Measures for the Building of GHWP Academy

(Exposure Draft)

Article I [Purpose]

To facilitate the implementation of the *Global Harmonization Working Party Strategic Framework towards 2026*, and fulfill GHWP's mission, vision and goals, GHWP management team decides to establish the GHWP Academy in its member countries and regions, to be responsible for carrying out training, research and knowledge exchange in the field of medical devices, enhancing medical device regulatory capability of its member countries and regions, promoting global medical device regulations toward convergence, harmonization and reliance, and protecting and promoting people's health across the globe.

Article II [Operation Mechanism]

To coordinate resources and strengths, and promote smooth operation of the GHWP Academy, GHWP establishes the Capacity Building (CB) Committee, which consists of GHWP leadership, SAB members, CB team leaders, academy presidents, and internationally renowned company leaders.

The Committee is responsible for determining the development strategies, curriculums, faculty building, funds management, assessment criteria, recognition of contributions, and other important matters, and strategically spurring the steady development of the GHWP Academy.

GHWP CB is responsible for the routine work of the Capacity Building Committee.

Article III[Principle]

GHWP Academy is built on the principles of balance, excellence, openness and sharing, with the support from reputable universities in the member countries and regions. GHWP announces the establishment requirements and procedures of the Academy, and encourages the reputable higher education institutions in the member countries and regions to participate and to support the running of the GHWP Academy, and the medical device companies, regulatory authorities, regulatory professionals, trade associations, industry organizations, academia, etc., to participate in the training and research organized by GHWP Academy.

Article IV [Name of Academy]

All GHWP Academy is named as GHWP (city name) Academy.

Article V [Objectives of Training]

GHWP Academy's training objectives are:

1. To improve the regulatory capabilities of GHWP's member countries and regions comprehensively, especially on the understanding and application of medical device regulatory science, the methodology to keep regulatory work abreast of the time, and the enabling knowledge to enhance their roles of regulatory authorities as the vanguard and promoter in medical technology innovations;

2. To enhance the capability of GHWP member countries and regions on referencing, transforming and applying the GHWP technical guidance into medical device regulations in their corresponding countries and regions, and to continuously improve the scientific, international and modern level of regulatory work;

3. To enhance the innovative and creative capabilities of GHWP member countries and regions, and to promote the high-quality development of the industry;

4. To advance global medical device regulations toward convergence, harmonization and reliance;

5. To promote the communication and cooperation between regulatory authorities and the medical device industry in member countries and regions.

Article VI [Objects of Training]

GHWP Academy is catering to medical device regulators and stakeholders from medical device industry in GHWP member countries and regions, as well as the stakeholders across the globe.

Article VII [Content of Training]

GHWP Academy offers training on the following aspects:

1. GHWP's mission, vision, goals, as well as its organization structure, development strategy, operation mechanism;
2. The status quo, trend, priority, mapping, and strategy of innovative development of global medical device industry;
3. The innovation of philosophy, legal system, mechanism, method, strategy and culture of global medical device regulations;
4. GHWP technical guidance;
5. Competency curriculum set out by GHWP (e.g. GHWP Training Curriculum For Medical Technology Regulatory Authorities and White paper on Competency Framework for Medical Technology Regulators (http://ghwp.info/index.php/node/263))

6. Development of medical device regulatory science;
7. Convergence, harmonization and reliance of medical device regulation;
8. Opportunities and challenges in the medical device industry and regulation;
9. Other key topics determined by GHWP Capacity Building Committee.

Article VIII [Modes of Training]

GHWP Academy mainly focuses on on-site trainings while online trainings are also encouraged to benefit a wider range of participants.

Article IX [Qualifications of Applicant]

Applicants who apply for the establishment of GHWP Academy shall fulfill the following requirements:

1. Support GHWP's mission, vision and goals, and familiarize with the operation and management of GHWP;

2. Universities or institutions in GHWP member countries and regions, with good reputations, capabilities and infrastructure (universities or institutions with medical device related majors are preferred);

3. Have sound fund-raising mechanisms or channels, and able to ensure the successful rollout of trainings, research, exchanges, etc.;

4. Have excellent management teams, modern philosophy and open mindset, and dedicated to promoting global medical device regulations toward convergence, harmonization and reliance;

5. Have outstanding faculty teams to facilitate the implementation of trainings, research and exchanges;

6. Have well-established training bases or reliable partnership;

7. Ability to organize at least two terms of on-site training annually;

8. Ability to complete the construction of the Academy within six months.

Article X [Faculty Team]

GHWP Academy should have a pool of outstanding trainers, composed of GHWP leaderships, GHWP TC experts, and prestigious experts in the field of medical device from GHWP member countries and regions, and from around the world.

The experts recruited by GHWP Academy should actively support GHWP's mission, vision and goals, and promote global medical device regulations toward convergence, harmonization and reliance.

Article XI [Development Fund]

GHWP Academy can raise funds for training. The funds raised should be dedicated for the trainings by the GHWP Academy, and should not be used for infrastructure or other unrelated programs without the consent of GHWP Capacity Building Committee.

All medical device companies are encouraged to support the training programs of the GHWP Academy.

Article XII [Required Materials for Application]

Applicant should submit their application to GHWP, which includes the relevant content specified in Article IX, as well as the advantages of their trainings, research and exchanges.

Article XIII [Selection Procedure]

GHWP Capacity Building Committee to shortlist the qualified applicant via the following selection procedure:

1. The candidate academy to present their educational philosophy, conditions, features and advantages;

2. GHWP Capacity Building Committee members to ask questions based on presentations by the candidate academy and their submitted application;

3. The responsible person and representatives of the candidate academy to answer the questions;

4. GHWP Capacity Building Committee members to comment and evaluate.

Article XIV [Overall Assessment]

GHWP Capacity Building Committee conducts a comprehensive evaluation on the candidate academy based on their capability, development potential and global balance. The GHWP leaders and SAB members vote and approve the establishment of the GHWP Academy. The qualified academy will be listed on the GHWP website.

Article XV [Curriculum]

GHWP Academy proposes the training program of the next year in the fourth quarter of each year, for approval by the GHWP CB team, further deliberation by GHWP Capacity Building Committee and report at the GHWP annual meeting.

Article XVI [Yearly Evaluation]

GHWP Capacity Building Committee makes assessment on GHWP Academy's

work annually.

Article XVII [Encouragements]

To fully play its role, GHWP Academy is encouraged to:

1. carry out research with regard to medical device regulatory convergence, harmonization and reliance;

2. conduct research on major issues related to medical device regulation;

3. undertake specific training programs of GHWP member countries and regions;

4. participate in GHWP related academic activities.

Article XVIII [Prohibitions]

To fulfill its responsibilities and grow steadily, GHWP Academy is not encouraged to:

1. engage in any activities unrelated to GHWP in the name of GHWP Academy;

2. spend the funds raised under the GHWP Academy on the matters other than GHWP programs.

Article XIX [Disqualification]

In case the management of the GHWP Academy fails to fulfill the commitments made during application, engages in activities unrelated to GHWP in the name of the GHWP Academy, spends the raised funds on the matters other than GHWP programs, and deviated from purpose and goals of the establishment of the GHWP Academy as determined by the GHWP Capacity Building Committee, one-year period for rectification will be given to the GHWP Academy. If it still fails to meet the requirements after the rectification period, the academy will be disqualified, the disqualification would be listed on GHWP website.

Article XX[Award]

GHWP Academy that makes outstanding contributions during the year will be commended by GHWP Capacity Building Committee and announced on GHWP website.