Guidance on the interpretation and implementation of European Good Distribution Practice

Chapter 7 – Outsourcing

A joint publication of the European Compliance Academy and the Pharmaceutical Quality Group of the Chartered Quality Institute

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Preface

It is of key importance that medicinal products are not only made to a high quality in accordance with Good Manufacturing Practice, but that the quality and integrity of these products are maintained through the entire supply chain to the patient. This is where Good Distribution Practice (GDP) comes into play.

The distribution network for medicinal products is often complex, involving many different parties. In addition to the challenges associated with this complexity, there is also a growing threat from criminal activities seeking to introduce falsified medicines into the legal supply chain. The European regulators recognised several years ago that there was a need to update the content of the 1994 GDP guideline to take into account advancements in practices and changes in legislation since it was issued. A consultation draft was issued in mid 2011 and, following the receipt of many comments from interested parties, a final revised version was issued in March 2013 with an effective date of 8 September 2013. A corrected version dated 5 November 2013 was published in the Official Journal on 23 November 2013 to be effective immediately. This version corrects factual mistakes identified in subchapters 5.5 and 6.3 of the March 2013 version and also gives more explanations on the rationale for the revision.

The new guideline has a much stronger focus on the quality system with clear responsibilities and processes and the application of risk management principles. More detailed guidance is given on most elements. New chapters relating to transportation and specific provisions for brokers have been added.

The Pharmaceutical Quality Group issued a monograph on Pharmaceutical Distribution in 1997 and initiated planning to revise this in line with the new regulatory guideline. Whilst undertaking this planning it was identified that the European Compliance Academy were also planning to produce some guidance in response to requests from members. The two organisations therefore decided to join forces and set up a joint steering committee led by Afshin Hosseiny with Philip Butson, Ashley McCraight and Oliver Schmidt.

An early decision was that we would initially target key chapters and issue each as it became available rather than wait until a complete guide had been prepared. This has enabled us to shorten the time to the provision of some guidance and also provides an opportunity for us to collect feedback and enhance the material before issuing a complete guide. The first versions of the chapters will have different formats and styles due to the different volunteer teams involved in their preparation which we have chosen not to edit into a common format for the time being. We would appreciate feedback on what works best for you, the user.

In this document, text from the EMA guideline is given in italic Calibri font, followed by guidance from the team in normal Times New Roman font.

Please provide any feedback and suggestions for improvement using the email address monographs@pqg.org or info@gmp-compliance.org.

For this particular chapter on Outsourcing, we would like to thank the hard work of the authoring team Neil Wayman, Chris Forrest, Ursula Greene, Fiona Ryan, Emma O'Kelly and Tatjana Vorobjova. Additional material was provided by Afshin Hosseiny and editing was undertaken by Philip Butson, Afshin Hosseiny and Ashley McCraight.
A note about terminology

The GDP Guide uses the term ‘Contract’ for the written arrangements between the Contract Giver and Contract Acceptor. A number of different documents may make up the ‘contract’ covering both commercial and technical/quality arrangements, e.g., ‘Master Service Level Agreements’; ‘Commercial Agreement’; ‘Technical/Quality Agreements’. For consistency, the term ‘Contract’ is therefore used in the ECA/PQG guidance and relates to both technical and quality arrangements of outsourcing.

7.1 Principle

Any activity covered by the GDP Guide that is outsourced should be correctly defined, agreed and controlled in order to avoid misunderstandings which could affect the integrity of the product. There must be a written Contract between the Contract Giver and the Contract Acceptor which clearly establishes the duties of each party.

- What is the rationale for this point in the guidance?

To ensure that adequate consideration is given to outsourced GDP activities such that an appropriate level of oversight and management can be demonstrated where such an activity/service has the ability to impact product quality, patient supply and safety of the product.

- What are the risks and benefits associated with this aspect of the guidance?

It is necessary for companies to understand the importance of effective oversight and management of all outsourced activities and to be aware of and appropriately mitigate the risks associated with handing over responsibility for certain activities to a third party. If the Contract is inadequate, then there is a risk that both parties (Contract Giver and Contract Acceptor) will be unclear as to the expectations, requirements and standards to be applied during the provision of the service. This lack of understanding could result in adverse impact on product or failures in supply. A good Contract will mitigate these risks, providing the Responsible Person with confidence that adequate controls are in place and maintained.

- How might this be implemented/ what does it mean?

Companies engaged in outsourcing as Contract Givers should have a procedure detailing the activities that must be undertaken to put in place clear Contracts and provide an appropriate level of oversight and management of contractors. Likewise, companies intending to be Contract Acceptors should have a procedure which ensures that their requirements are met by the Contract. Both parties should ensure that a Contract is written, reviewed, approved and readily accessible to relevant staff prior to any work being outsourced. Both parties should ensure that the Contract is revised as required to maintain its currency.

- Additional guidance

An outline Contract for GDP outsourcing is given as an Appendix to this document in order to provide additional guidance on required content. It is stressed that every Contract Giver – Contract Acceptor arrangement is unique and should therefore be subject to an appropriately customised Contract with input from relevant staff from both parties.
### 7.2 Contract Giver

The Contract Giver is responsible for the activities contracted out.

#### What is the rationale for this point in the guidance?

The Contract Giver is ultimately responsible for the product in the marketplace even where certain activities are contracted out. They are therefore responsible for defining appropriate controls in a clear written Contract and monitor to ensure that the Contract Acceptor performs the outsourced activity as required.

#### What are the risks and benefits associated with this aspect of the guidance?

Where responsibilities are not clearly understood, it may potentially lead to risk to product quality with consequent risk to the patient due to mistakes that could be made by the Contract Acceptor’s staff.

#### How might this be implemented/what does it mean?

The Contract Giver should have procedures that include appropriate arrangements for the selection and management of contractors, including monitoring/oversight ensuring that a Contract is put in place and accepted before any outsourced work takes place.

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### 7.2 Contract Giver

The Contract Giver is responsible for assessing the competence of the Contract Acceptor to successfully carry out the work required and for ensuring by means of the contract and through audits that the principles and guidelines of GDP are followed. An audit of the Contract Acceptor should be performed before commencement of, and whenever there has been a change to, the outsourced activities. The frequency of audit should be defined based on risk depending on the nature of the outsourced activities. Audits should be permitted at any time.

#### What is the rationale for this point in the guidance?

Given the preceding point that the Contract Giver is responsible for the activities contracted out, this clause provides further detail regarding the assessments that the Contract Giver is responsible for carrying out to ensure that the Contract Acceptor’s systems, staff and facilities are fit for use. Such assessments allow the Contract Giver to understand and mitigate risks associated with the outsourced activity.

The assessment of the suitability of the Contract Acceptor goes beyond initial selection and approval and should be a feature of the on-going relationship between the parties for the lifetime of the contract, so repeat audits should be undertaken at a frequency determined by the Contract Giver’s risk assessment.

It should be possible for audits to be carried out at any time the Contract Giver determines to enable ‘for cause’ investigations in the event of a problem arising.

#### What are the risks and benefits associated with this aspect of the guidance?

If the Contract Giver fails to adequately assess the competence of the Contract Acceptor to successfully carry out the required work, then there is a risk that the contract will be awarded to an unsuitable contractor resulting in quality issues which could affect the supply chain or patient safety.

If periodic audits of the Contract Acceptor are not frequent enough there is a risk that GDP standards could slip without the Contract Giver being aware until a significant issue occurs. However, there is a risk of wasting resources if audits are conducted too frequently.
When the Contact Giver selects an appropriate party to carry out the contract activity/activities and ensures, through an appropriate level of oversight that the Contract Giver remains suitable, this will help build understanding of the Contract Acceptors business and organisation and will facilitate relationships and future communications.

A key element of risk assessment is to ensure a thorough understanding of the full supply chain, making sure that all contractors, sub-contractors, and their facilities are known. Risk is increased where supply chains are long and complex involving many steps and actors, e.g., hub/depot sites, freight forwarders.

**How might this be implemented/what does it mean?**

There are four key steps in outsourcing:

1. Selection of a contractor from a commercial perspective based on declared capabilities and cost
2. Auditing to ensure that the required GDP standards and any specific technical requirements are in place
3. Approval of the contractor and agreeing the Contract, including Key Performance Indicators
4. Maintaining the approved status of the contractor through monitoring and periodic reassessment

A risk-based approach should be used throughout to minimise the risk of using an inappropriate Contract Acceptor without excessive resource expenditure. Risk assessments should be documented and periodically reviewed to ensure that the risk level and required level of oversight has not changed.

From experience, most outsourced activities should be audited every 2-3 years to maintain a good understanding of the effectiveness of the Contract Acceptor’s quality system and personnel. More frequent audits will typically be undertaken during the early years of an outsourcing arrangement to build initial understanding and good relationships.

The text states that assessments of the competence of the Contract Acceptor should be “through audits”. This will typically involve an assessment at the point where the service is provided (e.g., cleaning); for some activities (e.g., pest control) it is possible that this could be achieved through a questionnaire and desk-top review of key documents.

The scope of audits should be determined based on current and potential future outsourced activities (which may be a sub-set of the full services offered by the contractor). During the audit particular attention should be paid to the level of non-conformances and the Corrective and Preventive Actions (CAPAs) as these may provide valuable insight of the overall level of GDP compliance at the site. Recent regulatory performance is also important to understanding potential risks arising from the use of the contractor.

Where there has been a change to the scope of the contracted activities, a formal review in the form of an audit should be carried out to ensure that the contracted party remains suitable to carry out the contracted activity.

The Contract should specify that the Contract Giver can perform an inspection of the Contract Acceptor’s site at any time with an appropriate notice period and that if required a representative of a Regulatory Authority can enter the premises of the Contract Acceptor for the purpose of auditing in relation to GDP activities carried out on behalf of the Contract Giver.

Note that auditing is only one part of ensuring the ongoing performance of the Contract Acceptor. Agreement on performance indicators and good regular communication between parties is also needed.
7.2 Contract Giver

The Contract Giver should provide the Contract Acceptor with all the information necessary to carry out the contracted operations in accordance with the specific product requirements and any other relevant requirements.

- **What is the rationale for this point in the guidance?**

It should be obvious that the Contract Giver needs to provide the Contract Acceptor with all the information necessary for them to ensure that they do as expected. This could include specific product requirements, such as:
  - storage conditions
  - other relevant requirements
  - particular documentation requirements for certain countries.

It should not be assumed that the Contract Acceptor already has the required information or can obtain it through other sources.

- **What are the risks and benefits associated with this aspect of the guidance?**

Where this information is not freely exchanged between the parties the Contract Acceptor will not be able to ensure that they act in accordance with the Contract Giver’s requirements and this may result in a subsequent risk to patients.

- **How might this be implemented/what does it mean?**

  - The Contract Giver should provide the information that they believe the Contract Acceptor will require as part of the contractual arrangements.
  - The Contract Acceptor should provide the Contract Giver with a list of their requirements.
  - A joint review should occur to ensure that both parties are satisfied with the information provided.

The Contract template in the Appendix provides a number of points to consider that will facilitate this information exchange.

The Contract Giver and Contract Acceptor should ensure that the Contract includes appropriate confidentiality clauses that enable full disclosure of information required by the Contract Acceptor, e.g., product safety datasheet so that accidental spillages can be managed.

Where new information becomes available, the Contract should be updated.

7.3. Contract acceptor

The Contract Acceptor should have adequate premises and equipment, procedures, knowledge and experience, and competent personnel to carry out the work ordered by the Contract Giver.

- **What is the rationale for this point in the guidance?**

The Contract Acceptor should have adequate premises, equipment, procedures and personnel to enable them to fulfil the requirements of the Contract Giver in a compliant manner and safeguard the product on its journey from manufacturer to patient.

- **What are the risks and benefits associated with this aspect of the guidance?**

Without these things in place and verified by the Contract Giver, there is risk to product quality, patient supply and safety.
How might this be implemented/ what does it mean?

This is implemented by applying the general requirements of GDP and any additional specific requirements in the Contract.

Although it is primarily the responsibility of the Contract Giver to ensure that the Contract Acceptor is suitable, the Contract Acceptor should identify any challenges to the Contract Giver prior to accepting work. For example, if they do not have sufficient capacity of the stipulated storage facility for the anticipated volume of work over a full year.

<table>
<thead>
<tr>
<th>7.3. Contract acceptor</th>
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<tbody>
<tr>
<td>The Contract Acceptor should not pass to a third party any of the work entrusted to him under the contract without the Contract Giver’s prior evaluation and approval of the arrangements and an audit of the third party by the contract giver or the Contract Acceptor. Arrangements made between the Contract Acceptor and any third party should ensure that the wholesale distribution information is made available in the same way as between the original contract giver and Contract Acceptor</td>
</tr>
</tbody>
</table>

What is the rationale for this point in the guidance?

To ensure that where sub-contracting takes place it occurs in an appropriately controlled manner.

To ensure that the Contract Giver maintains a full knowledge of the supply chain and is in a position to evaluate any changes and assess their impact.

To ensure that where a Contract Acceptor sub-contracts work to another third party that the arrangements agreed with the Contract Giver are fully maintained.

What are the risks and benefits associated with this aspect of the guidance?

The risks with further sub-contracting are that standards become lower as delegation extends beyond the initial contracting parties.

How might this be implemented/ what does it mean?

The Contract Acceptor should have a process to manage sub-contracting.

Approved sub-contractors should be defined in the Contract and any changes notified to the Contract Giver. However, the Contract Giver should specify in the Contract when they would wish to audit and/or approve sub-contractors prior to use.

<table>
<thead>
<tr>
<th>7.3. Contract acceptor</th>
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<tbody>
<tr>
<td>The Contract Acceptor should refrain from any activity which may adversely affect the quality of the product(s) handled for the Contract Giver.</td>
</tr>
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</table>

What is the rationale for this point in the guidance?

To ensure that product quality is not adversely affected in the supply chain.

What are the risks and benefits associated with this aspect of the guidance?

If the Contract Acceptor engages in activities that may adversely affect the quality of products there is a potential risk to patients arising from use of sub-standard product and potential consequent liability on the business and/or key personnel.
Examples could include:
- Activities resulting in physical damage to product packs
- Transportation or storage in close association with materials that could taint the product
- Storage or transportation at temperatures outside the specified storage conditions which can lead to chemical or physical degradation, or contamination, e.g., of sterile vials damaged by freezing allowing microbial contamination.

**How might this be implemented/ what does it mean?**

This requirement can be met by:
- Complying with general GDP requirements
- Complying with any product specific requirements detailed in the Contract
- Taking account of any additional information provided by the Contract Giver
- Being mindful of limitations in knowledge and if in doubt asking the Contract Giver for advice

### 7.3. Contract Acceptor

*The Contract Acceptor must forward any information that can influence the quality of the product(s) to the Contract Giver in accordance with the requirement of the contract.*

**What is the rationale for this point in the guidance?**

To ensure that product quality is maintained throughout the supply chain.

To ensure that the party best able to determine potential impact, is aware of information and can take appropriate action or provide advice. The Contract Giver should either have the knowledge or know where this may be obtained. The ultimate expertise on the product and parameters which may impact its quality will lie with the Marketing Authorisation Holder.

**What are the risks and benefits associated with this aspect of the guidance?**

If information that can influence the quality of the product(s) is not reported to the Contract Giver there is a risk that it will not be appropriately assessed and acted on.

**How might this be implemented/ what does it mean?**

By building regular and effective communications with the Contract Giver. Face to face meetings are ideal but Skype or teleconferences can be very effective.

Where the Contract Giver does not have the expertise to assess the information provided, they should forward the information and seek advice as appropriate. For example, if a third party logistics provider is Contract Acceptor to a wholesaler (Contract Giver) and the information relates to a temperature excursion during transportation, there will probably be a need to share the information with the Marketing Authorisation Holder and seek their advice as to whether the product remains suitable for use.
APPENDIX: OUTLINE CONTRACT FOR USE IN GDP OUTSOURCING

DISCLAIMER: This outline is provided in order to prompt consideration and give additional guidance on content. It is stressed that every Contract Giver – Contract Acceptor arrangement is unique and should therefore be subject to an appropriately customised Quality/Technical Agreement with input from relevant staff from both parties. ECA and PQG take no responsibility for any Quality/Technical Agreements that may be created based on this outline.
QUALITY/TECHNICAL AGREEMENT Between

(1) Contract Giver details, including licence holding detail

(2) Contract Acceptor details, including licence holding detail

SIGNED

(1)                        Date

(2)                        Date

Review Date: X years from final signature date
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1 Definitions

Unless otherwise specifically provided in this Agreement, the following terms shall have the following meanings:

EXAMPLES:

**Applicable Laws and Regulations**

With respect to each Product, means all supranational, national, and local laws, and the rules, regulations, guidances, guidelines and requirements of all Regulatory Authorities in effect from time to time applicable to the handling of such Product in Territory including applicable cGMP principles and GDPs.

**Distribution**

With respect to each Product means all processes related to the handling from receipt of order up to customer invoicing.

**FMD**

Falsified Medicines Directive (EU/EEA applicable)

**Service Provider Procedures**

means Service Provider’s written standard operating procedures in full compliance with Applicable Laws and Regulations.
Introduction and Scope

Detail in this section, for example,

- The purpose and scope of the agreement,
- Business expectations,
- Renewal period for QTA and responsibilities for update
- Responsibilities for maintaining licenses/approvals etc. for contracted services
- Reference to a separate commercial agreement including any legal and financial statements (including any compensation clauses for damages, poor performance etc).
- Confidentiality arrangements

2 General

Example clauses:

2.1 Service Provider shall conduct all contracted activities in compliance with all applicable Laws and Regulations, the applicable Product Requirements and Service Provider Procedures.

2.2 Service Provider shall, among other things ensure that all of its personnel engaged in the service provision shall have the education, training (including GDP training), and experience sufficient to perform their assigned functions. This includes any temporary/contract resource.

2.3 Service Provider shall have facilities and equipment of the required standard in place in order to ensure provision of service according to current GDP standards.

2.4 Service provider shall ensure that each Product is prepared for transport in accordance with Applicable Laws and Regulations and the labelling for such Product such that the quality and integrity of such Product is not compromised during transport. Where required by Contract Giver, specific temperature monitoring devices shall be consigned with each shipment of Product to verify that the required conditions have been complied with.

2.5 Perform and document validation, qualification and calibration, as appropriate for all equipment, facilities, processes, computers, systems, electronic records and cleaning used
in the Storage and Handling of each Product in accordance with Applicable Laws and Regulations and the applicable Product Requirements.

2.6 Further clauses – to confirm compliance in the following aspects: environment control/monitoring, housekeeping, specific Responsible Person activities, FIFO/FEFO requirements, Documentation retention requirements and lead times for access/provision of such documentation to contract Giver, SOP requirements (can include a list of SOPs), Self Inspection requirements, expectations versus continuous compliance improvement, sub-contractor management/auditing, need for written procedures, QMS expectations, Product security expectations, Safety Health and Environment expectations, waste management.

3 Receipt, Identification and Inspection of Incoming Products

Example clauses:

3.1 Contract giver shall deliver Product to Service Provider with accompanying documentation showing identity and quantity of the Product in accordance with Applicable Laws and Regulations and Product Requirements.

3.2 Service Provider shall identify and inspect all Products it receives for any damage or evidence of tampering and for the integrity of the seal of the immediate container, if applicable. Any Product container suspected of being tampered with must be segregated and reported to Contract Giver within x hours. Shippers that are partially full are not required to be opened for checking contents.

3.3 Service Provider shall perform receipt checks and disposition decision in their Warehouse Management System according to internal written procedures to include:

3.3.1 General – damage and general condition.

3.3.2 Temperature compliance during transport

3.3.3 Physical delivery of Product matches expected delivery of Product (Product and Product code, quantity and expiry date.)

3.3.4 Products will be stored one batch per one pallet per pallet location.
4 Personnel

Detail in this section, for example,

- Responsible Person (RP) and Deputy RP will be appointed
- Personnel involved in GDP activities have appropriate ability and experience and are periodically trained in GDP and in the procedures that pertain to their job description
- Training records will be maintained

5 Premises/Storage

Detail in this section, for example,

- Premises to ensure proper conservation, security and distribution of products
- Pest control program
- Temperature mapping
- Monitoring and recording of storage conditions
- FEFO (First Expired First Out) stock rotation system
- Separate and segregated area for receipt and storage of rejected goods, returned products and quarantined products

6 Storage of Product

Detail in this section, for example,

- Storage conditions available (e.g. storage under refrigeration (2-8°C), storage less than 25°C, controlled drug storage etc)
- Documentation, investigation and communication of temperature excursions

7 Delivery to Customers

Detail in this section, for example,

- All product is distributed in accordance with GDP
• Distribution only to parties entitled to receive products

• Transport under any special storage conditions required using own vehicles or approved carriers

• Traceability

8 **Quality Assurance and Quality Control**

Detail in this section, for example,

• Product disposition responsibilities

• Customer verification responsibilities

• Responsibility for attaching temperature monitors, where applicable

• Right for Contract Giver to audit, including notice periods and requirement for contract acceptor to define and deliver CAPA

• Arrangements for notifying each other of regulatory inspections, and details to be shared, how to deal with actions etc.

• Prohibition of outsourcing activity to 3rd party without Contract Giver approval.

• Any specific activity exclusions (such as product rework)

• Key Performance Indicators, performance review meeting frequency.

9 **Deviations and Investigations**

Detail in this section, for example,

• How to handle non-conformances/deviations including timescales and documentation requirements.

• CAPA expectations

• Issue Management processes, including references to key contacts in Appendices

• Recall roles and responsibilities, including expected timescales, documentation and product handling expectation.
10 **Change Control**

Detail in this section, for example,

- Requirement for change management according to a written procedure and including QRM principles
- Expectations to inform the Giver/Acceptor party of changes, and prior approval expectations.

11 **Product Quality Complaints/Adverse Events/Counterfeits**

Detail in this section, for example,

- Two-way communication expectations in the event of the above, including timing (verbal and written)
- Responsibilities for respective investigations, including documentation and timing.

12 **Product Returns and stock adjustments**

Detail in this section, for example,

- Responsibilities for management of returns, and requirements for specific checks.
- Responsibilities for disposition decisions, and criteria for accepting material back to saleable stock.
- Any specific “above GDP” requirements – for example a policy of no cold chain returns.
- Stock discrepancy procedures/responsibilities, and what to do in the event of possible product quality impact of a discrepancy.
- Product destruction requirements (Written authorisation may/may not be required from contract Acceptor, Certificate of Destruction, provision of an itemized list to the Contract Acceptor, method of disposal etc.)
13 **Product Recall**

Detail in this section, for example,

- Responsibilities, timescales and documentation requirements.
- Decision owners
- Communications with regulatory authorities
- Requirements for quarantine, reconciliation reports etc.
This matrix is for reference purposes. The full wording of each Article is contained in the main body of the QA Agreement and takes precedence over this matrix wording in the event of any conflict.

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<tr>
<th>RESPONSIBILITY FOR</th>
<th>Contract Acceptor</th>
<th>Contract Giver</th>
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<td>INTRODUCTION AND SCOPE</td>
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<td>GENERAL</td>
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<td>RECEIPT, IDENTIFICATION AND INSPECTION OF INCOMING PRODUCT</td>
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<td>QUALITY ASSURANCE AND QUALITY CONTROL</td>
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List Sites relevant to service provision
List, for example, the products applicable to the service provision, with key information tabulated. Consider product description, codes, storage and shipping temperature requirements, temperature monitoring requirements, and hazardous materials etc – all the information a Contract acceptor might need to execute responsibilities properly.
Contact names

### Contract Giver

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<th>Primary Contact</th>
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### Contract Acceptor

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Deviation definition and Form to report Deviations to Contract Giver

Define here what events should be reported to contract giver, and provide a template for reporting such events.
Provide a standard form to Contract Acceptor to inform Contract Giver of proposed changes.
Define here those changes at Service Provider that should be communicate/approved using the form in appendix 7.

Include a list of approved sub-contractors and suppliers, changes to which require prior approval.
Define Key Performance Indicators and review processes

e.g.

- number of deviations due to service provider (specify target limit)

- complaints due to service provider (specify target limit)
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<th>Revision No.</th>
<th>Description of Change</th>
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