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The documents posted below include the various publications that contributed to the development of final rules related to FDA's regulations on good clinical practice and clinical trials. Parts 50

...

Good Clinical Practice Promo 1

Good clinical practice (GCP) is a set of internationally-recognised ethical and scientific

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quality requirements
that must be followed
when designing,
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Good Clinical Practice - NIDA GCP

The following resources are provided to help investigators, sponsors, and contract research organizations who conduct clinical studies on investigational new drugs comply with U.S. law and ...

NHG :: RDO:: Good Clinical Practice (GCP)

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The principles of Good Clinical Practice (GCP) help assure the safety, integrity, and quality of clinical trials by addressing elements related to the design, conduct, and reporting of clinical trials. GCP training describes the responsibilities of investigators, sponsors, monitors, and IRBs in the conduct of clinical trials.

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**Good Clinical
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tively referred to as
“Good Clinical
Research Practice”
(GCP). This handbook
is issued as an adjunct
to WHO’s “Guidelines
for good clinical
practice (GCP) for trials
on pharmaceutical
products” (1995), and
is intended to assist
national regulatory
authorities, sponsors,
investigators and
ethics committees in

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The Medicines for
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relating to GCP and
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The principles of Good
Clinical Practice (GCP)
have their origin in the
World Medical
Association's
Declaration of Helsinki.

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The Declaration of Helsinki was responsive to the revelations of the Nuremberg trials conducted after World War II, and its drafters sought to ensure that human subjects involved in clinical research would, in future, have their rights, safety and

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**Requirements for
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Protection
(HSP)/Good ...**

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Medlemmerne af
Dansk Selskab for
Good Clinical Practice
udgør en bred vifte af

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klinikere, ansatte ved offentlige forskningsenheder, ansatte i medicinal- og biotekindustrien, ansatte ved de danske GCP-enheder, medlemmer fra Det Videnskabetiske Komité system og Lægemiddelstyrelsen samt medlemmer, der beskæftiger sig med, eller interesserer sig for GCP og kliniske forsøg.

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Frequently Asked
Questions This section
provides answers to
the frequently asked
questions regarding
the Requirements for
Human Subject
Protection (HSP)/Good
Clinical Practice (GCP)
Training. Who are
considered “key”
personnel? For the
purposes of this policy,

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key personnel are those individuals engaged in the conduct of research as defined by the Office for Human Research Protections who

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Define Good Clinical Practice (GCP) Outline the goals of GCP Provide a historical perspective on GCP Outline FDA regulations relating to

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The Good Clinical Practice (GCP) course is designed to prepare research staff in the conduct of clinical trials with human participants. The 12 modules included in the course are based on ICH GCP Principles and the Code of

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Federal Regulations
(CFR) for clinical
research trials in the
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Good clinical practice
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international ethical
and scientific quality
standard for designing,
recording and
reporting trials that
involve the
participation of human

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subjects. Compliance with this standard provides public assurance that the rights, safety and wellbeing of trial subjects are protected and that clinical-trial data are ...

Regulations: Good Clinical Practice and Clinical Trials | FDA

Good Clinical Practice (GCP) is the international ethical, scientific and practical

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standard to which all clinical research is conducted. It is important that everyone involved in research is trained or appropriately experienced to perform the specific tasks they are being asked to undertake.

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Practice**

GOOD CLINICAL
PRACTICE ICH E6(R2)

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INTRODUCTION Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and

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**Practice (GCP) - CITI
Program**

Good Clinical Practice (GCP) Based on the ICH GCP E6(R2) guidelines and incorporating local regulatory requirements, the GCP course seeks to equip participants with basic knowledge and understanding of how GCP principles may be applied to the conduct of clinical trials. Experienced speakers from various clinical

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research-related
sectors will ...

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HANDBOOK FOR GOOD CLINICAL RESEARCH PRACTICE (GCP)

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involved in behavioral
intervention and social
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