Chapter 3
The Principles of GCP

3.1 The Principles of ICH GCP [1]

1. 'Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with GCP and the applicable regulatory requirement(s)'.
2. 'Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for individual trial subjects and society. A trial should be initiated and continued only if the anticipated benefits justify the risks'.
3. 'The rights, safety, and well being of trial subjects are the most important considerations and should prevail over the interests of science and society'.
4. 'The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial'.
5. 'Clinical trials should be scientifically sound, and described in a clear, detailed protocol'.

C. Cingi, N. Bayar Muluk, *Quick Guide to Good Clinical Practice*,
DOI 10.1007/978-3-319-44344-7_3,

6. ‘A trial should be conducted in compliance with a protocol that has received prior IRB/IEC approval/favourable opinion’.
7. ‘The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist’.
8. ‘Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s)’.
9. ‘Freely given informed consent should be obtained from every subject prior to clinical trial participation’.
10. ‘All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation, and verification’.
11. ‘The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s)’.
12. ‘Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol’.
13. ‘Systems with procedures that assure the quality of every aspect of the trial should be implemented’.

3.2 WHO Principles of GCP [2]

Principle 1 ‘Research involving humans should be scientifically sound and conducted in accordance with basic ethical principles, which have their origin in the Declaration of Helsinki. Three basic ethical principles of equal importance,

namely, respect for persons, beneficence, and justice, permeate all other GCP principles'.

Principle 2 'Research involving humans should be scientifically justified and described in a clear, detailed protocol'.

Principle 3 'Before research involving humans is initiated, foreseeable risks and discomforts and any anticipated benefit(s) for the individual trial subject and society should be identified. Research of investigational products or procedures should be supported by adequate non-clinical and, when applicable, clinical information'.

Principle 4 'Research involving humans should be initiated only if the anticipated benefit(s) for the individual research subject and society clearly outweigh the risks. Although the benefit of the results of a trial to science and society should be taken into account, the most important considerations are those related to the rights, safety, and well being of the trial subjects'.

Principle 5 'Research involving humans should receive IEC/IRB approval/favourable opinion prior to initiation'.

Principle 6 'Research involving humans should be conducted in compliance with the approved protocol'.

Principle 7 'Freely given informed consent should be obtained from every subject prior to research participation, in accordance with national culture(s) and requirements. When a subject is not capable of giving informed consent, the permission of a legally authorised representative should be obtained in accordance with applicable law'.

Principle 8 'Research involving humans should be continued only if the benefit-risk profile remains favourable'.

Principle 9 'Qualified and duly licensed medical personnel (i.e. physician(s) or, when appropriate, dentist(s)) should be

responsible for the medical care of trial subjects, and for any medical decision(s) made on their behalf'.

Principle 10 'Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s) and currently licensed to do so, where required'.

Principle 11 'All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation, and verification'.

Principle 12 'The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s)'.

Principle 13 'Investigational products should be manufactured, handled, and stored in accordance with applicable GMP and should be used in accordance with the approved protocol'.

Principle 14 'Systems with procedures that assure the quality of every aspect of a trial should be implemented'.

References

1. Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER). ICH, April 1996.
2. Handbook for Good Clinical Research Practice (GCP). Guidance for implementation. World Health Organization, 2002. http://apps.who.int/prequal/info_general/documents/GCP/gcp1.pdf. Accessed online at 13 Oct 2015.