Introduction

Quality Agreements have been utilized in the pharmaceutical industry for many years to describe responsibilities, costs, and contract terms for the sale or purchase of goods, services, and clinical entities. Quality Agreements are a tool to clearly define responsibilities for both the sponsor and vendor to ensure proper oversight and compliance is maintained. The poster focuses on the Quality Agreements in the GCP world.

Types of Pharma Quality Agreements

<table>
<thead>
<tr>
<th>Type of Contact/Vendor</th>
<th>Service Provided</th>
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<tbody>
<tr>
<td>Manufacturer</td>
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<td></td>
<td>Provides raw materials to manufacture API or API intermediates.</td>
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<td>Laboratory</td>
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<td></td>
<td>Performs tests or assays on investigational products.</td>
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<td>Excipients Supplier</td>
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<td>Supplies excipients used in the drug product formulation.</td>
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<tr>
<td>API Intermediates</td>
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<tr>
<td></td>
<td>Provides raw materials utilized to manufacture API or API intermediates.</td>
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<tr>
<td>Raw Material Supplier</td>
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<tr>
<td></td>
<td>Provides raw materials utilized to manufacture API or API intermediates.</td>
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<tr>
<td>Supplier</td>
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<tr>
<td></td>
<td>Provides raw materials utilized to manufacture API or API intermediates.</td>
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<tr>
<td>Facility</td>
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<tr>
<td></td>
<td>Provides raw materials utilized to manufacture API or API intermediates.</td>
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<tr>
<td>CRO</td>
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<td></td>
<td>Provides clinical services and products that are used in the clinical process.</td>
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Benefits of a Quality Agreement in the GCP Setting

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Ensures GCP compliance</td>
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<tr>
<td>Ensures the sponsor/vendor relationship is well-defined and understood</td>
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<td>Ensures documented collaboration and oversight</td>
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Key Performance Indicators for Compliance through Quality Agreements

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<thead>
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<tbody>
<tr>
<td>Measure the performance of the Quality Agreement to ensure compliance</td>
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<tr>
<td>Ensure that the Quality Agreement is well-defined and understood</td>
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Conclusion

Putting a sound Quality Agreement in place at the start of the business relationship can prevent problems later. The Quality Agreement is intended to define responsibilities relative to quality tasks to assure the development of safe products. A Quality Agreement is based on the quality procedures in place at both the sponsor and vendor. The Quality Agreement is intended to be a contract between the parties. The agreement should be negotiated and reviewed by the parties. The Quality Agreement is intended to define responsibilities relative to quality tasks to assure the development of safe products. The Quality Agreement should be reviewed on a regular basis to ensure it is still relevant. The Quality Agreement is intended to define responsibilities relative to quality tasks to assure the development of safe products. The Quality Agreement should be reviewed on a regular basis to ensure it is still relevant.