

| AGENT OPERATING PROCEDURE (AOP) |             |               |             |                                                                                                               |
|---------------------------------|-------------|---------------|-------------|---------------------------------------------------------------------------------------------------------------|
| LSP Good Distribution Practice  |             |               | AOP-GDP-002 |                                                                                                               |
| Version No                      | 3.0         | Tier Level    | 1, 2 and 3  | <br>A Kuehne+Nagel Company |
| Issue Date                      | 13-May-2024 | Revision Date | 12-May-2026 |                                                                                                               |

### Approval:

|                          |                               |             |
|--------------------------|-------------------------------|-------------|
| Issued By:               | Emmanuel Remba                | 13-May-2024 |
|                          | EMEA Supplier Quality Manager |             |
| Issue Approver:          | Robert Tungatt                | 13-May-2024 |
|                          | VP Quality & Compliance       |             |
| Quick Quality Assurance: | Renata Markiewicz             | 13-May-2024 |
|                          | Quality Assurance Officer     |             |

This **Agent Operating Procedure (AOP)** is supplemental to and shall not amend or supersede the terms and conditions of any written agreement entered into between the Logistics Service Provider and QIC International Couriers LLC.

This AOP is issued under QIC International Couriers LLC (here in referred to as QIC) Logistics Service Provider (here in referred to as LSP) Quality Management System.  
The **purpose** is to ensure that our Logistics Service Providers are appropriately trained and monitored in the performance of key operational functions they are authorized to perform under QIC responsibility, direction and control.

#### Effective Date:

This AOP will become Effective One Calendar Month from the signature of the Logistics Service Provider Approver.

## 1. Purpose:

The purpose of this Agent Operating Procedure (AOP) is to document and confirm the procedure to be followed by Quick approved LSPs, in their performance of the prescribed function specific task, for which they are authorised by Quick to perform.

The specific purpose of this AOP is for Quick to document the requirements and responsibility of ALL staff undertaking the transportation of Time and Temperatures Sensitive Pharmaceutical Products, Healthcare and Life science materials in accordance with Good Distribution Practices

## 2. Scope:

The scope of this procedure applies to QuickSTAT LSP's designated within the Tier Level indicated on this Agent Operating Procedure, for the provision of services documented within the signed and agreed Quality and Technical Agreement (QTA).

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### 3. Safety, Health and Environment:

N/A – Administrative procedure.

### 4. Related Documents:

AWI-OPS-001-01 – LSP Dispatch & Delivery  
AWI-OPS-001-15 – LSP Collection  
AOP-GDP-001 – LSP Good Documentation Practice

### 5. Responsibilities:

| Function / Activity                                                                | Responsibility         |     |           |
|------------------------------------------------------------------------------------|------------------------|-----|-----------|
|                                                                                    | QIC Network Management | LSP | LSP Staff |
| Develop & ensure training of QIC Logistics Service Providers in QIC service        | X                      |     |           |
| Ensure all staff completing QIC service is trained and competent in relevant tasks |                        | X   |           |
| Ensure tasks are completed according to 6. Procedure                               |                        |     | X         |

### 6. Procedure:

#### Good Distribution Practices (GDP)

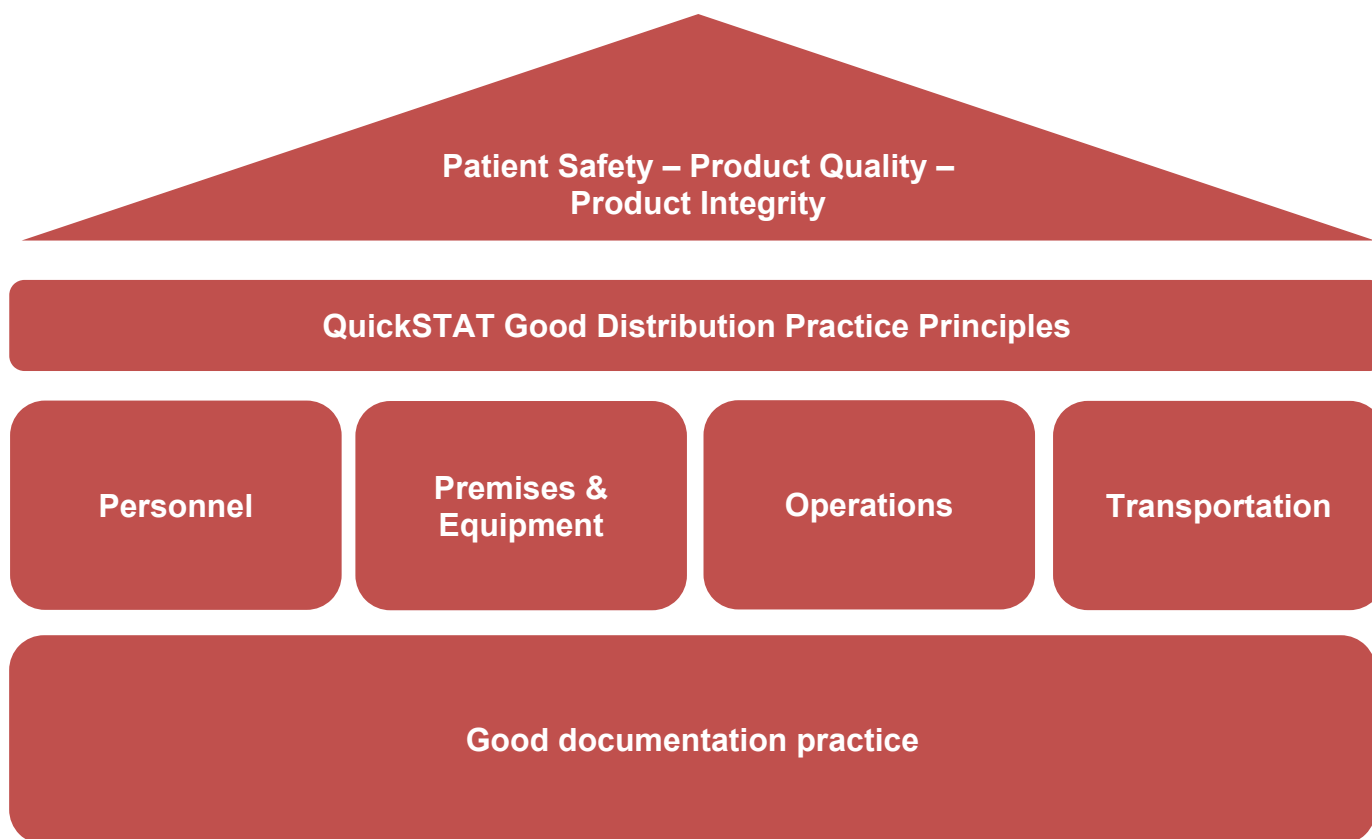
#### Section 1: Introduction to GDP

Good Distribution Practice is a guidance regime with the principle aim of insuring the safe & secure delivery of medicines to the patient, from point of manufacture or distribution to point of administration to the patient.

The GDP Compliance requires that all parts of the supply chain are trained and knowledgeable and that, Vehicles and equipment used to distribute, store or handle pharmaceutical products should provide adequate protection to the products to prevent exposure to conditions that could affect their stability and packaging integrity.

To insure this, all LSPs involved in the distribution of product on behalf of QuickSTAT must be trained in this AOP and understand the responsibility in every subsection of GDP. The following graphic shall introduce the sub-sections involved within GDP and section 2 shall provide the further detail:

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## Section 2: Good Distribution Requirements

In order to comply with the regulations relevant to the area in which the LSP is located, the below aspects cover the core responsibilities relevant to the safe & secure delivery of medicines to the patient:

### 2.1 Personnel

- 2.1.1** All staff handling product supplied by Quick must be adequately assessed for competency using a system based on proven experience and applicable training. Personnel hygiene of staff must be well kept in order to avoid any negative contamination to the product.
- 2.1.2** At all times personnel handling the product within the warehouse or upon deliver must comply to the below requirements:
- Be well groomed and suitably dressed
  - Be professional and polite
  - When communicating with the customer, a driver should only discuss the elements of the job they are performing.
  - Carry valid identification and produce it upon request from the customer

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## 2.2 Premises & Equipment

- 2.2.1** Premises used to temporarily hold product as part of the transportation supply chain and conditioning of gel packs must be appropriately validated. The premises should include clear segregation of areas in order to avoid handling errors and an accidental swap of product.
- 2.2.2** Premises must:
- Have an appointed pest control regime in place
  - Have a documented cleaning regime in place
  - Be secure with a demonstratable way of controlling exits and entries
- 2.2.3** Vehicles must be checked daily for road worthiness; checks must be documented and include but not limited to:
- Fuel
  - Oil
  - Water
  - Tyres
  - Cleanliness
- 2.2.4** Cleanliness of the vehicle must be detailed in terms of area coverage. The vehicles must be clean internally and externally to a degree where medicinal products will be stored free of pests, dirt, dust and other items such as fuel cans.
- 2.2.5** Equipment impacting the storage of any product supplied by Quick with the intention of use for the distribution of medicinal product must be maintained regularly enough to provide efficient and safe functionality. Temperature controlled areas must be mapped prior to use.

## 2.3 Operations

- 2.3.1** All operations performed by QuickSTAT LSP must be in line with the instructions given, which derive from the Quick QMS.
- 2.3.2** Operations completed must be sufficiently documented at each stage. Within the duty of supply, all original copies of documents (e.g. delivery notes) must be kept and archived for appropriate traceability.
- 2.3.3** All operatives that are tasked with handling product must complete the activities in line with the packaging labels. All products will have specific labels that determine their classification, i.e dry ice packaging or dangerous goods. These products must be segregated and handled in line with the product training.
- 2.3.4** Product seals must not be broken while in the care of the QuickSTAT LSP, unless authorized by QuickSTAT via a traceable instruction.
- 2.3.5** Any subcontracted activity must be approved via an approved supplier qualification procedure in order to sustain the operational values.

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## 2.4 Transportation

- 2.4.1** Shipments must **only** be delivered to the address stated on the delivery note and into the care / premises of the Named Consignee. Products should not be left on alternative premises or delivered to an unauthorised person.
- 2.4.2** Security of the vehicle and product must be maintained therefore the below factors must be sustained:
- All vehicles transporting product should be locked during transit and when unattended
  - Products must not be exposed to conditions outside of the validated packaging instruction
  - Products must be secured and free from risk of damage during transit
  - The conditions inside the vehicle must not adversely affect the product and should not contain any elements that could contaminate the product
  - Drivers must ensure that pallets are not double stacked
  - Product must be protected from external temperature extremes
  - Only hardsided vehicles should be used, curtain side vehicles should be avoided. The use of open bed trucks is not permitted, unless authorised by QuickSTAT.
- 2.4.3** Delivery of products requiring special conditions must be delivered in accordance with the additional special instruction provided by QuickSTAT.
- 2.4.4** All documentation completed by the QuickSTAT LSP must be completed in line with Good Documentation Practice AOP-GDP-001.
- 2.4.5** All drivers, tasked with collecting product must ensure that on collection, they arrive at the agreed time and report to the named person only. In the event that the named person is not available, QuickSTAT must be informed prior to proceeding.

## 7. Document History:

| Version Number | Reason for Change                                                                                                                          |
|----------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| 1.0            | This is the first issue of this AOP                                                                                                        |
| 2.0            | Change of name from 'Driver Good Distribution Practice' to 'LSP Good Distribution Practice'<br><br>Re-structure of the content and format. |
| 3.0            | Addition of AWI-OPS-001-01 LSP Dispatch & Delivery and AWI-OPS-001-15 LSP Collection to related documents                                  |