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Supplier Qualification: Pre-Selection Process

by Stefanie Blum, PhD

If a new service or material is required, the competent department first checks whether this service or material can be obtained from an already qualified supplier. If this is the case, the department initiates a follow-up qualification. Otherwise, the identification and pre-selection of potential new suppliers is carried out by the department itself.

In this context, the department defines an employee as coordinator ("SQ coordinator *SUPPLIER COMPANY*"). This employee is responsible for coordinating the pre-selection and qualification of a specific supplier. Where necessary, the responsible employees request support from other departments, e.g. purchasing or quality assurance, via the SQ coordinator.

Chicken or egg – that is the question here. The qualification of suppliers is time-consuming and can therefore be perceived as a nuisance. So the question naturally arises: (From when) does it have to be done? Why make the effort at all if the supplier is possibly not even eligible? In the case of material suppliers, for example, would it not be better to wait for the results of the first test batches produced with the new material before starting the qualification procedure? If this shows that the new material is not suitable, then the clarification of regulatory and financial aspects could simply be dispensed with. Or?

That's right. But what if the test batches succeed and it then turns out that the supposed active ingredient supplier does not have a GMP certificate and does not intend to obtain one?

Whatever you do, it's wrong ...

It is therefore a good idea to precede the actual supplier qualification with an easily manageable pre-selection process. During this pre-selection, the most important basic requirements of a future cooperation can be clarified (and, if necessary, already optimised) with reasonable effort. If the result of this pre-selection is positive, the actual qualification of the supplier follows.

As part of the pre-selection process, the department shall clarify at least the following points – insofar as they apply to the material/service and accordingly to the supplier (bullet points in bold, the sub-points are exemplary in nature):

- **Basic technical suitability and general information, e.g.**
  - Expertise of the supplier
  - Production process (synthetic, human, animal, plant, microbiological origin, genetic engineering production)
  - Specification (pharmacopoeia or in-house)
  - Supplier capacity (largest/smallest batch size, delivery times, lead times)
  - Possibility to order smaller test batches
  - Production site(s)
  - Supply chain
  - Product range

- **Basic regulatory suitability and quality aspects, e.g.**
  - REACH requirements, safety data sheets
  - BSE/TSE requirements
  - Quality system (e.g. GMP, ISO, accreditation ...)
  - Inspection history
- **Basic financial suitability, e.g.**
  - Financial stability
  - Prices, price structure, possible discounts
- **Basic cooperative aptitude, e.g.**
  - Dealing with enquiries and response time
  - Kindness
  - Flexibility
  - Possible language problems

The SQ coordinator documents this pre-selection together with the master data, the risk class and the category of the supplier using the "Supplier Qualification" form. In coordination with the employees involved in the pre-selection, he also carries out the evaluation of the supplier.

This evaluation initially comprises the three-stage evaluation of the individual selection points (individual evaluation):

- A - very good, no measures required
- B - satisfactory, action optional
- C - deficient, action required

Based on this evaluation of the individual selection points, the SQ coordinator in turn carries out the overall evaluation of the supplier in consultation with the employees involved in the pre-selection:

- YES - the supplier is basically suitable, qualification process is to be carried out
- NO - no cooperation with the supplier planned

Suppliers with deficiencies (evaluation of one or more parameters with "C") are then evaluated with "NO" if the identified deficiencies cannot or should not be eliminated by suitable measures (e.g. for cost or time reasons).

If the supplier is rated "YES" overall, the SQ coordinator transfers the measures that are possible in the case of a rating of "B" and mandatory in the case of a rating of "C" into the CAPA system. The SQ coordinator documents the CAPA number(s) on the "Supplier Qualification" form.

The SQ coordinator now also starts the change control procedure and in this course arranges for QS to add the potential supplier with the status "in qualification" to the ERP system Logifixx.

If the supplier is evaluated with "NO", the process ends and no further qualification takes place.

The documents that Maas & Peither Pharma GmbH has already received in the course of the pre-selection process are documented by the SQ coordinator and these documents are filed in accordance with the requirements of Section 7 Document Management and Filing.

Finally, the SQ coordinator and QS conclude the pre-selection with a dated signature on the "Supplier Qualification" form.

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