



HDA GDP Accreditation Program – Individual Certification **Fact Sheet**

Good Distribution Practices (GDP) involve certain important processes that must be met while ensuring the quality and integrity of medicinal products within a pharmaceutical supply chain. GDP can apply not only to product manufacturers and distributors but also to entities outside of the pharmaceutical industry that support the distribution of pharmaceutical products.

The most well-known GDP standards are those of the European Medicines Agency, created in 2013.

There are currently no regulatory-monitored GDP standards in the United States. However, in recent years, there has been an increasing desire to mirror compliance with European standards in anticipation that similar regulatory requirements will eventually be instituted in the United States.

The HDA GDP Accreditation Program – Individual Certification allows those within the pharmaceutical supply chain to demonstrate familiarization with recognized GDP operational and training criteria. Such familiarization could assist in mitigating distribution deviations, such as product damage, environmental excursions, or the potential of product theft within a supply chain.

Some of the topics that are included in the individual GDP certification syllabus are:

- Quality Management Systems
- Personnel and Equipment
- Training
- Documentation
- Operations
- Supply Chain Security
- Complaints and/or Recalls
- Outsourced Activities
- Self-Inspection
- Transportation

An individual GDP Certification indicates that:

- a.) The applicant has been evaluated against the EU Guidelines on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01) and the PIC/S Guide to Good Distribution Practice for Medicinal Products



b.) That, at the time of the certification, the principal elements of the applicant's GDP knowledge are consistent with the EU and the PIC/S Guidelines

c.) That the certification period is two years in duration

When awarded certification, the applicant will have become an official member of the HDA's GDP Program. As such, they are entitled to GDP consultations with those mentoring the Program upon request during the two-year accreditation period.

GDP Training Fees (USD) - Individual

There are three phases to the required training for an individual to obtain certification. They are:

- GDP Introductory Training (1 Hour - conducted virtually)
- GDP Awareness Training (6 hours – conducted virtually over a one or two-day period)
- GDP Responsible Person Training (12 hours – conducted in person over a two-day period)

Introductory and Awareness Training are conducted virtually, while Responsible Person Training, due to its intensity level, is conducted in person over a two-day period. Responsible Person training class size is typically small, no more than 16 students.

Responsible Person training will be offered quarterly - or four times per year - at a site of the HDA's choosing.

Due to the generic nature of the type of training, multiple individuals can be trained in the same session.

Training Fee Structure - Business Entity:

GDP Introductory Training: **\$100.00/person**

GDP Awareness Training: **\$750.00/person (2 person minimum)**

GDP Responsible Person Training: **\$1,500.00/person (2 person minimum)**

Training fee compensation is due upon invoice.

Revalidation Fee – Individual:

Revalidation training, at the conclusion of the 2-year certification period, would involve a one-day refresher course for **\$750.00/person**.