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An Overview on Supplier Qualification Process in Pharmaceutical industry

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ABSTRACT-
To ensures quality & safety of medicines drug industries follow Good Manufacturing Practices in all working systems. One of the parts of GMP is to certify the manufacturer of raw materials to meet products quality requirement and to avoid major consequences like recalls, deaths, adverse events & serious illness.
Supplier qualification is the process by which the supplier assessment is done to evaluate the supplier to make sure that it can deliver goods & services as per the quality standards set by the organization. This article describes about need of supplier qualification, the detailed course of actions for qualifying manufactures of all raw materials, packaging materials along with service providers. Also it explains the supplier periodic reassessment process to maintain the quality of the materials & services, supplier ratings and supplier removal action from qualified supplier list if it doesn't adhere to the defined quality criteria. Supplier should be informed about its removal with proper reasons and after satisfactory action from supplier, it can be further qualified.
Key words: GMP, supplier qualification, quality assessment.

INTRODUCTION

The pharmaceutical industry is one of the important & biggest industrial sectors all around the globe. As it is directly connected to human health medicinal product quality is a key concern for all organizations. To deliver the best quality of product all finished & raw
material manufactures are adhering to the Good Manufacturing Practices principles (GMP). It is part of the quality assurance which ensures that products are producing with qua lity standards and suitable
for use. The main objective of the GMP is to reduce the risk associated with pharmaceutical production. There are mainly two types of such risks as cross-contamination and false labelling.
Under cGMP rules and regulations, pharmaceutical product manufacturer has the whole responsibility of maintaining the quality standards throughout all the operations together with the quality of components as active ingredients, excipients and the packaging
materials. Hence to ensure to manufacture a great q uality of product industries
are paying more attention to purchasing good qualit y of
raw materials by following the supplier qualificatio n stage before placing an order to the supplier. The various steps included in the qualification process depending upon
the type of material & its direct impact on the quality of the finished product for example API, excipient & packaging material.

Need of supplier qualification in Pharmaceutical Industries [1]

As a medicinal product manufacturer, every organization is paying more attention to product safety, quality & effectiveness. Also, the cGMP regulations for final medicinal products are clearly defined in each country and region by their respective regulatory authorities.

The main objectives of all authorities are the same as below:
- To deliver high quality, safe & effective medicines manufactured and distributed under controlled procedures to treat diseases and
- To stop deaths, major diseases, unexpected incidents or recalls resulting from inadequacy in the production and distribution processes.

There are many cases in the pharmaceutical industry, due to the failure of Regulatory Authorities and lack of appropriate cGMP practices the quality standards expected from production companies have not been maintained. Some of these had major issues as below –

The heparin case in 2008, causing around 150 deaths in the U.S. due to intended contamination of the API with a false substance (over sulphated chondroitin sulphate)
Lack of controls in the distribution networks of glycerine and
respective manufacturing

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sites caused the contamination of glycerine with diethylene glycol that resulted in 107 deaths in the USA (1937), around 300 deaths in Bangladesh (1990), 88 deaths (young children) in Haiti (1996), and 138 deaths in Panama (2006). Due to unknown contaminants in the gentamicin sulphate caused approximately 65 deaths in the USA in 1994 and 1999 respectively .

There are other many cases of medicines, falsified APIs and medicinal product recalls due to contamination of medicines or APIs c aused because of loopholes in the supply chain process.

In some cases to gain more profit the lowest cost of APIs and the raw materials purchasing used to do that resulted in the low quality of medicines. Due to such practice in industries supplier used to get an opportunity to enrol them into the supply chain process and introduce substandard materials. To avoid these practices the need for honest, authentic & quality supplier was realized & the supplier qualification stage was introduced in the complete procurement process to ensure that raw material would not affect the quality of a final product.

Supplier selection criteria [1]

For raw materials that are a key element of the finished product like APIs, API intermediates or any other material's main selection criteria have been identified as shown in below fig. 2,

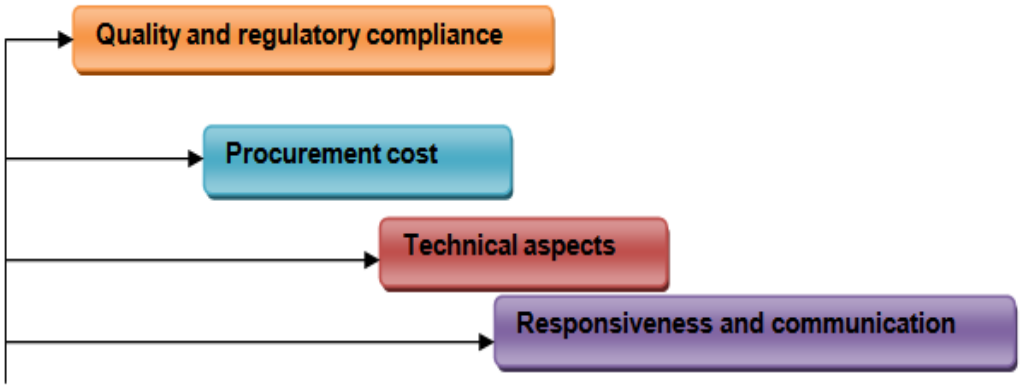

Fig.1: Supplier selection criteria

Also, with the above main points, the supplier should be selected consider in following aspects as well.

1. Whether existing or new supplier.
2. Whether the material is new.
3. Supplier's image of servicing for below,
(a) FDA inspection audits
(b) Relationships with other companies.
(c) History of complaints or recall.

4. Manufacturing process reports qualification.
5. Supplier location.
6. Technical evaluation.
7. Production samples analysis.
8. Qualification assessment data of the finished batch concerning quality & safety.
9. The final report is made using the following data.
(a) Supplier history
(b) Audit reports
(c) Laboratory findings
10. If supplier management changes re-qualification should be done.

Steps for supplier qualification [2]

Procedure for inclusion of the supplier an approved supplier list (raw materials)

New the supplier should be qualified and approved by GMP/QA Department before the regular supply of raw materials as per below steps,

1. Procurement the department should find out the new supplier and get the material details manufactured/supplied by them. For existing materials, they should provide a specification to the new supplier.

2. To know about the process at the supplier site, the preliminary GMP questionnaire should be sent t

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o the supplier by the procurement department & for active as well as
excipients, assurance/declaration of compliance wit h TSE/BSE requirement & any other certificates should be taken from the supplier & forwarded to QA Department for review with the filled questionnaire.
3. Samples from 3 consecutive lots/batches of the active ingredient as a pre-shipment sample along with
the certificate of analysis should be taken from the supplier & submit to
the QA Department or R&D Department for evalua tion.
4. After a complete analysis, the analytical report should be sent to
the procurement department with QA department c omments. If the results are appropriate the supplier can be included in the temporary approved supplier list and
a supplier site audit should be planned.
5. The audit should be performed by a qualified auditor team.
6. Based on documents, questionnaire score, audits, previous history, background and quality trial lots supplied by the supplier, the supplier may be included in the approved supplier list.
7. Following factors should also take into consideration before qualifying the supplier.

a. Quality
b. Price
c. Delivery schedule
d. Service

8. After ensuring compliance with specifications, the supplier should be included in the permanent approved supplier list.
9. During the process/product development stage all suppliers evaluated by R&D should be included in the temporary approved supplier list. And after the initiation of commercial production supply, they should be transferred to
an approved supplier list or
permanent approved supplier list.

Procedure for inclusion of the supplier an approved supplier list (packaging material) New the supplier should be qualified and approved by GMP/QA Department before the regular supply of packaging materials as per below steps,
1. Procurement the department should find out the new supplier and get the material details manufactured/supplied by
them. For existing materials,
they should provide a specification to
the new supplier.
2. Supplier audit should be performed for printed and primary packaging materials by a qualified auditor team.
3. If required printed packaging material sample should be submitted to the QA Department for evaluation.
4. Following factors should also take into consideration before qualifying the supplier;
a. Quality
b. Price
c. Delivery schedule
d. Service

6. Based on documents, audit reports, QA remarks procurement of
packaging material should be continued. After ensuring compliance with specifications, the supplier should be included in the permanent supplier's list.
7. During the process/product development stage all suppliers evaluated by
R&D should be included in the temporary approved supplier list. And after the initiation of commercial production supply, they should be transferred to
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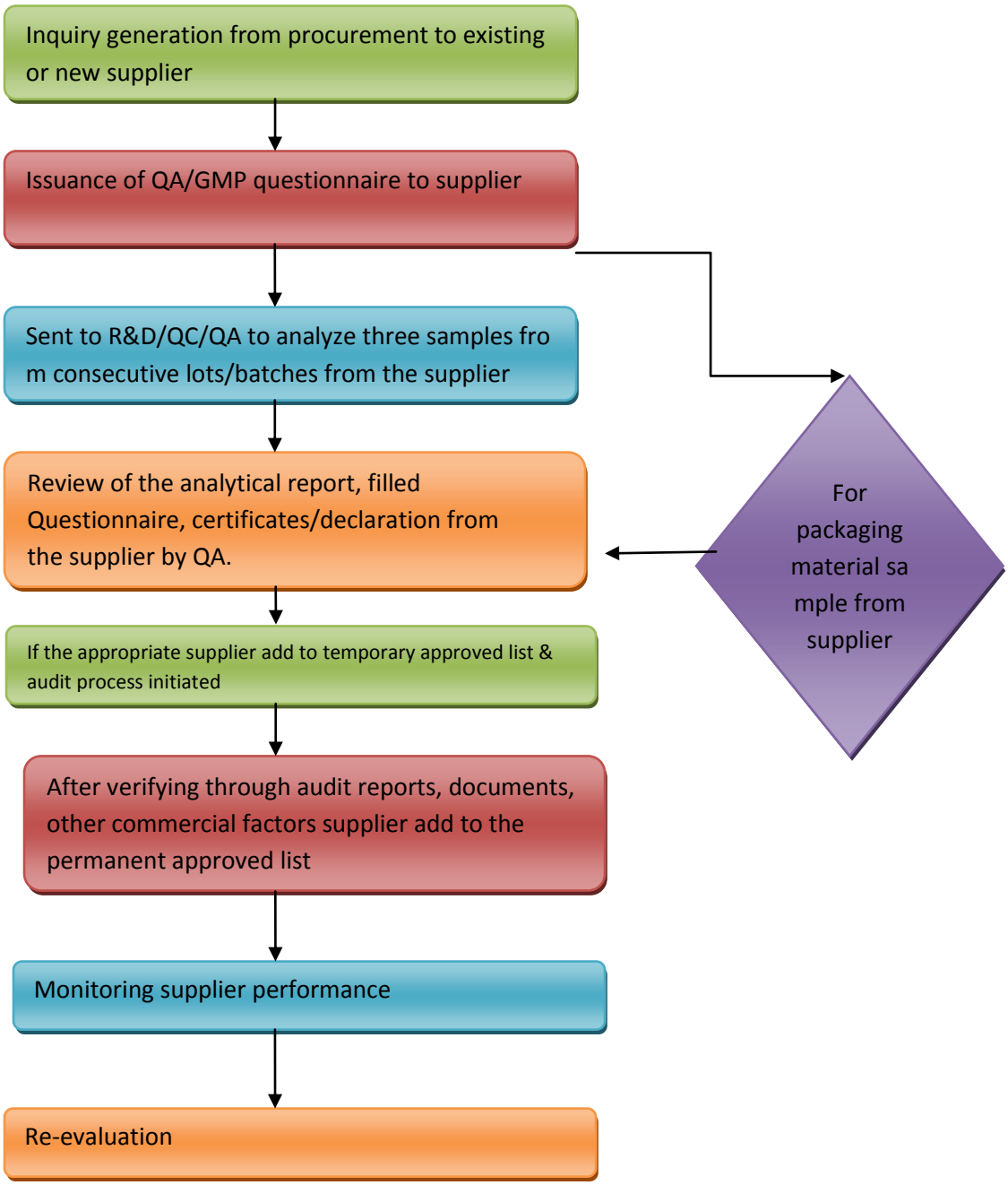

Fig.2: General supplier qualification process for raw materials & packaging material

Questionnaire, Audit & Agreement [3]

The supplier qualification process should start with initial screening, it should confirm that the supplier is able to meet the required specifications for the material or service to be provided and is in compliance with the regulatory requirements.

The supplier should be requested the below details as part of the questionnaire procedure.

- Material Specifications
- Production/packaging/labeling information
- Materials Safety Data Sheets
- Delivery schedule

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- Certificates regarding the Quality system, residual solvents, etc.
- BSE/TSE evaluation
-Impurity declarations
-Analytical test method

If the supplier is a contract manufacturing organization, contract laboratory, or an active pharmaceutical ingredient supplier then with the questionnaire more detailed documentation should be requested

All corresponding departments should review the screening questionnaire and documents before making the decision for the qualification of the supplier.

Supplier audit points should taken into consideration [5]

Qualification Audit

The most important step in the supplier qualification process is an audit. The decision to conducting the supplier audit is based on the type of material he is providing, the risk associated with the finished product quality.

• Audit the plan should send to the supplier in advance with the agenda focusing on the critical aspects that are necessary to ensure the quality of the product, or service meets the requirements of the firm.
• It is also important to ensure that a qualified audit team is assigned to perform supplier audit. If any shortcomings are coming to conduct the suppli er site audit due to site location, or lack of expertise in auditing then they can use a third party audit report or should seek out the assistance of a consulting firm or other organization to conduct the same.
• To ensure an efficient and effective audit the customer can request relevant documentation or details in advance for the auditor's reference to review the factors prior to arriving at the site.

Information during the audit should be to be gathered may include but not limited to:

-Site Master File
-Drug Master File
-Manufacturing site location, alternative sites used and subcontracted sites
–The GMP and other quality systems used in manufacturing sites
–Certificates of Analysis (CoA) on original letterhead and/or certificates of conformance
-Information on test methods and who actually tested the material.
–Information on of entire supplier chain
-Information of earlier conducted audits of the manufacturing site
–Other products produced at the site
–TSE, BSE, Impurities declarations, etc.
-Transport Stability information & method of transportation and packaging.
–Other history, complaints, recalls, etc. of the manufacturer

Change in auditing procedure during the pandemic [6]

Due to Covid 19 pandemic started lately in 2019 many restrictions caused hurdles to various processes throughout the industries & in the pharmaceutical sector too. Quarantining, social distancing and travel restrictions were impacted on traditional on-site audits processes. However, in an increasingly risky market, customers had to qualify new suppliers and manage existing relationships which technology made simple. With internet video conferencing companies continued to conduct supplier audits remotely that could help both parties to follow the process.

Supplier quality evaluation [2]

Supplier quality evaluation plays important role in pharmaceutical industries to compare between different suppliers with respect to most important factors like quality of material, service, pricing, and delivery schedule for the following aspects.

Quality of material-

1. Quality related critical or non-critical test specification should have complied.
2. Product reliability and durability specifications should comply.
3. Warranty certificates should be provided.

Customer servicing-

1. Prompt response for customer's queries or enquiries should be provided.
2. Proper technical or other required assistance should be provided.

Delivery-

1. On delivery should be provided.
2. Right material with the right amount should be provided with the required transportation or temperature conditions.
3. Correct documentation practice should be followed for delivering materials.

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Pricing-
1. Competency in pricing should be maintained.
2. Unnecessarily price variation should be prohibite d.
3. If price changed should be informed customer in advance.

Supplier rating [4]

After assessing the supplier quality on the above aspects ratings can be given to them as below,

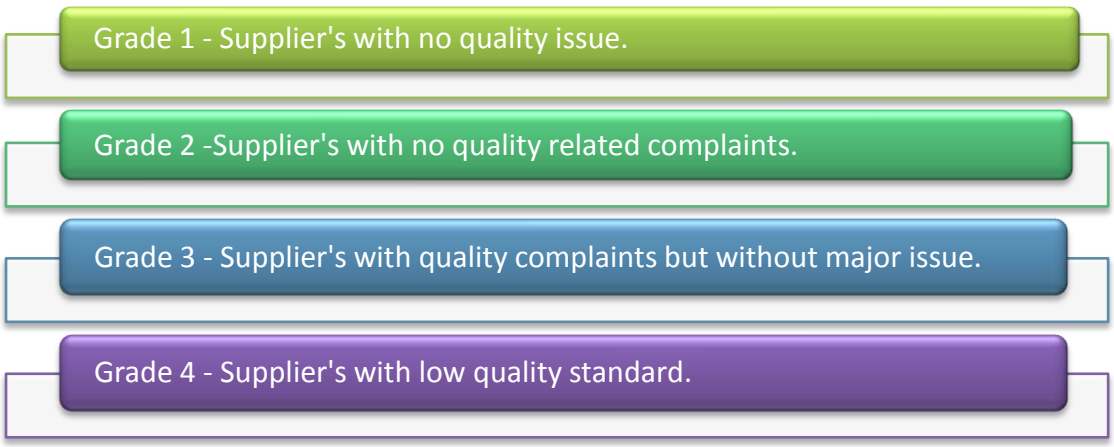

Fig. 2: Supplier ratings according to grades

Supplier Management
1. It is always significant to keep a healthy relationship with the suppliers, suppliers, service providers, etc.
Procurement heads should keep in contact with them regularly.
2. Particularity should be maintained for on-time payment.
3. Conflicts should be resolved immediately between both parties if arise.
(Supplier Management, 2016),

Process for removal of the supplier from approved list, reasons for disqualification & supplier re-assessment [2]

- After approval supplier re-assessment should be carried out at least once a year for all starting materials & packaging material.
- The rate of rejection should be assessed for approx. 30 batches of specific materials from the same supplier.
  For data compilation, data should be taken from different plant units.
- If the rate of approval is not less than 90%, then the supplier can be approved and re-assessment may not be required further.
- If the rate of rejection is more than 10% then QA department must conduct a supplier re-audit to get the information for non-consistency in supplies.
- The supplier must be rejected in case of a nontransferable reason.
- QA/GMP department of the company should update the approved supplier list consequently and communicate to other respective departments within the company.

Procedure for the exclusion of the supplier from the approved supplier list
1. The supplier should be removed from the approved supplier's list for the following causes:
a) If a lot does not meet the required specification of critical tests then the supplier should be disqualified. The supplier can qualify again after further evaluation and investigation.
b) If a lot does not meet the required specifications of non-critical tests then the supplier should be disqualified if it is observed for 3 continue lots.
c) If 30% of lots failed to meet the specification in a particular period under evaluation.
d) If 40% of supplies failed to meet the agreed delivery schedule.
e) If the difference occurs between rates mentioned in the procurement order & rates mentioned in delivery challan and invoice.
Corrective and preventive action
The supplier, who has been removed from the approved supplier's list may be incorporated again by taking the following corrective and preventive actions;

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1. The supplier should be explained the causes of his removal & should be asked to clarify.
2. Supplier's manufacturing site should be audited by QA & GMP head to make sure that quality system exists in the premises & activities.
3. Brief talk should be conducted about factors that are not related to quality for example price, payments terms, delivery schedule, etc.
4. After an acceptable assessment with all the above points, the supplier could be included in the temporary approved list.

CONCLUSION-

To satisfy the primary aim of producing good quality, safe & effective medicinal product pharmaceutical industries follows the one of essential step of GMP is supplier qualification. It mainly deals with selection of suppliers by considering different criteria & parameters. After these evaluation supplier considered as qualified supplier until it meets all technical & commercial requirements. Supplier requalification will be done if any change or deviation in the quality of material, service or any other parameter which may affect the quality of product.

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