



## **HDA GDP Accreditation Program – Business Entity** **Fact Sheet**

Good Distribution Practices (GDP) involve certain important processes to 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 those entities outside of the pharmaceutical industry that support the distribution of pharma products.

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

There are no regulatory-monitored GDP standards currently 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.

For this reason, the Healthcare Distribution Alliance has created a Good Distribution Practice Accreditation Program - through its Pharmaceutical Cargo Security Coalition.

The Accreditation Program is designed to provide partners in the pharmaceutical supply chain, primarily those providing vendor services such as transportation, warehousing, freight-forwarding, customs brokerage, 3PL, and cargo insurance – the ability to demonstrate not only familiarization but also a measured level of adherence to recognized GDP operational and training criteria. Such adherence can assist in the mitigation of distribution deviations - such as product damage, environmental excursions, or the potential of product theft within a supply chain.

ASC Associates Ltd, a European-based firm with extensive experience developing and implementing GDP training programs consistent with European standards worldwide, will assist with the administration of the HDA's program.

Companies seeking this type of accreditation may apply for acceptance into the Program. Once an application into the Program is accepted, a **Program Agreement** between the applicant and the HDA will be required to solidify the business relationship. In the event of a conflict between this Application and the **Program Agreement**, the terms of the Program Agreement will govern.

Once both parties have signed the **Program Agreement**, the HDA and the applicant will form a project team. The applicant must then agree to the overall assessment process (all phases of the Program), which will be memorialized in a **Statement of Work**.

The HDA will utilize a recognized assessment methodology to determine where the applicant's GDP Program (at the initial point of review) stands in relation to 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.



The specific steps included in the assessment methodology are:

A review of all existing documentation - as per a pre-assessment questionnaire  
If necessary, an on-site assessment.

During the assessment activity, the following areas will be reviewed

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

The amount of time it takes to complete each step of the assessment will depend on the maturity of the applicant's existing GDP efforts.

At the conclusion of the initial assessments, the HDA will be responsible for developing a **Gap Analysis Report** that covers all findings. The report will outline the areas and/or elements reviewed, identifying items that are not consistent with the Guidelines being measured against or that don't currently exist. The report will also include a list of recommendations to upgrade/improve the level of the company's GDP Program, consistent with existing Standards.

As part of this phase, together with the issuance of the report, the HDA will make a presentation to the applicant. During that presentation, a date/time will be targeted for a reassessment of the company's GDP program.

The determining factor regarding the date/time for re-assessment will be dependent on the applicant having the appropriate resources available. The length of time between the analysis and improvement phases of the assessment process is very much dependent on how quickly any identified gaps can be closed.

The applicant is afforded the opportunity to request support with the project monitoring and status reporting activities, including, but not limited to:

Executing project management plans  
Directing and managing project execution  
Setting up tracking systems  
Supply chain security reviews  
Ensuring task assignments are executed.  
Facilitating status meetings  
Updating project schedule  
Modifying project plans as needed



At a mutually agreed-upon date/time, the HDA will reassess the company's GDP Program against the recommendations provided during the first assessment. The reassessment could include a virtual and/or on-site review/analysis. Once the process is completed, a brief **Reassessment Findings Report** will be issued.

A detailed training program will be an integral part of the accreditation process and will need to be completed by all the pertinent members of the applicant's staff, identified in the **Statement of Work**. Each staff member will be trained according to their respective role and responsibility

If the reassessment findings meet the accreditation process's acceptable standards and all requested employees have completed all of the respective accreditation training requirements, the HDA will accredit the applicant.

**An Accreditation Certificate indicates that:**

- a.) The applicant has a GDP Program that 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 accreditation, the principal elements of the applicant's GDP Program are consistent with the EU and the PIC/S Guidelines
- c.) That the applicant's relevant employees have received documented GDP Familiarization and Operational Training
- d.) That the accreditation period is two years in duration
- e.) That, upon receiving accreditation, the applicant is committed to maintaining the principal elements of its GDP Program for that period of two years

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

**GDP Assessment Fees (USD):**

The total cost of an accreditation process for a business entity is broken down into three categories:

- Fee for the accreditation assessment itself
- Fees for the required training
- Fee for revalidation after the two-year accreditation period

A differentiating factor in the business assessment process could be whether the overall assessment can be performed virtually or needs to be done in person.

For example, a freight forwarder, freight broker, customs agent, or insurance entity wouldn't necessarily require a "site" inspection, as these companies are principally involved in administrative processes - rather than the actual handling of goods.



Entities such as transportation vendors, warehousing/3 PLs, manufacturers, or distributors may require a visual inspection during the accreditation process.

### ***Assessment Fee Structure – Business Entity:***

Transportation company/trucking firm: **\$7,500.00**

Freight Broker/Freight Forwarder/Customs Agent/Insurer: **\$6,500.00**

Warehousing/3PL: **\$14,000.00**

Manufacturer/Distributor: **\$18,000.00**

If the applicant desired an independent assessment for an additional site(s), the additional assessments would be ½ of the overall fee (each) to obtain a unique accreditation for that particular location.

Payment of ½ of the Program fee is required in advance of the initiation of the necessary assessment. If the accreditation effort is successful, this would count as a first-year installment. The remainder of the fee is payable upon initiating the second year of the accreditation period. If the applicant is unsuccessful in attaining an accreditation (for whatever reason), they forfeit the first-year Program payment.

All stated fees do not include the cost of any travel expenses, which would be extra.

### **GDP Training Fees (USD) - Business Entity:**

There are three phases to the required training for a business entity to obtain accreditation. 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)

At least two individuals from each business entity that has applied for accreditation must be trained in all three phases of the program. It is suggested that more than two individuals should receive GDP introductory training.

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 in groups preferably no larger than 10.

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 companies 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 – Business Entity:**

Revalidation (or the process of renewing an accreditation after the two-year membership period) would cost the same as when the entity first entered the Program.

If the cost increased during the participation period, the entity could be allowed to renew their participation in the program at the last price they paid once.

Revalidation training (for the same people who had been originally trained in the program) would involve a one-day refresher course at the cost of **\$750.00/person**. Any new individuals to be trained would revert to the original training fee matrix.