

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Food/GTDP	Office	Operations	Score
-----------	--------	------------	-------

Item N°	Question	Guideline
		<p><b>Introduction</b></p> <p>This section describes the general handling and distribution principles, which are applicable to all stages of the distribution chain of Food, Cosmetic or/and Pharma grade products. All practices of this guideline comply with Good Manufacturing Practices (GMP) and the recommendations of the ISO 9000 series, or equivalent quality systems. However, this section is not fully comprehensive and does not cover all GMP principles. In case the ESAD scheme will be used to verify compliance with Good Trade and Distribution Practices (GTDP) principles for pharmaceutical starting materials, especially excipients, the sub-section GTDP has to be applied in addition to the basic section F.</p> <p><b>Purpose</b></p> <p>Products with a pharmaceutical nomenclature according to a Pharmacopoeia, Cosmetic, Food Grade Products and Pharmaceutical Starting Materials are high purity products, which have to meet all required specifications. The manufacturers of these high quality products are firmly committed to comply with Quality Assurance Systems, with appropriate principles of Good Manufacturing Practices (GMP) and with Responsible Care programmes. Before reaching the final consumer, these products are distributed through a chain of operations (handling, storing, transport, packaging, etc) often performed by several successive actors.</p> <p>Every person involved in the distribution chain should be aware of the importance to preserve the initial quality of these products from the manufacturers to the final customers for their sensitive applications, and of the need to ensure a high level of protection for public health.</p> <p>Contamination or mislabelling may lead to dramatic consequences for human life, especially in injection fluids and in orally administered pharmaceuticals, in dermal creams and in all possible food applications.</p> <p>Any company which transports, packages and/or stores these products (in bulk or packed) should have a system in place which protects the end users from any quality alterations of the products from the initial manufacturing stage to the final destination.</p> <p>Under Responsible Care these guidelines are binding as an Industry Code of Practice for all parties involved in distribution of these products. These guidelines apply to all commercial transactions, including swaps, processing, resale and customer collection and transportation arrangements.</p> <p>The requirements of this section provide precautions to all actors to be incorporated in a Quality Management system such as ISO 9000 series or equivalent, in GMPs and in Responsible Care programmes.</p>

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Food/GTDP	Office	Operations	Score
-----------	--------	------------	-------

Item N°	Question	Guideline
		<p><b>Scope</b></p> <p>This section only refers to Food, Cosmetic or/and Pharma grade products: Products with a pharmaceutical nomenclature according to a Pharmacopoeia (e.g. ...EP, ...USP, ...DAB etc.), Food grade products, pharmaceutical starting materials, cosmetic grade products. Some of these products may also be commercialised as "Industrial/Technical Grade" for various industrial applications. The manufacturing and distribution process of "Industrial / Technical Grade Products" does not meet the high standards required by the regulations (e.g. pharmacopoeias and law relating to food and drugs) and therefore should not be used for sensitive applications such as for pharmaceuticals, food and cosmetics. Excluded are Active Pharmaceutical Ingredients (APIs).</p> <p>The scope of this section is mainly concerned with the distribution chain, starting after the manufacturer's final storage facilities and ending at the final user's storage facilities. This involves storage in tanks/silo's, loading and unloading, packaging, transport, blending, processing, warehousing, etc.</p> <p>Typical actors involved in these operations are manufacturers, transport companies, terminal operators, distributors, traders, brokers, importers, packaging and warehousing companies.</p> <p>The section defines minimum requirements such as quality certification, traceability, out shipment control, intake control, re-testing and re-certification, equipment selection and control, documentation, personnel qualification, labelling and re-labelling.</p> <p>This Section considers the General Notices of the current Pharmacopoeias (EP, USP, JP etc.), Council Directive 2001/83/EEC including its amendments and basic GMP principles. These guidelines are in compliance with the Guidelines for Handling and Distribution of Propylene Glycol USP/EP of CEFIC's PO/PG-Sector Group.</p> <p>In case this section should be used to evaluate compliance of a distributor with Good Trade and Distribution Practices following sub-section GTDP, reference should be made to additional guidance documents (e.g. WHO GTDP guidelines [1] and IPEC GDP Guide [2]).</p>
<b>1.</b>	<b>General</b>	<b>General</b>
<b>1.1.</b>	<b>Is the company applying GTDP, HACCP or equivalent quality principles to the operations ?</b>	<b>Is the company applying GMP and/or HACCP principles to the operations ?</b>

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline	Food/GTDP	Office	Operations	Score
1.1.1.	Are there GTDP, HACCP or equivalent quality principles part of the quality system ?	Check if the quality manual, standard operation procedures and other documents contain chapters or parts with references to GMP/HACCP standards. Applicable GMP standards are e.g. <i>IPEC GMP Audit Guidelines for Distributors of Bulk Pharmaceutical Excipients</i> and <i>WHO Good Trade and Distribution Practices for Pharmaceutical Starting Materials</i> . Verify if the people responsible for quality are familiar with the standards applied.	F	X	X	
<b>1.2.</b>	<b>Does the company's personnel policy comply with the special requirements for the handling of Food, Cosmetic or/and Pharma grade products ?</b>	<b>Does the company's personnel policy comply with the special requirements for the handling of Food, Cosmetic or/and Pharma grade products ?</b>				
1.2.1.	Has the company a sufficient number of qualified employees for these operations ?	Operation personnel engaged in product sampling, testing, handling, storage, packaging and transportation operations which may affect the quality of Food, Cosmetic or/and Pharma grade products, should: * be qualified for the tasks to be performed in accordance with the company policy, * have received the proper information and / or training for working on sensitive product applications and for using job-specific procedures (SOP's), * practice good sanitary and health practices, * wear clean clothing adequate for the work performed.	F	X	X	
1.2.2.	Have all (including administrative) personnel, involved in handling and distributing Food, Cosmetic or/and Pharma grade products been made aware of the risks for human health ?	All operational, technical and administrative personnel involved in handling and distribution of Food, Cosmetic or/and Pharma grade products should be fully aware of the requirements of these guidelines, and be trained accordingly. Check training records.	F	X	X	
1.2.3.	Have all (including administrative) personnel, involved in handling and distributing Food, Cosmetic or/and Pharma grade products been formally qualified according to written criteria ?	Check qualification records. Also non-operational personnel (e.g. logistics, marketing, etc.) involved in the administration of Food, Cosmetic or/and Pharma grade products distribution chain should have received a proper training focused on the sensitivity of the product applications.	F	X	X	
1.2.4.	Is there a person with the specific responsibility and the appropriate authority to deal with food, pharma and/or cosmetic related quality issues in your company ?	Check organisational charts. Verify that this person has enough time and resources to assure compliance with these Guidelines.	F	X	X	
1.2.5.	Are there enough employees involved in operations related to the Food, Cosmetic and Pharma business ?	Verify that there are enough employees for the different activities related to the business (e.g. sampling, testing, loading and unloading, repackaging, cleaning etc.)	F		X	
1.2.6.	Are these employees qualified according to quality principles applied related to food, pharma and/or cosmetic products?	Verify that there is enough internal and external training related to the operations carried out. These training have to be held periodically and should be documented. The current regulations should always be considered (food and drug law, GMPs etc.).	F		X	

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline
1.2.7.	Is there a specific qualification required for employees responsible for key activities in Safety, Health, Environment and Quality ?	Verify that employees responsible for quality assurance, quality control, engineering, SHE etc. have an appropriate specific qualification and education.
<b>1.3.</b>	<b>Are traceability, shelf life and product conformity issues sufficiently implemented in all processes ?</b>	<b>Are traceability, shelf life and product conformity issues sufficiently implemented in all processes ?</b>
1.3.1.	Is the company able to provide full traceability on product origin ?	1.3.1/3 : Traceability requires having a process in place for tracking the history of material from the manufacturer's final storage to the final delivery to customers by means of recorded identification. The entire distribution chain should provide a full traceability (via lot numbers etc.) in order to allow fast and efficient investigation of any quality issue and product recall when required. To be traceable, every delivery should be identified by the product name, a lot number and should be accompanied by the appropriate shipping and quality documentation. The distribution records should document all shipments of Food, Cosmetic or/and Pharma grade products and be properly filed. These records should, as a minimum, identify by batch or lot where and to whom the product was shipped, the quantity, the carrier and the date of shipment.
1.3.2.	Is the company able to provide full traceability in its own operations ?	
1.3.3.	Is the company able to provide full traceability on product destinations ?	
1.3.4.	Do you have written procedures on product shelf life control ?	The shelf life assigned to Food, Cosmetic or/and Pharma grade products should be approved by the manufacturer of the products. The shelf life should be taken into consideration at any step of the distribution chain and specified/labelled if possible. If the product is delivered in the originally sealed containers or transport equipment of the manufacturer, stability and shelf life information should only be handed over by the distributor and trader to the final customer. If the product is transferred to another container or repackaged by the distributor/trader, stability and shelf life considerations have to be made. The type of container, primary packaging materials and storage conditions used by the repackaging site have to be taken into account when a shelf life is defined. The recommended expiration date / shelf life provided by the original manufacturer should not be extended without demonstrating stability to justify an extended shelf-life. In such a case the type of container and storage conditions must be clearly defined.

Food/GTDP	Office	Operations	Score
F	X	X	

F	X	X	
F	X	X	
F	X	X	

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline
1.3.5.	Do you have written procedures on how to handle non-conforming, returned and rejected lots ?	If any material fails to conform to the specifications, or has been found otherwise to be adulterated, contaminated, or mislabelled, such material should be clearly identified and segregated to prevent inadvertent use or delivery. A system should be in place to record any non-conformance and to take the appropriate actions immediately. In those cases, product quality investigations should be conducted promptly and, when necessary, the non-conforming shipment should be recalled as well as possibly the entire lot. For this purpose, a product recall procedure should be in place. Records should be kept showing the final destination and utilisation (for instance downgrading or destruction of the product) of all non-conforming quantities as well as the root cause analyses and the corrective actions applied to avoid re-occurrence of such an event.
1.3.6.	Do you have a written procedure for product recall in case of a quality concern ?	Procedures for a product recall should be in place, describing responsibilities and the required actions to ensure a fast notification to all parties involved and if necessary a fast recall of the whole lot.
<b>1.4.</b>	<b>Are there procedures in place and documentation available to ensure consistency of product quality ?</b>	<b>Are there procedures in place and documentation available to ensure consistency of product quality?</b>
1.4.1.	Are all product receptions performed according to written procedures ?	There should be written procedures for reception of packed and unpacked products.
1.4.2.	Are there appropriate intake control procedures in place with conformity inspection, including the seals ?	For all receptions, the identity of the product should be checked against the delivery documents and the manufacturer's quality certificate. The integrity of the seals should also be checked.
1.4.3.	Is product reception recorded/documented according to a written procedure ?	It should be clearly defined, which shipping documents are to be expected with every delivery. The documents should provide sufficient information about the origin of the product and the parties involved in storage, transport and distribution. Quality and grade of the product should also be part of these documents. These documents should be checked during each product reception.
1.4.4.	Is every Product lot accompanied by a certificate of analysis (COA) or certificate of conformity (COC)?	For each product lot there should be an appropriate quality certificate such as a certificate of analysis or a certificate of conformity (see the Glossary) issued by a qualified laboratory (in-house or external) which certifies the conformance to all items of the specification. No data from original certificates of the manufacturer should be missing or changed on copies of COA's, especially batch numbers.
1.4.5.	Do COA's clearly indicate which tests are performed on every lot and which results are obtained via skip lot testing ?	Clear indication should be given, if the analytical test results on a certificate of analysis were obtained from a specific lot or from a periodical, statistically based testing (skip lot testing). If COA's of the original manufacturer are passed over to the customers, this information should be maintained.

Food/GTDP	Office	Operations	Score
F	X	X	
F	X	X	

F		X	
F		X	
F		X	
F	X	X	
F	X		

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline
1.4.6.	Is this certificate providing information about the origin of the product ?	Complete analytical data and data necessary to ensure traceability of Food, Cosmetic and Pharma products should be given on the COA and on other shipping documents.
1.4.7.	Are records and documents for every delivered batch retained for a defined period of time ?	Quality records (certificate of analysis, traceability and shipping documents, inspection reports, analytical records, etc.) should be kept as a minimum for the recommended product shelf life plus one year.
1.4.8.	Is it ensured that COA's of the original manufacturer are only used for originally sealed and properly stored products ?	The quality certificate of each lot remains valid during the shelf life period. The analytical data of the manufacturer only remain valid, if the manufacturer's containers are not unsealed, damaged, the original lot number is traceable and the storage conditions comply with the requirements. Under these conditions, the quality certificate of the initial packed lot can be used for each shipment.
1.4.9.	Is it ensured that no upgrading of industrial or technical grade products with identical names to food, cosmetic and/or pharma grade products can occur ?	Upgrading or otherwise certifying industrial / technical grade products with identical names to Food, Cosmetic or/and Pharma grade products (possibly with Pharmacopoeia nomenclature) is forbidden at any point of the distribution chain. Even if an analysis showed compliance with the Food, Cosmetic or/and Pharma specification, it can not be assumed that the material can be used as such a grade, because Food, Cosmetic or/and Pharma quality has to be designed and produced by the manufacturer from the beginning and not tested into the product by a downstream distributor.
1.4.10.	Is it ensured that bulk transport equipment and containers received and delivered are properly sealed ?	All tank/silo trucks, rail cars and containers should be properly sealed with tamper-resistant devices. It is recommended to record seal numbers on shipping documents. The identification and the integrity of the seals should be checked at the sending and the receiving locations. Any product received with violated or broken seals should be considered as no longer a Food, Cosmetic or/and Pharma grade product, unless an investigation of the cause, a risk assessment and a full analysis of all specification items allow a qualified person to re-qualify the product with proper documentation kept on file.
1.5.	<b>Are there proper testing procedures in place for bulk products and products intended to be repackaged ?</b>	<b>Are there proper testing procedures in place for bulk products and products intended to be repackaged ?</b>

Food/GTDP	Office	Operations	Score
F	X		
F	X	X	
F	X		
F	X	X	
F		X	

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline	Food/GTDP	Office	Operations	Score
1.5.1.	Is the Product received in bulk checked and/or tested for quality and identification at the receiving site ?	<p>All lots of Food, Cosmetic or/and Pharma grade products in bulk should be checked and tested at the receiving site before being unloaded. These checking / testing records should be kept in writing by the manufacturing plants, the terminals, the distributors and the end customer. Appropriate key point analyses for detection of obvious contaminations and for positive product identification should be performed and documented before bulk material being released for unloading or refilling/re-packing, in accordance to a documented procedure. Key point controls are simple tests performed to identify the product and check for possible contamination. Their purpose is not to modify the initial quality certificate unless limits of the specification are exceeded.</p> <p>Key points for product identification can be any characteristic test such as density, refractive index, GC, UV or IR spectrum or others. The test should be performed after each bulk loading/packing and before each bulk unloading or bulk refilling, as detailed in the following paragraphs. Key points for contamination detection should include, as a minimum, a visual detection of colour and suspended or foreign matter, and a check for foreign odours. It is also recommended to analyse for water content, as appropriate. These tests should be performed each time after bulk products are transferred into a different tank or container. If key point controls are in compliance with the sales specifications, the operations are performed in accordance to these guidelines, and there is no mixing of different lots, the analytical data of the quality certificate of the upstream materials can be carried over to the downstream lot.</p>	F		X	
1.5.2.	Is the Product checked and/or tested for quality and identification each time it is transferred from one container to another ?	<p>Each time Food, Cosmetic or/and Pharma grade products are transferred from one container to another in the distribution chain (tank, iso-container, drum, etc.), they should be sampled to allow further investigation in case of a quality claim. Samples should be taken from the transport equipment after the filling according to precise procedures to ensure that they are representative. Key point testing of these samples (after each loading and/or repackaging process) should be defined to cover possible risks from non-dedicated filling equipment and containers. As long as key point analyses are performed with positive results, the quality certificate may refer to the tank/silo from which the shipment is done. This is not always necessary in case of fully dedicated equipment and the use of brand new packaging materials.</p>	F		X	

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline
1.5.3.	Is each Product lot released and re-certified each time it is mixed with another lot?	If the product is unloaded into an intermediate and not emptied (drained) storage tank and / or mixed with another lot, the initial analytical data are no longer valid. The analytical data are also no longer valid in case of processing/reprocessing of the material (e.g. grinding, drying, distilling or dissolving). A new lot number should be assigned and as a minimum, a new certificate of conformity should be issued in conformance with specification requirements. In case a certificate of analysis is required, new analysis should be performed, reporting actual test results. If no new full analysis can be performed only a certificate of conformity based on key point analysis without analytical data can be issued (EN 10204 2.1). These batches have to be released by a qualified person prior to any further operation like packaging, labelling, bulk loading etc.
1.5.4.	Are appropriate laboratory facilities and controlled testing equipment available?	
1.5.5.	Are written testing procedures in place for all tests carried out?	
1.5.6.	Are all test data recorded and archived in a traceable way?	
<b>1.6.</b>	<b>Are there written procedures for sampling in place and maintained ?</b>	<b>Are there written procedures for sampling in place and maintained ?</b>
1.6.1.	Are all samples taken and retained according to written procedures ?	Written procedures should be in place, describing in sufficient details the sampling process, as well as the sample storage conditions. The samples taken for quality certification of lots should also be retained during the product recommended shelf life plus one year.
1.6.2.	Are sampling procedures sufficient to ensure representative samples for quality control ?	All samples should be representative and properly labelled. Extreme care should be taken to avoid contamination by the sampling equipment (e.g. ropes).
1.6.3.	Are utensils and sampling devices cleaned and stored in a manner to prevent contamination ?	During sampling, only clean odourless glassware (or other suitable material) should be used. Every sampling device should be dedicated to only one product.
1.6.4.	Do sampling processes ensure sufficient protection of product quality?	
1.6.5.	Are retained samples of sufficient size kept for each lot or shipment of repackaged or bulk products for a defined period ?	Sample size should be twice the amount required to perform specification testing. The volume may vary based on the type of analysis required. Samples should be stored during the product recommended shelf life plus one year under proper conditions to preserve the quality of the product.
<b>1.7.</b>	<b>Are there appropriate precautions taken to avoid cross-contaminations during product handling ?</b>	<b>Are there appropriate precautions taken to avoid cross-contaminations during product handling ?</b>

Food/GTDP	Office	Operations	Score
F		X	
F		X	
F		X	
F		X	
F		X	
F		X	
F		X	
F		X	
F		X	



## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline	Food/GTDP	Office	Operations	Score
1.7.1.	Is each piece of equipment in contact with the product dedicated to the product or effectively cleaned according to a written procedure?	Each piece of equipment in contact with Food, Cosmetic or/and Pharma grade products should be fully dedicated to one Food, Cosmetic or/and Pharma grade product, the same product as industrial/technical grade, or as a minimum to acceptable food grade products (e.g. consider toxicity, odour, physical properties influencing the cleaning) .	F		X	
1.7.2.	Is each piece of equipment in contact with the product clearly identified?	Self explanatory.	F		X	
1.7.3.	Is each piece of equipment in contact with the product made of suitable materials ?	All equipment surfaces in contact with Food, Cosmetic or/and Pharma grade products should be made of a material that does not affect its quality and should be easy to clean.	F		X	
1.7.4.	Is each piece of equipment in contact with the product maintained according to written procedures ?	Written records of equipment cleaning, maintenance and operations should be maintained. When cleaning of equipment is necessary, for instance in case of product change or maintenance activity, a documented cleaning procedure, validated for effectiveness, should be applied. In all circumstances, strict restrictions should be applied to the last product handled, and efficient inspection should be performed, in accordance with written procedures, before putting the equipment in service.	F		X	
1.7.5.	Is each piece of equipment designed and used in a manner that minimizes the potential for contamination of the product with lubricants, coolants, metal fragments, or other extraneous materials e.g. from pressurised air ?	Any substance required during the operation e.g. lubricants or coolants, should not come into contact with Food, Cosmetic or/and Pharma grade products. These substances should be non toxic and/or authorised for food grade applications. When pressurised air is used in direct contact with the product special precautions should be taken to avoid any contamination with extraneous materials like hydraulic oil and particles.	F		X	
<b>2.</b>	<b><u>Storage in tanks/silos</u></b>	<b><u>Storage in tanks/silos</u></b>				
<b>2.1.</b>	<b>Is the bulk storage equipment designed and used to protect the product quality ?</b>	<b>Is the bulk storage equipment designed and used to protect the product quality ?</b>				
2.1.1.	Is there a system in place to ensure that equipment for bulk storage is designed according to product requirements ?	Food, Cosmetic or/and Pharma grade products have to be stored in tanks or silos under conditions not affecting product quality. Special attention should be taken to avoid any contamination of the product while residing in the storage tank/silo and piping system. The recommendations of the manufacturer concerning design and material of the storage equipment should be followed.	F		X	
2.1.2.	Are all pieces of equipment coming in contact with the product compatible with the product and in compliance with legal requirements ?	Verify proper documentation about the compatibility of equipment materials with the product, e.g. inspection and approval of storage tank, silo and piping system by the manufacturer of the product or his authorised third party. Verify that materials of construction for the storage equipment comply with all legal requirements for the kind of product and type of equipment. Check related documentation.	F		X	

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline	Food/GTDP	Office	Operations	Score
2.1.3.	Is the equipment only used for Food, Cosmetic and/or Pharma grade products ?	It is recommended that the entire storage equipment, including storage tank/silo, piping system, pumps, filters is dedicated for usage of only one particular Food, Cosmetic or/and Pharma grade product and is clearly labelled. Alternatively, the last utilisation of the entire equipment should be the same product in industrial/technical grade or as a minimum for acceptable Food, Cosmetic or/and Pharma grade products.	F		X	
2.1.4.	Is there an effective cleaning procedure in place, whenever product change is necessary ?	Verify that there is a written cleaning procedure, validated for effectiveness, used whenever a change in product service is necessary. The extend of validation has to be defined on the basis of product characteristics. In many cases testing of the final rinse for Total Organic Carbon (TOC) or other simple methods are sufficient.	F		X	
2.1.5.	Is the storage tank equipped with a monitored nitrogen blanketing system or a drying equipment, if necessary, to protect the product against oxidation and / or moisture?	Food, Cosmetic or/and Pharma grade products may be hygroscopic and sensitive to oxidation. Atmospheric vents should be equipped with drying devices to protect the product against humidity. Nitrogen blanketing is the preferred means of keeping the product dry, preventing oxidation and ensuring the shelf-life. The quality of the blanketing gas should be controlled and should comply with legal requirements (food and drug law, GMPs etc.), especially regarding <u>absence of dust</u> .	F		X	
2.1.6.	Is the quality of the blanketing gas, if used, compatible with the Product ?	Verify documentation to give evidence for compatibility of the blanketing gas.	F		X	
2.1.7.	Is it ensured that the storage temperature is always kept within a defined range and controlled, if necessary for product quality or stability ?	The storage temperature should always comply with the individual requirements of the particular Food, Cosmetic or/and Pharma grade product. The recommendations of the manufacturers should be considered.	F		X	
2.1.8.	Are there appropriate written procedures for cleaning and maintenance of tanks/silos ?	Verify written procedures for these operations. Cleaning and maintenance activities of the storage equipment of Food, Cosmetic or/and Pharma grade products should be carried out according to written procedures and should be documented. Only compatible cleaning agents should be used. All activities should be performed without any risks of product contamination. Before return to operation, the equipment should be flushed with the product and the last flush (final rinse) should fulfil the requirements of the specification.	F		X	
2.1.9.	Do you ensure that your sampling installation is able to provide a representative sample ?	Verify that sampling points and devices are installed at places in bulk storage systems to provide representative samples. This is of special importance when batches are mixed. In these cases ring systems (circulation line) are recommended. Otherwise sampling has to be conducted at the filling station after line clearance.	F		X	
<b>2.2.</b>	<b>Do bulk storage operations ensure batch homogeneity and authenticity of COA's ?</b>	<b>Do bulk storage operations ensure batch homogeneity and authenticity of COA's ?</b>				

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline
2.2.1.	Are written procedures in place to ensure batch homogeneity in case of mixing different batches in tanks/silos ?	Verify that written procedures define the process of mixing different batches depending on product and equipment characteristics (e.g. viscosity, particle size and distribution, batch size, pump capacities etc.).
2.2.2.	Is there always a representative sample taken after batch mixing ?	When different batches are mixed, a new batch is formed. To have a representative retained sample and a sample for re-certification, a sample from the new batch is required.
2.2.3.	Is there always a new batch number assigned in case of batch mixing ?	Batch mixing is forming a new batch. For clear identification a new batch number has to be assigned. There should be a system in place to ensure that these numbers are clearly identifying every single batch.
2.2.4.	Is it ensured that analytical data on COAs for mixed batches are always based on new analyses ?	For mixed batches analytical data from original manufacturer's COA's are no longer valid. In these cases analytical data to be reported on the COA should be based on new analyses of a representative sample taken from the bulk storage tank/silo, or a COC been issued based on key point controls found within specifications (see also 1.5.3).
2.2.5.	Is it clearly indicated on COAs issued by the distributor on the basis of own analyses, which items are performed on the specific lot and which are created via skip lot testing ?	For the usefulness of analytical data it is important for downstream users to know which tests have been performed on a representative sample of the delivered lot and which data are based on statistical testing. See also 1.4.3. : It should be clearly defined, which shipping documents are to be expected with every delivery. The documents should provide sufficient information about the origin of the product and the parties involved in storage, transport and distribution. Quality and grade of the product should also be part of these documents. These documents should be checked during each product reception.
2.2.6.	Is it clearly indicated on COAs issued by the distributor on the basis of own analyses, who performed the analyses and who released the product ?	COAs may be used by downstream-users to reduce their intake controls and to ensure traceability. Therefore it is important to provide information about the original source of these analytical data and the responsible function in the company releasing individual batches created via batch mixing by the distributor.
<b>3.</b>	<b><u>Loading and unloading of unpacked products</u></b>	<b><u>Loading and unloading of unpacked products</u></b>
<b>3.1.</b>	<b>Are appropriate loading and unloading procedures in place ?</b>	<b>Are appropriate loading and unloading procedures in place ?</b>

Food/GTDP	Office	Operations	Score
F		X	
F		X	
F		X	
F		X	
F	X	X	
F	X	X	

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline
3.1.1.	Do you have written procedures and documentation for loading of products ?	<p>Verify that all loading activities are described in written procedures. It is recommended to use and file a loading checklist, signed by the loading operator. Special attention should be given to exclude filling mistakes. In particular, the following controls should be performed as a minimum: Check of certificate of adequate cleaning and pre-load restrictions for transport equipment, visual inspection for cleanliness of transport equipment and its accessories (like valves outlets etc.), cleanliness of the loading equipment, proper connection(s) between loading and transport equipment, proper closing and sealing of all valves and openings after completion of loading.</p> <p>For loading of larger product volumes (capacity higher than 100 metric tons) into ships and barges, it is recommended to use a modified procedure, controlled by an independent surveyor, including the following steps: visual inspection for cleanliness, loading of an initial, smaller amount of material (approximately 20 metric tons), circulation of this material through all lines, tanks and accessories, used for the corresponding shipment, taking a sample of this material and performing key point analysis for contamination detection, continue the loading process till completion, if key point controls are in compliance with the specification of the product. Otherwise remove the initial amount, go back and start again with step 2. Verify that sampling and key point control analyses after the completed loading process are performed.</p>
3.1.2.	Do you have written procedures and documentation for unloading of products ?	All unloading activities should be described in written procedures. It is recommended that an unloading checklist is used and signed by the unloading operator and filed. Prior to unloading, all seals should be verified for correctness and the material identified based on shipping documents. A representative sample should be taken, analysed for key point items.
3.2.	Is all equipment in contact with products designed to protect product quality?	Is the entire equipment in contact with products designed to protect product quality?

Food/GTDP	Office	Operations	Score
F		X	
F		X	

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline
		<p>Loading facilities should be designed and constructed in a way to ensure product quality and to avoid any product contamination during the loading process. Food, Cosmetic or/and Pharma grade products are typically unloaded from transport in tank/silo trucks, tank/silo containers, rail tank/silo wagons, ships or barges into a storage tank/silo, for repackaging into smaller containers like IBC's, drums, bags or smaller packages or for end-use at final customers. Direct packaging from transport equipment into smaller containers is also usual. Unloading facilities and operations should be designed and constructed in a way to ensure product quality and to avoid any product contamination during the unloading process.</p>
3.2.1.	Is all equipment in contact with products located in clean areas?	The entire loading and unloading area should be clean and preferably equipped with a roof and weather protection. A clean environment should provide protection from foreign material such as dust, insects and odorous and/or toxic compounds as much as possible.
3.2.2.	Is the loading equipment in contact with products dedicated, or, are validated cleaning procedures applied between loadings ?	It is recommended that the entire loading equipment, including the piping system, pumps, valves, flow elements, rigid loading arms or flexible hoses are dedicated for only one particular Food, Cosmetic or/and Pharma grade product and clearly labelled. Alternatively, the last utilisation of the entire loading equipment should be as a minimum for the same product of industrial grade or another acceptable Food, Cosmetic or/and Pharma grade product. In any case, a written cleaning procedure, validated for effectiveness, should be used whenever a change in product service is necessary.
3.2.3.	Is the unloading equipment in contact with products dedicated, or, are validated cleaning procedures applied between unloadings ?	It is recommended that the entire unloading equipment, including piping systems, pumps, filters, valves, flow measuring elements, is also dedicated for only one particular Food, Cosmetic or/and Pharma grade product and clearly labelled. Alternatively, the last utilisation of the entire unloading equipment should be as a minimum for the same product in industrial/technical grade or other acceptable pharmaceutical or food grade products. In any case, a written cleaning procedure, validated for effectiveness, should also be used whenever a change in product service is necessary. Unloading is preferably carried out by using a pump and a rigid arm or a flexible hose connected to the bottom valve of the transport equipment. A filter on the vapour phase inlet is recommended to avoid ingress of particles during unloading. Alternatively, the unloading may be achieved by pressurising the transport equipment with clean nitrogen or dry, filtered air.

Food/GTDP	Office	Operations	Score
-----------	--------	------------	-------

F		X	
F		X	
F		X	

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline
3.2.4.	Is the entire equipment in contact with products labelled ?	Check for proper and resistant labelling of pipes, unloading valves, hoses etc.
3.2.5.	Is the entire equipment in contact with products drained and capped after the operation, according to written procedures ?	The entire equipment including all connections and hoses should be immediately drained and capped after usage in order to avoid contamination with dust and moisture. Flexible hoses and other loading devices have to be properly stored to avoid contamination and misuse. It is recommended to use the customer's own dedicated hoses and connectors for unloading at customer sites.
3.2.6.	Are loading and unloading operations designed to avoid contamination of products?	Loading of tank/silo trucks, railcars and tank containers is preferably carried out in a dedicated loading bay via a rigid loading arm through the bottom valve. In case of loading through the top dome, it should be covered during the loading process to avoid contamination by dust or water. Loading via dedicated flexible hose may also be done, as long as they are properly stored to avoid contamination and misuse.
3.2.7.	Do you inspect the cleanliness of the transport equipment before loading ?	3.2.7/8 : Verify proper inspections of cleanliness, e.g. visual inspections or final rinse tests. Inspection documents are important for traceability.
3.2.8.	Do you keep cleanliness inspection documents ?	
3.2.9.	Do you take a retain sample from the filled transport equipment after loading ?	3.2.9/14 : Prior to unloading, all seals should be verified for correctness and the material identified based on shipping documents. A representative sample should be taken and analysed for key point items.
3.2.10.	Do you perform key point analysis for positive identification and detection of evident contamination after loading ?	
3.2.11.	Do you seal all valves and openings after loading ?	
3.2.12.	Do you check the integrity of the seals before unloading ?	
3.2.13.	Do you perform key point analysis for positive identification and detection of evident contamination before unloading ?	
3.2.14.	Do you take a retain sample before unloading ?	
<b>4.</b>	<b>Transportation of unpacked products</b>	<b>Transportation of unpacked products</b>
<b>4.1.</b>	<b>Are appropriate transportation procedures in place ?</b>	<b>Are appropriate transportation procedures in place ?</b>

Food/GTDP	Office	Operations	Score
F		X	
F		X	
F		X	
F		X	
F		X	
F		X	
F		X	
F		X	
F		X	
F		X	

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline	Food/GTDP	Office	Operations	Score
4.1.1.	Do you evaluate your transporters in accordance to SQAS or similar schemes ?	The transport of Food, Cosmetic or/and Pharma grade products requires high quality standards in order to avoid any product contamination. Every transport company should demonstrate commitment to these standards by using quality management systems like ISO 9000 series, GMP and Responsible Care. It is recommended that hauliers for road transportation be evaluated in accordance with the Cefic Safety and Quality Assessment System (SQAS) or similar schemes. Ships used for transport of Food, Cosmetic or/and Pharma grade products should be evaluated by the CDI (Chemical Distribution Institute) or similar organisations. Rail companies also should have quality management systems in place. Trans-boarding between intermediate vessels should be avoided, unless specific controls are in place to prevent contamination.	F	X	X	
4.1.2.	Do you prohibit sub-contracting unless specific controls are performed ?	Contractual arrangements with transport companies should explicitly ensure that the transport is not sub-contracted, unless specific controls are satisfied, ensuring the same level of quality.	F	X	X	
4.1.3.	Do you exclusively use dedicated transport equipment ?	It is highly recommended to use tank trucks, containers and railcars, dedicated to only one Food, Cosmetic or/and Pharma grade product. In case of non-dedicated transport equipment, a specific cleaning procedure, e.g. suitable for food grade materials, should be used and the actual last cargo should be mentioned on the cleaning certificate.	F	X	X	
4.1.4.	If you use non-dedicated equipment, do you impose a specific cleaning procedure with a cleaning certificate ?	<p>Proper cleaning and inspection of the transport equipment is of utmost importance and should be performed on every container prior to loading, including pumps, hoses, seals and other equipment, coming into contact with the product. Tank trucks, rail cars and containers, used in dedicated transport for a particular Food, Cosmetic or/and Pharma grade product, may not need to be cleaned before being reloaded, if all valves are immediately resealed after unloading at the offloading site and after return are proven to be undamaged. However, to avoid any risks of cross contamination, possibly caused during the unloading process at the customer, at least a simplified cleaning is recommended. Only appropriate cleaning agents should be used. The cleaning procedure should be documented and should not be changed without proper notification and approval. A cleaning certificate should be provided, including the type of last cargo.</p> <p>It is highly recommended that ships and barges be inspected and analytically tested for prior cargo according to written procedures, by an authorised laboratory or an independent surveyor, before the full loading of a Food, Cosmetic or/and Pharma grade product is allowed.</p>	F		X	

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline	Food/GTDP	Office	Operations	Score
4.1.5.	Are cleaning procedures validated ?	Verify that cleaning procedures are carried out following written procedures. Data should exist that demonstrate a scientific basis for cleaning procedures. Validation in that context is showing that cleaning procedures applied are sufficient to avoid any cross-contamination of a product by the prior cargo of the transport equipment. Swap tests and final rinse analyses are examples for basic cleaning validation procedures.	F		X	
4.1.6.	If you use non-dedicated equipment, do you impose a list of prohibited or allowed last cargoes ?	<p>A list of prohibited or allowed last cargoes should be defined on the basis of the acceptability criteria as stated above and applied to shipments in transport equipment not dedicated for a particular Food, Cosmetic or/and Pharma grade product. A policy for previous and adjacent cargoes should be developed and applied for all shipments in non-dedicated transport equipment to protect end-users from product cross contamination. This policy should include either a positive or a negative list (allowed or prohibited cargoes). The following criteria should serve as a guideline to develop a positive list with allowed prior cargoes, as appropriate: food grade material with the exception of those originating from animal substances; a material not classified as toxic, carcinogen, teratogen, mutagen or reproductive toxin by any respected publication or authority; a material not classified as insecticide, pesticide, herbicide, biocide or fungicide; a material not reactive with the product.</p> <p>It is highly recommended that any deviation from these criteria should be tolerated only if competent personnel carry out a specific and documented risk analysis. This risk analysis might involve consideration about for example physical properties of the material under question and application of specific cleaning procedures and surveillance activities.</p> <p>Ships and barges: A list for approved or prohibited prior cargo for the last pre-load should be applied for non-dedicated ships and barges, ensuring that the product is not loaded after compounds that would affect the quality even at very low levels of contamination. It is recommended that multi-compartment deliveries be carried out with product compatible to the Food, Cosmetic or/and Pharma grade product in the adjacent tank compartment in accordance with the prior cargo list.</p>	F	X	X	



## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline
4.1.7.	With your transport companies, do you have a formal agreement specifying your sealing requirements ?	Loading and unloading valves and domes (as well as the tube boxes) of transport equipment, used for transportation of Food, Cosmetic or/and Pharma grade products, should be sealed after loading, using tamper-proof seals in order to ensure that impurities cannot be introduced either inadvertently or on purpose during transport. A way to ensure this is to record seal numbers on the shipping documents, so that the offloading site is able to match the numbers against the incoming papers. If the shipment arrives at the final destination with one or more of these seals broken, replaced or missing, the incident should be documented and the supplier informed. The product should be downgraded to industrial or technical grade or sent back to the supplier. When trucks and railcars, exclusively dedicated to a Food, Cosmetic or/and Pharma grade product, are used, the same sealing procedures should be applied to the empty, returned transport equipment if it is not cleaned before next loading. Sealing of ships and barges is recommended as well.
4.1.8.	With your transport companies, do you have a formal agreement specifying the suitable materials in contact with the products ?	Materials of construction for the transport equipment should comply with all legal requirements and be approved by the manufacturer of the stored Food, Cosmetic or/and Pharma grade product.
4.1.9.	Are distribution records kept for each shipment ?	Distribution records should be kept for all shipments of Food, Cosmetic or/and Pharma grade products, including as a minimum lot number, name and location of receiving party, quantity, carrier and date of shipment.
<b>5.</b>	<b>Packaging</b>	<b>Packaging</b>
		In these guidelines, Packaging of Food, Cosmetic or/and Pharma grade products is defined as filling containers such as 200/250 litre steel or plastic drums, and 1 m3 intermediate bulk containers (IBC's), bags and smaller packages from any bulk storage or transport equipment (e.g. tank/silo trucks, containers, drums, big bags etc.).
<b>5.1</b>	<b>Is the environment and the entire equipment in contact with products designed to protect product quality ?</b>	<b>Is the environment and the entire equipment in contact with products designed to protect product quality ?</b>

Food/GTDP	Office	Operations	Score
F	X	X	
F	X	X	
F	X	X	

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline	Food/GTDP	Office	Operations	Score
5.1.1.	Is the equipment in contact with products dedicated or are validated cleaning procedures applied in case of product changes ?	It is recommended that every piece of equipment in contact with the product, including piping systems, hoses, pumps, filters, valves, flow measuring elements, be dedicated for usage of only one particular Food, Cosmetic or/and Pharma grade product and clearly labelled. Alternatively, the last utilisation of the relevant equipment should be as a minimum for the same product in industrial/technical grade or other acceptable pharmaceutical or food grade products. In any case, a written cleaning procedure, validated for effectiveness, should be used whenever a change in product service is necessary. The equipment should be made of material that is easy to clean. All accessories such as gaskets or pump seals should be made of food/cosmetic/pharmaceutical compatible material (asbestos is forbidden).	F	X	X	
5.1.2.	Is the equipment in contact with products clearly labelled ?	Check for proper and resistant labelling of pipes, hoses, repackaging instruments etc. for product name and direction of flow.	F		X	
5.1.3.	Are there procedures in place to ensure compatibility of equipment with the products ?	Packaging equipment should be constructed such that contact surfaces will not be reactive, additive, or absorptive and thus not alter the quality of the Food, Cosmetic or/and Pharma grade products. Equipment should be designed to minimize the possibility of contamination caused by direct operator contact. All auxiliaries such as for example pump lubricants or greases on loading arm joints, which might contaminate the Food, Cosmetic or/and Pharma grade products in case of mechanical failure should be food grade approved.	F		X	
5.1.4.	Can liquid product be filtered prior to the packaging operation when required ?	For certain liquid products filtration is recommended.	F		X	
5.1.5.	If a filter is used, are there procedures in place for use and maintenance of the filter system?		F		X	
5.1.6.	Is the environment of the packaging operation separated from other operations (or at least devoted to compatible products) ?	The industrial site on which such operations are performed should comply with the following conditions: The site should be efficiently secured. Access to the site should be limited to authorised persons. The areas devoted to handling and storing of Food, Cosmetic or/and Pharma grade products should be clearly designated, preferably dedicated to compatible products such as pharmaceuticals, cosmetics or food grade materials, and effectively separated from other types of products. The site should be kept in clean and orderly conditions, and industrial hygiene should be maintained.	F		X	

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline
5.1.7.	Is the environment of the packaging operation clean and dust free ?	The packaging operation should be conducted in a clean environment, preferably in a room pressurised with air of appropriate quality to ensure product integrity during the filling operation. Adequate control of dust, dirt, insects, chemical vapours, etc. should be maintained to prevent any contamination of the product. Opening of empty and filled containers and sampling of the bungs should be done in the clean environment before releasing for storage.
5.1.8.	Is the environment of the packaging operation pressurised with filtered air if necessary for the products ?	Verify that there have been sufficient investigations performed, if products need additional protection during packaging. Pressurized and filtered air can avoid microbial and particle contamination or degradation. The degree of protection required may vary depending on the type of product. As a minimum Food, Cosmetic or/and Pharma grade products should be repackaged in a clean and protected environment.
5.1.9.	If hazardous (e.g. toxic, corrosive etc) products are present on the site, is there a written procedure for segregation or prevention of contamination ?	The presence of any toxic product in the packaging area should be identified and recorded. Any risk of cross contamination and handling mistakes with a toxic product should be evaluated and proper prevention enforced.
<b>5.2.</b>	<b>Are there packaging operations in place to ensure product quality and traceability?</b>	<b>Are there packaging operations in place to ensure product quality and traceability ?</b>
5.2.1.	Is each packed lot fully traceable (including the packaging material) ?	All packaging procedures should be designed and carried out to ensure full traceability of the products back to the original manufacturer and downstream to the final customer. Verify shipment documents and order handling files that the destination of every packed container can be traced. Therefore lot number and container reference number should provide full traceability allowing the identification of the packaging site, the packaging date and the origin of the product. It is recommended that the filling and marking/labelling operations are done simultaneously.
5.2.2.	Is each lot homogeneous in quality ?	Mixing of different batches of the same product can lead to non-homogenous blends. Verify that mixing processes are always carried out according to written procedures to make sure, that homogenous lots are achieved. In these cases new batch numbers have to be assigned. Original manufacturers` lot numbers are no longer valid for mixed batches.
5.2.3.	Are there written procedures in place for all packaging and labelling operations ?	Written procedures should contain precautions to avoid cross-contamination during packaging operations, especially when materials are exposed to the environment. Written procedures for marking and labelling of products should be in place to avoid wrong labelling.

Food/GTDP	Office	Operations	Score
F		X	
F		X	
F		X	
F	X	X	
F		X	
F		X	

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline
5.2.4.	Are there packaging and labelling records available for each packaging and/or re-labelling operation ?	A written documentation of every filling process is required as a minimum. These records should contain product name, lot number, equipment, packaging operators, packaging materials, date and sample(s) of labels used.
5.2.5.	Is each packed lot linked to a retain sample ?	Retain samples can be taken from the bulk product before packaging or during packaging operations. There should be one representative retain sample available from each lot as a minimum.
5.2.6.	Is the expiry date, re-test date or the shelf- life written on each container (drums, IBC's, bags, etc) ?	It is recommended that the production date, the expiry date or the shelf life be written on each container.
5.2.7.	Are there key point controls performed prior to each repackaging process ?	<p>Key point controls are simple tests performed to identify the product and check for possible contamination. Their purpose is not to modify the initial quality certificate unless limits of the specification are exceeded. Key points for product identification can be any characteristic test such as density, refractive index, GC, UV or IR spectrum or others. The test should be performed after each bulk loading/packing and before each bulk unloading or bulk refilling, as detailed in the following paragraphs. Key points for contamination detection should include, as a minimum, a visual detection of colour and suspended or foreign matter, and a check for foreign odours. It is also recommended to analyse for water content, if appropriate.</p> <p>These tests should be performed each time after bulk products are transferred into a different tank or container. If key point controls are in compliance with the sales specifications, the operations are performed in accordance to these guidelines, and there is no mixing of different batches/lots, the analytical data of the quality certificate of the upstream material can be carried over to the downstream batch/lot.</p>
<b>5.3.</b>	<b>Are there control procedures in place to ensure appropriate quality of packaging materials ?</b>	<b>Are there control procedures in place to ensure appropriate quality of packaging materials ?</b>
5.3.1.	Are you controlling the quality and the cleanliness of containers prior to filling ?	The quality and internal cleanliness of the packaging materials should be controlled according to written procedures, with special care to prevent dust, foul odours, insects or foreign matter.
5.3.2.	For each cleanliness inspection, do you keep a written report ?	Check records.

Food/GTDP	Office	Operations	Score
F		X	
F		X	
F		X	
F		X	
F		X	
F		X	
F		X	

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline
5.3.3.	Is there a system to guarantee compatibility between Product and packaging material ?	The packaging materials should be compatible for the intended content. Plastic containers should be made of a food grade approved material, with opaque plastics being recommended to protect the product against any sunlight induced decomposition, as appropriate. Plastic drums made of translucent materials have to be protected from longer direct exposure to sunlight with a corresponding remark on the product label, if the containing product requires it.
5.3.4.	Do you ensure that packaging material is compatible with the product shelf-life ?	If the distributor is using packaging materials different from the materials used by the original manufacturer, it should be ensured that products can be stored in these containers for the shelf life assigned.
5.3.5.	Are container suppliers selected according to quality criteria ?	The quality of containers may have significant influence on the quality of Food, Cosmetic or/and Pharma grade products. Therefore suppliers should be selected on the basis of defined quality criteria. Specifications should be established and discussed with these suppliers. Packaging materials suppliers should be officially approved.
5.3.6.	Are container suppliers qualified and periodically assessed?	The manufacturing and handling of empty packaging materials should be considered as an important part of the distribution chain of Food, Cosmetic or/and Pharma grade products. Therefore suppliers should be qualified and periodically audited.
5.3.7.	Are container suppliers informed about the sensitive usage of the product(s) ?	The manufacturers of packaging materials need to be informed about the sensitive usage of their containers. Containers should be closed at the manufacturing facilities and opened just before filling in the packaging area or protected against contamination by an appropriate secondary container. It is recommended that on each drum, the drum manufacturing lot number and the supplier identification should be marked to provide a full quality traceability along the distribution chain.
5.3.8.	Are you prohibiting the use of reconditioned containers and the re-use of primary packaging materials ?	Reconditioned containers should not be used. Exception: Stainless steel IBC's dedicated to one particular Food, Cosmetic or/and Pharma grade product may be re-used, if they are cleaned according to validated cleaning procedures for food grade products prior to refilling or, if heels are analysed and released before refilling is carried out.
<b>5.4.</b>	<b>Are there appropriate procedures in place for processing operations ?</b>	<b>Are there appropriate procedures in place for processing and re-processing operations?</b>
5.4.1.	Are there written procedures in place for each processing operation ?	Check written procedures.

Food/GTDP	Office	Operations	Score
F		X	
F		X	
F		X	
F	X	X	
F	X	X	
F	X	X	
F	X	X	
F	X	X	

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline
5.4.2.	Are batches of processed products sufficiently tested for quality and released ?	If operations such as drying, micronisation, milling, distilling, blending etc. are carried out with the material, it has to be decided by a qualified person, which analytical tests have to be performed again to confirm the quality of the material. Key point testing is required as a minimum. In any case the processing/reprocessing operations should be documented on the certificate of analysis.
<b>6.</b>	<b>Warehousing and shipments of packed products</b>	<b>Warehousing and shipments of packed products</b>
<b>6.1.</b>	<b>Are there appropriate warehousing procedures in place to protect product quality ?</b>	<b>Are there appropriate warehousing procedures in place to protect product quality ?</b>
6.1.1.	Are containers stored in dedicated areas with adequate separation from other products in order to prevent errors ?	Containers should be stored in dedicated areas, with adequate separations from other products, especially hazardous products.
6.1.2.	Are containers stored subject to a shelf life control system ?	"First in/First out" inventory management or equivalent should be applied for the control of shelf life.
6.1.3.	Are containers stored protected from adverse weather conditions ?	Containers should be stored in closed warehouses or under roofs as a minimum to avoid direct contact to rain, snow, sunlight etc.
6.1.4.	Are containers of sensitive products stored under appropriate storage conditions that are adequately monitored ?	Some Food, Pharma and/or Cosmetic grade products require special storage conditions to avoid degradation during warehousing. These products and conditions should be identified and written procedures should be established to ensure the required storage conditions for every product. Light exposure, atmospheric humidity and maximum temperature conditions as indicated by the manufacturer should be respected.
6.1.5.	In case you have to open a container, e.g. for sampling, do you have a written procedure to prevent contamination ?	Opening of product containers is a sensitive operation with high risk of contamination. Written procedures should clearly define protective measures to avoid contamination. It is important to define the appropriate environment for opening, the equipment used, and how this should be done. Any opening of the containers in the normal storage area is prohibited. Every opening operation should be recorded and traceable.
6.1.6.	In case you have to open a container do you have a quality re-certification and release procedure ?	It should be clearly defined in written procedures how containers will be re-certified and released after they have been opened.
6.1.7.	Do you have a procedure for re-sealing of containers after opening ?	After opening every container has to be re-sealed. A seal is providing important information for the customer about possible contamination during shipment.
<b>6.2.</b>	<b>Are there appropriate loading and shipment procedures in place ?</b>	<b>Are there appropriate loading and shipment procedures in place ?</b>

Food/GTDP	Office	Operations	Score
F	X	X	

F		X	
F		X	
F		X	
F		X	
F		X	
F		X	

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline
6.2.1.	For container loading/shipment do you use a check list for final inspection ?	Loading and shipment controls should ensure that product quality is not badly affected by improper transport conditions and that there is no high risk of container damage. Therefore appropriate check lists for final inspections should be used.
6.2.2.	Are loading/shipment data documented so that details can easily be traced back ?	Every shipment should be done according to a written procedure. The internal documentation and the accompanying documents of shipments should provide full traceability of the products.
<b>6.3.</b>	<b>Are there appropriate procedures in place for the handling of returned Food, Pharma and/or Cosmetic grade products ?</b>	<b>Are there appropriate procedures in place for the handling of returned Food, Pharma and/or Cosmetic grade products ?</b>
6.3.1.	Are returned products stored separately and appropriately handled according to written procedures ?	Any returned Food, Cosmetic or/and Pharma grade product should be quarantined and not fed back into the distribution chain for these products, unless re-certification via extensive analytical testing assures full compliance with the specification and other quality standards. Returned product should be stored separately and should be appropriately labelled. In order to avoid any risk of undetected contamination, it is recommended to downgrade any returned product from pharmaceutical/food to industrial grade.
<b>7.</b>	<b>Product stewardship</b>	<b>Product stewardship</b>
7.1.	Does the distributor demonstrate his responsibilities to assure compliance with Product Stewardship principles along the entire supply chain ?	Product Stewardship is one of the basic tenets of Responsible Care. The whole distribution chain for Food, Cosmetic and/or Pharma grade products should be controlled, traceable and safe. If several actors are involved in the distribution chain, every actor should make sure that Food, Cosmetic and/or Pharma grade products are strictly handled according to these guidelines at every stage. This means every actor in the distribution chain is also responsible for subsequent actors down to the end-user. The Assessor should seek evidence that the company has tried to ensure integrity of the distribution chain using techniques such as: Contracts, agreements, inspections, assessments and audits.
7.2.	If you supply a sub-distributor, are they signatories to a Responsible Care programme run by a National Association?	Look for evidence.
7.3.	If you supply a sub-distributor, have they been assessed to SQAS Distributor/ESAD- Section F?	Look for evidence.
7.4.	Is there a system in place to ensure compliance of contractors with the principles of section F?	

Food/GTDP	Office	Operations	Score
F		X	
F		X	

F		X	
---	--	---	--

F	X	X	
F	X	X	
F	X	X	





## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline	Food/GTDP	Office	Operations	Score
	<i>(Covered in case of ISO 9001:2008 certification or third party HACCP verification)</i>					
1.3.	Is there a library of relevant regulations on excipients for pharmaceuticals ?		G	X	X	
1.4.	Is a person designated or a source defined to keep the company informed about legislative developments in the area of starting materials for pharmaceuticals ?		G	X	X	
1.5.	Are responsibilities for assessing the impact of such legislative developments and for proposing actions to comply with these clearly defined ?		G	X	X	
1.6.	Is a regular review made of the system for compliance with legal requirements ?		G	X	X	
1.7.	Does the company have a written policy including management's active commitment to Quality ?		G	X	X	
1.8.	Is the policy signed by top management ?		G	X	X	
1.9.	Does the company operate a documented system for quarantining suspect product ?		G	X	X	
1.10.	Is there a procedure for internal audits of the management system including an audit plan?		G	X	X	
1.11.	Do those carrying out auditing have training in auditing and evaluation techniques ?		G	X	X	
1.12.	Is a formal management review held at least once a year ?		G	X	X	
1.13.	Do management reviews consider:					
1.13a	- findings of internal audits, recommendations made and corrective actions taken ?		G	X	X	
1.13b	- the overall effectiveness of the system in achieving quality objectives ?		G	X	X	
1.13c	- opportunities for updating and/or improving the system ?		G	X	X	
1.14.	Do management reviews consider trends in customer complaints ?		G	X	X	
1.15.	Do management reviews consider trends in non-conformance claims from suppliers ?		G	X	X	
<b>2.</b>	<b>Organization and Personnel</b>					
2.1.	Have job descriptions been made and regularly updated ?		G	X	X	

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline	Food/GTDP	Office	Operations	Score
2.2.	Has an evaluation been made of all activities to identify training needs ?		G	X	X	
2.3.	Is there qualified personnel for GTDP relevant operations with specific (technical) background/education ?		G		X	
2.4.	Are GTDP principles part of regular trainings ?		G	X	X	
2.5.	Are employee training and qualification records maintained ?		G	X	X	
2.6.	Are internal and external training courses documented ?		G	X	X	
2.7.	Are there procedures in place ensuring good hygiene of the personnel where exposure to material in open containers may occur (e.g. monitoring of health conditions, wearing of protective clothes etc.)?		G	X	X	
<b>3.</b>	<b>Premises</b>					
3.1.	Are areas where pharmaceutical starting materials are handled designed and operated in a way to ensure cleanliness, appropriate hygiene and a minimisation of cross-contamination risks ?		G		X	
3.2.	Are premises well constructed and in visibly good condition ?		G		X	
3.3.	Has the site implemented security measures to control access of unauthorized persons ?		G		X	
3.4.	Is there an effective pest control program in place?		G		X	
3.5.	If sampling is performed, are sampling areas arranged and procedures in place to prevent contamination and cross-contamination?		G		X	
<b>4.</b>	<b>Warehousing and Storage</b>					
4.1.	Are receipt and dispatch bays equipped with means to protect materials from weather ?		G		X	
4.2.	Are rejected and recalled materials stored in a defined segregated area ?		G		X	
4.3.	Are segregated materials appropriately labelled ?		G		X	
4.4.	Are specific storage conditions maintained, monitored and controlled where necessary ?		G		X	

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline	Food/GTDP	Office	Operations	Score
4.5.	Is adequate spill clean-up equipment available and are procedures in place for containing/collecting any spillage ?		G		X	
4.6.	Can spills be adequately contained ?		G		X	
4.7.	Is the warehouse well ventilated ?		G		X	
4.8.	If a heating/air-conditioning system is installed is it compatible with the stored products ?		G		X	
4.9.	Are the racking systems in good condition and protected from vehicle collision ?		G		X	
4.10.	Is there adequate lighting in the warehouse ?		G		X	
4.11.	Does the procedure for storage of packaged products consider the risk of incompatibilities between products ?		G		X	
4.12.	Is there a separate storage area provided for pharmaceutical starting materials ?		G		X	
<b>5.</b>	<b><u>Equipment</u></b> (general)					
5.1.	Is pipe work in contact with product labelled with direction of flow, where applicable ?		G		X	
5.2.	Are there a sufficient number of balances and measuring devices available which are necessary for the operation carried out ?		G		X	
5.3.	Is there evidence of regular equipment calibration ?		G		X	
5.4.	Do operation procedures detail how each piece of equipment critical to the processes should be used ?		G		X	
5.5.	Is the maintenance policy covered by written procedures ?		G		X	
5.6.	Is there a Preventative Maintenance Plan ?		G		X	
5.7.	Are maintenance records available ?		G		X	
5.8.	Is there a process in place for monitoring and approving the quality of maintenance ?		G		X	
5.9.	Is appropriate cleaning equipment selected to avoid contamination of products ?		G		X	
<b>6.</b>	<b><u>Documentation</u></b>					
6.1.	Is there a document control system in place ensuring proper design, approval, review and distribution of necessary documentation ?		G	X	X	

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline	Food/GTDP	Office	Operations	Score
	<i>(Covered in case of ISO 9001:2008 certification)</i>					
6.2.	Is there evidence that documents are laid out in an orderly manner and with clear and unambiguous content ?		G	X	X	
6.3.	Are COAs from original manufacturers checked against agreed specifications ?		G	X	X	
6.4.	Is regulatory and quality information from the manufacturer transferred to customers ?		G	X	X	
6.5.	Are labels applied to containers clear, unambiguous and permanently fixed ?		G		X	
6.6.	Is it ensured that the following information is provided with each shipment, either on the label or on the COA :					
6.6a	- the name of product, including grade and amount ?		G	X	X	
6.6b	- the batch number assigned by the original manufacturer or the batch number assigned by the repacker, if the material has been repacked and relabelled ?		G	X	X	
6.6c	- the retest date or expiry date and storage conditions (where applicable) ?		G	X	X	
6.6d	- identification of the original manufacturing site and contact details of the supplier ?		G	X	X	
6.7.	Is a Safety Data Sheet (SDS) provided in the local language :					
6.7a	- with each sample of a commercialised product ?		G	X	X	
6.7b	- with a first order in a timely manner ?		G	X	X	
6.8.	Is the dispatch of the SDS recorded by addressee and date ?		G	X	X	
6.9.	When new updated information becomes available, is it dispatched in a timely manner ?		G	X	X	
<b>7.</b>	<b><u>Repackaging and Relabelling</u></b>					
7.1.	Are line clearance checks and label controls carried out to avoid mislabelling ?		G		X	
7.2.	Are there appropriate hygiene procedures in place for repackaging operations and repackaging personnel ?		G		X	
7.3.	Are samples of each batch of labels kept with the repackaging/relabelling records ?		G		X	

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline	Food/GTDP	Office	Operations	Score
7.4.	Is the customer informed when mixed lots are supplied ?		G	X	X	
7.5	Is mixing of lots from different manufacturers avoided?		G		X	
7.6	Is there a system in place to avoid mixing of lots that do not conform to the specification with conforming lots?		G		X	
7.7.	Is there an agreement about the primary packaging materials used with the original manufacturers ?		G	X		
7.8.	In the event of reuse of primary packaging material is a validated cleaning procedure followed ?		G		X	
7.9.	Do you review label contents, prior to use, with information from product suppliers ?		G	X	X	
7.10.	Are repackaged batches released by a person independent from operations?		G		X	
7.11.	Are repackaging and quality records reviewed prior to batch release ?		G		X	
7.12.	Are only official pharmacopoeial methods or validated analytical test methods used ?		G		X	
7.13.	Are stability studies carried out in case products are repackaged into containers different from the containers used by the original manufacturer when this may be critical to product stability ?		G	X	X	
<b>8.</b>	<b><u>Complaints</u></b>					
8.1.	Does the complaint procedure contain recall criteria ?		G	X	X	
8.2.	Are complaints recorded and investigated to identify the origin and reason ?		G	X	X	
8.3.	Are other batches considered during an investigation of a complaint ?		G	X	X	
8.4.	Are appropriate follow-up actions including a possible recall taken ?		G	X	X	
8.5.	Is there a procedure ensuring the original manufacturer and customers are informed in case of serious quality problems including recalls ?		G	X	X	

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline	Food/GTDP	Office	Operations	Score
<b>9.</b>	<b><u>Recalls</u></b>					
9.1.	Is the recall procedure regularly reviewed and updated ?		G	X	X	
9.2.	Is there a procedure ensuring all customers and authorities are informed in case of serious or potentially life-threatening situations ?		G	X	X	
9.3.	Is the effectiveness of the recall system evaluated ?		G	X	X	
<b>10.</b>	<b><u>Returned goods</u></b>					
10.1.	Is there a system in place to ensure that returned goods are placed in quarantine ?		G		X	
10.2.	Is there a procedure defining the process of deciding about the fate of returned goods ?		G	X	X	
<b>11.</b>	<b><u>Handling of non-conforming goods</u></b>					
11.1.	Is there a procedure ensuring that non-conforming materials are prevented from reintroduction into market unless downgraded or reprocessed ?		G	X	X	
11.2.	Are product non-conformances investigated including consideration of other batches ?		G	X	X	
11.3.	Are activities with non-conforming products documented ?		G	X	X	
11.4.	Is feedback from customers entered into the non-conformance system ?		G	X	X	
11.5.	Is there a procedure in place to avoid blending of non-conforming materials with compliant materials ?		G		X	
<b>12.</b>	<b><u>Dispatch and Transportation</u></b>					
12.1.	Are there procedures in place to ensure controlled conditions during transportation of products where necessary ?		G	X	X	
12.2.	Are special transport conditions stated on the label where necessary ?		G	X	X	
12.3.	Are packaging materials used which prevent damage to the materials ?		G	X	X	
<b>13.</b>	<b><u>Contract Activities</u></b>					

## ESAD F&G - Questionnaire & Guidelines - English version - March 2011

Item N°	Question	Guideline
13.1.	Is there a written procedure for selection and use of contractors for handling of pharmaceutical starting materials ?	
13.2.	Does this procedure include safety and quality criteria for the selection of contractors ?	
13.3.	Does this procedure include performance evaluation of these contractors ?	
13.4.	Are contract acceptors evaluated to comply with GTDP principles prior to entering into the contract ?	
13.5.	Are contract acceptors periodically re-evaluated according to GTDP principles ?	
13.6.	Are contracts specifying the distribution of GTDP related task between contract giver and contract acceptor ?	
13.7.	Are contractors provided with :	
13.7a	- information relevant to the job to be done ?	
13.7b	- appropriate training if necessary ?	
13.7c	- appropriate personal protective equipment ?	

Food/GTDP	Office	Operations	Score
G	X	X	
G	X	X	
G	X	X	
G	X	X	
G	X	X	
G	X	X	
G	X	X	
G	X	X	
G	X	X	
G	X	X	