objective structured clinical examination (OSCE) is a practical examination format used to assess clinical competence, especially in medicine, pharmacy and other health care disciplines 85d1702410

The purpose of the GxP quality guidelines is to ensure a product is safe and meets its intended use. GxP guides quality manufacture in regulated industries including food, drugs, medical devices, and cosmetics. 85d1702410 The most central aspects of GxP are good documentation practices (GDP), which are expected to be "ALCOA": 85d1702410 Starting with Oklahoma in 2016, a growing number of states have passed or are considering passage of legislation prohibiting use of participation in Maintenance of Certification as a reason to exclude a physician from hospital staff appointment or from... 85d1702410

Clinical data management It also supports the conduct, management and analysis of studies across the spectrum of clinical research as defined by the National Institutes of Health (NIH). The ultimate goal of CDM is to ensure that conclusions drawn from research are well supported by the data. Good clinical data management practice (GCDMP) is the current Clinical data management (CDM) is a critical process in clinical research, which leads to generation of high-quality, reliable, and statistically sound data from clinical trials. various stages in the Clinical data management process and is normally mandated by SOP. Achieving this goal protects public health and increases confidence in marketed therapeutics. Clinical data management ensures collection, integration and availability of data at appropriate quality and cost

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Clinical behavior analysis (CBA) therapies include acceptance and commitment therapy (ACT), behavioral medicine (such as behavioral gerontology and pediatric feeding therapy), community reinforcement approach and family training (CRAFT), exposure therapies/desensitization (such as systematic desensitization), functional analytic psychotherapy (FAP, such as behavioral activation (BA) and integrative behavioral couples therapy), and voucher-based contingency management. 85d1702410 The format was developed in the 1970s by Ronald Harden and colleagues as a response to limitations of traditional clinical examinations, including variation in the patients and examiners assigned to candidates. OSCEs are structured through planned stations, standardised instructions, checklists or rating scales, and, in many cases, real or simulated patients. 85d1702410 In general, GxP is a placeholder abbreviation for the good practice within a particular field or fields, where the "x" can be substituted for the field(s) in question. GxP can also be used to refer to collections of quality guidelines. 85d1702410

Medical laboratory scientist Clinical scientists who attain both part 1 examination certification and part 2 certification are awarded Fellowship of the A medical laboratory scientist (MLS), clinical laboratory scientist (CLS), or medical technologist (MT) is a licensed healthcare professional who performs diagnostic testing of body fluids, examples: blood, urine, sputum and other body tissue. by a Medical Royal College. The scope of a medical laboratory scientist's work begins with the receipt of patient or client specimens, and finishes with the delivery of test results to physicians and other healthcare providers. The medical technologist is tasked with releasing the patient's results to aid in further treatment 85d1702410

Clinical research associate A CRA would subsequently grow into a Feasibility Leader, Study Start up Leader, Project Manager, and Project Director at a Pharmaceutical company or a contract research organization. The main tasks of the CRA are defined by good clinical practice guidelines for monitoring clinical trials, such as those elaborated by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. A CRA is usually required to possess an academic degree in Life Sciences and needs to have a good knowledge of good clinical practice and local regulations. The A clinical research associate (CRA), also called a clinical monitor or trial monitor, is a health-care professional who performs many activities related to medical research, particularly clinical trials. different

education and certification requirements may be necessary, although not usually required, to practice as a clinical research associate. Depending on the jurisdiction, different education and certification requirements may be necessary, although not usually required, to practice as a clinical research associate. Clinical research associates work in various settings, such as pharmaceutical companies, medical research institutes and government agencies 85d1702410

== Background == 85d1702410 To denote the current good practice, a "c" or "C" is sometimes added to the front of the initialism (cGxP), which may hint that any good practice may be subject to future change. For example, "current good manufacturing practice" may be abbreviated "cGMP". 85d1702410 == Role of the clinical data manager in a clinical trial == 85d1702410 == Purpose == 85d1702410 Prior to AACE's inception, the field of clinical endocrinology was not represented in the Health Care Financing Administration (HCFA), health policymaking bodies and many of the professional physician societies. AACE was founded in 1991 by a national committee of 26 clinical endocrinologists to address this inequity and become the voice for the specialty. Dr. Yank Coble, Jr., the driving force and co-founder of AACE, became the inaugural President of the Association. 85d1702410 == History and purpose == 85d1702410

Clinical behavior analysis CBA represents a movement in behavior therapy away from methodological behaviorism and back toward radical behaviorism and the use of functional analytic models of verbal behavior—particularly, relational frame theory (RFT). theory. The Behavior Analyst Certification Board (BACB), in partnership with subject-matter experts, has produced a "Clinical Behavior Analysis" fact sheet Clinical behavior analysis (CBA; also called clinical behaviour analysis or third-generation behavior therapy) is the clinical application of applied behavior analysis (ABA) 85d1702410

The clinical data manager plays a key role in the setup and conduct of a clinical trial. The data collected during a clinical trial form the basis of subsequent safety and efficacy analysis which in turn drive decision making on product development in the pharmaceutical industry. The clinical data manager is involved in early discussions about data collection options... 85d1702410 The main function of a clinical research associate is to monitor clinical trials. The... 85d1702410 Good manufacturing practice, along with good agricultural practice, good laboratory practice and good clinical practice, are overseen by regulatory agencies in the United Kingdom, United States... 85d1702410 OSCEs are used in undergraduate, postgraduate, licensing, certification

and formative assessment contexts. Although the format is intended to improve standardisation and sampling of clinical skills, its reliability and validity depend on how stations, examiners, scoring criteria and standard-setting procedures are implemented. 85d1702410 == Overview == 85d1702410 The rules that govern each industry may differ significantly; however, the main purpose of GMP is always to prevent harm from occurring to the end user. Additional tenets include ensuring the end product is free from contamination, that it is consistent in its manufacture, that its manufacture has been well documented, that personnel are well trained, and that the product has been checked for quality more than just at the end phase. GMP is typically ensured through the effective use of a quality management system (QMS). 85d1702410

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