Auditing Company:	**VCI-Questionnaire Packaging Product Audit**	Audit of:
Packaging supplier: Adress: Telephone: Fax: E-Mail:		**Page 1 von 13** **Revision: 14.10.2014**

Product: ..... Material-no.: …..……
Manufacturer article-no.: ……
Purchase Order/Position……

Reason of audit: **E.g. product audit according to audit plan**

Participants	Function	Company
Mr. / Mrs.		
Mr. / Mrs.		
Mr. / Mrs.		
Mr. / Mrs.	Auditor	

Packaging Manufacturer data

1. General

1.1 Production site in: ……

1.2 Head quarter in: ……..

1.3 Manufacturing assortment data:

Manufacturer delivers which packaging materials to the auditing company?

……

……

1.4 Percentage shares of sales

Chemistry: ……..
Cosmetics: …….
Technical Industry: ……
Pharmaceuticals: ……..
Foodstuffs: …….

1.5 Own purchasing volume with supplier: ……

1.6 Corporate group number of employees: ……..

2. Production site data

2.1 Name of site location: …….

2.2 Size of Production site: ……. (Area, Buildings): ……

2.3 Number of employees:
Thereof in production: ……in Quality Management: …….

2.4 Percentage of short term workers (hired temp staff): ……..

2.5 Technical Equipment: ……

Auditing Company:	**VCI-Questionnaire Packaging Product Audit**	Audit of:
Packaging supplier: Adresse: Telephone: Fax: E-Mail:		**Page 3 von 13** **Revision: 14.10.2014**

Note: All relevant questions have to be answered with Yes or No and have to be complemented with more precise explanatory notes in the comment fields. For some questions there are already more detailed additional questions in the comment fields.

No.	Issue / Question	Yes	No	Comment/Explanation
1.	**Quality Management**			
1.1	Is the QM-system certified by a neutral institution? If this question is answered "yes", the questions marked with * do not need to be answered. Is the whole enterprise matrix certified for all locations?			If yes, by whom? Valid until when?
1.2	Were the requirements for dangerous goods packaging according to DIN EN ISO 16106 observed within the scope of the ISO 9001 certification?			
1.3	Is there an officially approved quality assurance program for the manufacturing of dangerous goods packaging?			By which authority? For which location?
1.4	Is an organization plan for QM available, in which the responsibilities can be identified?			
1.5	Is the quality management department directly subordinate to the company management board?			Central or site-specific supervision by location?
1.6*	Is a quality manager designated and empowered with sufficient authority to decide (e.g. blocking of production)?			
1.7*	Is the QM system documented in a quality handbook?			
1.8*	Is the quality handbook accessible for all involved persons in the company?			
1.9 *	Are internal audits?			

Auditing Company:	**VCI-Questionnaire Packaging Product Audit**	Audit of:
Packaging supplier: Adresse: Telephone: Fax: E-Mail:		**Page 4 von 13** **Revision: 14.10.2014**

No.	Issue / Question	Yes	No	Comment/Explanation
1.	**Quality Management**			
1.10	Are measures being taken and tracked in order to eliminate weaknesses? Is a standardized communication process available for this?			
1.11	Are workflows and responsibilities for approvals within the QM system fixed in writing?			
1.12 *	Are the document record-keeping periods regulated?			
1.13	Is there a program for the training of employees?			
1.14	Are performances of trainings documented?			
1.15	Will the training success be monitored?			
1.16	Is there a procedure to determine customer satisfaction?			
1.17	Is there a system installed in order to control access to factory premises, manufacturing sectors, warehouses, research and development divisions?			

No.	Issue / Question	Yes	No	Comment / Explanation
2.	**Purchasing**			
2.1	Is there a system for qualifications, approvals and supplier ratings?			
2.2	Do you perform incoming goods inspections?			
2.3	Do you have separate storage areas installed for blocked stock in your goods receipt?			If no, how do you guarantee otherwise, that blocked stock does not end up in the production process?
2.4	Are certificates/test reports of the upstream suppliers available?			If yes, for which products and with what content?
2.5	Do you visit suppliers in order to verify availability and function of their QM systems?			
2.6	Do specifications, which have been agreed with the respective suppliers, exist for all purchased products?			
3.	**Production**			
3.1	Are production facilities inspected, maintained and mended according to schedule?			
3.2	Are statistics methods (e.g. SPC) applied for important product characteristics and process parameters?			If yes, for which?

3.3	Is the process of production regularly checked in case of series-production?			How often does the test take place? Which parameters are checked?
No.	**Issue / Question**	**Yes**	**No**	**Comment / Explanation**
3.	**Production**			
3.4	Are procedures for corrective measures in case of a deviation in the production progress regulated in a written form?			How are the intervention limits for essential parameters defined?
3.5	Do the production plans contain all essential information e.g. product and item lists, test methods, test and sampling plans?			
3.6	Is there in the production sector a designated storage area for blocked goods available?			If no, how is otherwise ensured that blocked products does not end up in the production process?
3.7	Are there written instructions which regulates handling of the defective products available?			
3.8	What tests are conducted during the production process to ensure the required quality of the finished product?			
3.9	Are the results of the quality testing documented and assessed?			
3.10	Is the traceability from used raw materials and pre-products to finished products guaranteed?			

3.11	Are the principles of traceability according to the EU-regulation 178/2002 considered?			
No.	**Issue / Question**	**Yes**	**No**	**Comment / Explanation**
4.	**Storage, Shipment**			
4.1	Is there a QM-agreement with the carrier in place?			
4.2	Are all products stored appropriately?			Are there internal rules for appropriate storage?
4.3	Are the means of transport checked for cleanliness before loading?			
4.4	Is the loading process compliant (e.g. consideration of stacking instructions, weight distribution, cargo securing)?			
5.	**Quality testing**			
5.1	Are there instructions for the release of raw materials / pre-products?			
5.2	Are there instructions for the release of the intermediate products?			
5.3	Are there instructions for the release of the finished products?			
5.4	Is all testing equipment available that is necessary for determination of the characteristics listed in specifications and quality criteria list?			

5.5	Is the testing equipment properly calibrated?			
5.6	Are specifications, test plans and defined test methods available?			
No.	**Issue / Question**	**Yes**	**No**	**Comment / Explanation**
5.	**Quality testing**			
5.7	Are reference samples (e.g. raw materials, pre-products, intermediates and finished products) available?			
5.8	How long will retain samples be stored?			
5.9	Is the procedure for complaints issued in writing?			
5.10 *	Is there a distribution list for quality management relevant data with change management?			
5.11 *	Are procedures and responsibilities for changes in the quality system regulated in writing?			
5.12	Are the valid documents with all requirements (e.g. standards, VPA, color indications, print templates, quality list of characteristics) available at all relevant locations?			
5.13	Are the customer requirements (e.g. specifications) implemented currently in the manufacturing documents?			

5.14	Is there a procedure to ensure the current validity of customer specifications for the order processing?			
5.15	Are there regulatory monitoring reports, such as BAM-GGR 001, available?			

No.	Issue / Question	Yes	No	Comment / Explanation
6.	**Environmental management / sustainability**			
6.1	Does the company have an environmental management system (e.g. by Regulation EEC 1836/93, DIN EN ISO 14001, DIN EN ISO 50001 or other)?			If no, is an environmental management system planned?
6.2	Is the environmental management system certified?			If yes, by whom and by when?
6.3	Are there corporate guidelines on environmental protection / sustainability?			
6.4	Are in the company objectives defined for the improvement of environmental protection?			
6.5	Are in the company environmental protection measures and results documented in relation to the set objectives?			
6.6	Are in the company production processes, supply and disposal processes and products based on their environmental impact examined periodically?			
6.7	Are environmental considerations an integral part of product planning (e.g. such as design, residual emptying, disposal, use of materials)?			
6.8	Are environmental protection measures audited regularly in the company?			If yes, by whom? Internal Auditor External Auditor

6.9	Are employees regularly informed and trained on the subject of environmental protection?			
No.	**Issue / Question**	**Yes**	**No**	**Comment / Explanation**
6.	**Environmental management / sustainability**			
6.10	Are environmental aspects considered in the selection of suppliers?			
6.11	Is the company committed to the initiative to comply with UN Global Compact?			If no, does the company ensure that the sustainability principles of human rights, labor protection, environmental protection and anti-corruption in the entire supply chain are respected?
7.	**Occupational Safety**			
7.1	Is a trained specialist assigned to be in charge of occupational safety?			
7.2	Are the employees trained in the area of industrial safety?			
7.3	Are externals and visitors trained / instructed regarding industrial safety?			
7.4	Are the training activities documented?			
7.5	Is the company providing suitable personal equipment to protect the employees and is it in use?			

7.6	Is the workplace inspected regularly?			
7.7	Are the inspections documented and measures are derived from that?			
No.	**Issue / Question**	**Yes**	**No**	**Comment / Explanation**
7.	**Occupational Safety**			
7.8	Is there a written system to eliminate all unsafe situations that are discovered in the plant?			
7.9	Is a procedure for notification and investigation of accidents or other incidences defined?			
8	**Hygiene-Management**			
8.1	Did the company establish a management for hygiene, which fulfills the requirements of standard DIN/EN 15593?			Is there a certification according to this standard available?
8.2	Is there an authorized representative for questions in hygiene nominated within the company?			
8.3	Are hazard analysis and risk assessments (HACCP-concept) conducted?			If so, when was the analysis conducted last time?
8.4	Are there measurements established to prevent physical, chemical and biological contaminations (e.g. in buildings, on equipment, and in warehouses)? Which control scheme is established in order to check the effectiveness of these measurements?			

8.5	Are hygiene rules established in the production area regarding the correct behavior of employees and external visitors?			
8.6	Does the company produce according to GMP-guidelines?			

9. Dokumentation of test criteria

	Documentation form		
9.1 Purchased Products	Test certificate	Quality check incoming goods	Remark

	Documentation form		
9.2 Process / test attribute	Quantitative	Qualitative	Remark
9.3 Final check			

10. Conclusion/Deviations

No.	Conclusion/Deviation	Measure/Responsibility	Due Date