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9.0.1 Introduction

Of central importance for the chemical industry is an efficient and market oriented quality assurance.

Developing a homogenous systematic quality concept by packaging manufacturers and users is fundamental for a harmonized approach to minimization of interface problems.

In the production of packaging it can‘t be ruled out that due to incorrect processes the final products have defects in the sense of non-compliance with product requirements. Therefore an efficient process control is to be endeavoured to save cost intensive rechecks in goods receiving. Homogenous quality assurance criteria and homogenous linguistic usage is suitable to achieve a regular quality level as well as to avoid communication errors. VCI made it its business to accomplish this common ground for users and packaging manufacturers.

On the following pages as a first step homogenous designs of packaging specifications with defined terms is presented to enterprises and their packaging suppliers. The packaging descriptions contained in the previous chapters are a sufficient basis for the specifications. They can be supplemented around by company specific requirements used in the attached blank form.

In the manufacture, testing and shipment of packages there are further benchmark figures for standard packaging which are not detailed in the examples displayed in Chapter 4. For this reason, the VCI has produced so-called Packaging testing and manufacturing guidelines (VPA), so that dealing with detailed questions can be made easier. In the respective chapters, references are made to the relevant VPA. VPA are set separately in the internet. Provided certificates are necessary at all, in many cases businesses use the DIN EN 10204 Inspection certificate similar to the VPA 8 version.

Quality management contracts are already undertaken between suppliers and buyers in order to guarantee that the demanded product-quality is in place from the planning of the product stage onwards. They are individually negotiated while also standard contracts of the respective companies can form the basis. Around the most essential goals - Quality improvement and simplification of the goods inward checking, different contract formations are possible. These contracts should be differentiated from the "SPC-contract" and clearly marked "QM-contract".

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The fundamental difference is that a QM - agreement can deal with an assortment of suppliers or at least entire parts of the supply chain can be covered, whilst a SPC - contract deals with defined individual articles and characteristics. Both types of contract are to be considered as principle-documents; over all, additional documents are necessary as part of the contract. These refer to, for example the relevant characteristics of delivered goods, the test procedure, the documents and also an evaluation of possible mistakes. QM - contracts have a considerable effect on commercial relations. It is recommended that all contracts are thoroughly tested juristic before there is any signature for admissibility of individual sections to avoid any possible legal proceedings. In section 9.3 possible contents are suggested for QM - contracts.

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9.0.2 Quality philosophy

Quality as fulfilment of customer requirements is achieved by continuous improvements. Hereby the main activity lies in a successive elimination of reasons for failure. This is done in a way specific for the company according to strategies and methods of quality management systems introduced in the companies, as well as by together agreed regulations for the interfaces between the companies.

Quality:

Quality is the totality of properties and features of a product or an activity, which refer to suitability to fulfil given requirements.

The requirements include security and environmental protection.

Explanation:

Requirements according to quality management systems (e.g. according to DIN EN ISO 9000 ff.) are requirements concerning procedures in the company organisation; the above mentioned standards do not determine how to fulfil a requirement, but which general requirements have to be considered. Core demand hereby is the avoidance of defects by prevention. Only with consequent preventive elimination of reasons for failure the products and processes can be improved in a way, which the consumer receives services meeting his requirements and expectations concerning suitability and security.
Within the scope of company specific quality management systems different strategies and methods can be used to achieve this goal.
Up to now to the description of the customers-supplier's- relationship the common procurements documents (e.g. order papers, terms of delivery, technical data sheets, specifications) are applied predominantly which themselves limit to the product to be delivered or the service to be rendered. By conclusion of quality assurance.-.agreements the contractual relationship between customer and supplier is supplemented with requirements concerning suppliers QM-systems.

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9.03 Cleanliness of packaging

Industrial packaging is used also for products with specific requirements for cleanliness e.g. electronic-chemicals, active pharmaceutical substances and cosmetic industry or additive substances for food industry. Such packaging is subject to stringent cleanliness requirements in manufacturing, warehousing and distribution.

Exposure hazards arising from biological, chemical and physical contaminants must be avoided by appropriate measures during the manufacturing process. Apart from the actual manufacturing process, measures can also be necessary e.g. in the following areas: buildings, installations, warehouses, raw material deliveries, internal transportation routes, staff, visitors, etc.
Limits for contamination of empty packaging and testing procedures are to be agreed with the manufacturer if necessary. The limits for the cleanliness of packaging should not be higher than those of the products to be filled.

Normative foundations for the manufacturing of pharmaceutical packaging are to be taken of DIN EN ISO 15378 - “Primary packaging materials for medicinal products-Particular requirements for the application of ISO 9001:2000, with reference to Good Manufacturing Practice (GMP) and the GMP-guidelines (EU-Comm.)
A HACCP (Hazard Analysis and Critical Point)-concept must be available for the quality control of manufacturing.
The DIN EN 15593 “Packaging-Management of hygiene in the production of packaging for foodstuffs-Requirements” comprises basic points for a hygiene management system for manufacturers of food packaging and their suppliers, including warehousing and transportation. The implementation of the standards for the manufacturing process should be documented as an HACCP-concept.

The general applicability to packaging for products of the chemical industry with high requirements of cleanliness results from the annotation in the scope of DIN EN 15593: It may be appropriate to implement this European Standard to other objects and parts that come into contact with food and on packaging for products, which are nonfood.

To that extent, this standard can be used for the above-mentioned industrial packaging. After the packages have been produced at hygienic requirements, it must be ensured that the packaging material is not contaminated by handling or storage and that the degree of cleanliness achieved is maintained across the entire chain of production up to the consignee.

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9.03 Cleanliness of packaging

For this purpose, required measures shall be defined and adopted. Such measures can be e.g.:

- Appropriate hygiene protection for transport
- Gradual unpacking
- Efficient handling of time and space in the filling process
- Identify sources of contamination
- Error review

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Section 9.1 Packaging specification

9.1.0 Introduction

A specification is a technical description of a procurement product or services of verifiable criteria.
Contents of specifications depend on their objectives which are listed in the following:

- ✧ Accurate description of expected values
- ✧ Facilitation of the contract review, order processing, production, inspection
- ✧ Facilitation of the procurement based on a standard document
- ✧ Technical instructions to avoid procurement errors

On the basis of a specification each type of packaging has been ordered.
If all the customers use individual specifications, it cannot be ruled out, that different quality relevant requirements are included in the specifications without technical necessity and the wanted standardization is at risk.
The use of the specification form (see section 9.1.2) guarantees, that the supplier receives all information that he needed for the description for a packaging to be produced. By use of the technical data given in previous chapters, it is secured that the customer orders and receives packaging common in the chemical branch.
The uniformity of specifications allows exchanging them amongst customers and thus to reduce work involved in preparing them.

Basis for the preparation of a specification is a packaging description.
Responsibilities for specification steering are shown in the following:

- ✧ Preparation: customer with supplier
- ✧ Checking: supplier in the scope of contractual checks
- ✧ Modification: customer with supplier
- ✧ Issue: customer
- ✧ Archives (place, time): customer and supplier

Specification modifications are marked with *. Standards of specifications also should be suitable for a transmission by data telecommunications.

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Section 9.1 Packaging specification

9.1.1 Fill out a specification

The sequence of individual items should be maintained by editor of specification, whereat not relevant items can be omitted or marked as not apply.

Maintenance of individual items sequence tends to a fast and clear readability of specification.

To show distinctly how a specification should look like, in section 9.1.3 an example for a filled out specification is displayed.

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Section 9.1 Packaging specification

9.1.2 Blank form

1. Editor: **2. Date:**

3. Packaging No.:

4. Indications of change (e.g. marking *):

5. Short text:

6. Drawing No.:

7.

Dimensions of	Measurements (mm)	Tolerances (mm)

8.

Mass for	Mass (g)	Tolerances (g)

9. Nominal volume: **Brimful volume**:

10. Materials including surface finish:

Packaging parts	Material

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Section 9.1 Packaging specification

9.1.2 Blank form

11. Technical requirements:

12. Type:

13. Marking:

14. Conditions of acceptance:

15. Special features:

16. Delivery:

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Section 9.1 Packaging specification

9.1.3 An example for a filled form

1. **Editor:** Chemical factory XY **2. Date:** 19. October 2012

3. **Packaging No.:** 1.000.000

4. **Indications of change (e.g. marking *):**

Replaces packaging specification of 01. February 2005
Changes marked with asterisks *

5. **Short text:** 120 L-PE container with removable lid (chapter 4, page 4.2.2.1) *
coloured blue, with ventilation system

6. **Drawing No.:** 2009 / 1208

7.

Dimensions of	Measurements (mm)	Tolerances (mm)
total outer height	800	± 5
outer diameter	495	± 4
fill opening	380	± 3

8.

Mass for	Mass (g)	Tolerances (g)
total	6.230 *	
body	4.400	± 110
lid	900	
clamp ring/ lever	930	

9. **Nominal volume:** 120 L **Brimful volume**: 124 L*

10. **Materials including surface finish:**

Packaging parts	Material
body	PE-HD
lid	PE-HD
clamp ring / lever	St 37, zinc coated
ventilation valve	NBR - rubber

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Section 9.1 Packaging specification

9.1.3 An example for a filled form

11. Technical requirements:

minimum wall thickness:	
body	2.5 mm
lid	2.0 mm
clamp ring	1.25 mm *

12. Type:

removable lid container according to DIN EN 12714
standard lid type, with two grip pockets in bottom, bottom and lid nestable, ventilation pin, clamp ring U-profile with sealable lever * body in blue (RAL 5010), lid in black coloured with soot *

13. Marking: according to VPA 6 *

body	mantle min.	UN/1H2/X150/S/year/land/manufacturer/No.
		date dial, packaging-No., double arrows, grade mark
bottom		recycling mark
lid		D/manufacturers acronym

14. Conditions of acceptance:

upset resistance min.	18 000 N
coefficient	360 N/mm
type test requirements have to be reached	
further requirements according to VPA 2, 3, 4, 5 *	

15. Special features

certificate according to VPA 8 *

16. Delivery:

4 drums on CP1, shrink wrapped *

Chapter 9 Quality assurance

Section 9.2 Packaging testing and manufacturing guidelines (VPA)

9.2.0 Contents

Chapter 9 Quality assurance

Section 9.2 Packaging testing and manufacturing guidelines (VPA)

9.2.1 Introduction

VPA were made in close cooperation with the packaging manufacturing industry, their associations and the VCI (German chemical industry association). VPA are supplementary texts to the descriptions of standard packaging in the VCI Packaging Handbook. In VPA basic technical details, testing conditions, contents of certificates and so forth are described. On the one hand applying to several packaging kinds they are on the other hand too comprehensive to be textually included in the individual packaging specification. VPA refer at all places where this is possible on higher regulations, e. g. on valid standards. Legal regulations, for example with labelling of packaging, always have priority.

VPA are not obligatory. Only when explicitly mentioned in packaging specifications or other documents (e. g. sales contracts) do they become binding.

For packaging manufacturers and users the advantage of applying VPA lies in making standardised demands upon packaging. The same testing methods and evaluation criteria are being applied for quality control. Production supervision at manufacturer sites can be done in the same way as quality control at customer sites.

Note: You will find the VPA on the internet: http://www.vci.de
(“Logistik, Verkehr & Verpackung”)

Chapter 9 Quality assurance
Section 9.3 QM – contracts

9.3.1 Possible contract contents

Notes for QM-Contracts are described in the German version and in the introduction in 9.0.1.
There are notes exemplary for the contents of QM-contracts:

1. Naming the contractor

2. Agreement
This agreement describes the requirement for the procurement/supply of packaging.

3. Technical documents
It is agreed that for every packaging delivered accurate and complete documentation (e.g. specifications, manufacturing regulations, drawings) must be submitted. It is agreed who is responsible and which procedures shell be applied in case of changes.

4. Performance and guarantee
It is agreed that the supplier of packaging material has to produce in accordance with applicable technical documents and that the packaging supplied corresponds to the required specification data.

5. Quality assurance
It is agreed that the supplier of packaging maintains an effective quality assurance system. Test methods, test equipment and test criteria are defined.

6. Documentation
It is agreed that the supplier of packaging shall document the results of the quality assurance measures and that the customer has the right to inspect the documents and the retention period of documents.

7. Access authorization
The customer has the right of entry for examining the quality level.

8. Certificate
It is agreed that the supplier of packaging makes certificates available upon request of the customer.

9. Reporting requirements / Changes
It is determined that the supplier for packaging shall inform the supplier in time of changes e.g. production process, pre-supplier, approval of the packaging type, material, dispensing. All changes must be approved by the costumer.

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Section 9.3 QM – contracts

9.3.1 Possible contract contents

10. Incoming inspection of packaging and complaints
By an indication of the quality control of the manufacturer of packaging, the incoming inspection of packaging can be reduced in a determined frame.
It shall also be agreed that because of that does not discovered defects can be reported at a later date.

11. Liability
The framework is determined in which the supplier of packaging is liable for damages resulting from defective delivery.

12. Insurance cover
It is determined that the manufacturer completes an insurance liability for the product range and the scope of liability.

13. Confidentiality
The parties commit to permanent confidentiality of information they obtain in the course of this contract by the other side.

14. Contract period

15 Relation to general terms and conditions

16. Written form clause
There is noted that require changes must follow in writing.

17. Severability clause

18. Place of performance and justification

19. Signatures of both parties

Chapter 9 Quality assurance
Section 9.3 QM – contracts

9.3.2 Packaging Product Audit questionnaire

Note: You will find the Packaging Product Audit questionnaire on the internet: http://www.vci.de (“Logistik, Verkehr & Verpackung”), see download to “VCI-Mitgliedsfirmen erarbeiteten Fragebogen, Produktaudit”.

Chapter 9 Quality assurance
Section 9.3 Quality characteristic lists

9.4.1 Introduction

Quality characteristics lists (QML) defin quality-characteristics of the different packaging – types.
Compliance with the characteristics is deciding for the usability of packaging in the chemical industry.
For the testing of packaging in the test centres of the chemical industries as well as in the test centres of the packaging manufacturer are details given, what has to be checked and which value (failure class) belongs to the single characteristic. This valuation can take place in the single companies in different ways, therefor in every quality characteristics list is given a note, that in single cases it is possible to diverge from the failure classes. Further on it is defined, in which basis the tests have to be done. Often there is the PMS (packaging specification) named. If in the packaging specification a characteristic is not spezified, this characteristic is irrelevant for this case. If there are advices “state of the art” and “approval”, the test has to be done in every case, even if the characteristics are not named in the packaging specification.
The in the quality characteristics lists named test method are exemplary, as described in the preamble. Even other agreed test methods can be used, if the results are comparable.

Note: You will find the QML on the internet www.vci.de
("Logistik, Verkehr & Verpackung”)

Chapter 9 Quality assurance
Section 9.0 Quality characteristic lists

9.4.2 Lists

No. 010 – Packaging made of metal

No. 020 – Packaging made of plastics

No. 030 – Fibreboard Drums

No. 040 – Packaging made of corrugated board

No. 050 – Combinations-IBC with plastic inner receptacle inside (K-IBC)

No. 060 – Flexible IBC (FIBC)

No. 070 – Flexible plastic packaging

No. 080 – Paper sacks

No. 090 – Pallets made of wood

No. 100 – Combination packaging steel / plastic

No. 110 - Labels

No. 120 – Stretch films / Shrinking hoods

No. 130 – Boxes made of wood

No. 140 – Expanded plastic packaging

No. 150 – Wet- and self-adhesives tapes

No. 160 – Plastic straps for load securing

No. 170 – Containers made of moulded glass

No. 180 – IBC made of fibreboard

Note: You will find the Quality characteristic lists on the internet: http://www.vci.de
("Logistik, Verkehr & Verpackung")