DNV·GL

P1 REPORT

Combipack Danmark A/S

Management System Certification

ISO 9001:2008, ISO 14001:2004

Audit Start - End date:	26-Sep-2016 - 26-Sep-2016
Project Number:	PRJC-294181-2011-MSC-DNK
DNV GL Team Leader:	Thorkil Johansen
Audit Team:	Thorkil Johansen

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Other Annexes:

- ✓ Audit Plan
- ✓ List Of Findings

Introduction

This report summarises the results and conclusions from the performed audit. The audit is performed as a formal part of the certification process with the aim to obtain or maintain certification of the management system. The key objective of a management system audit is to determine the conformity of the management system with the standard. Additionally to evaluate the effectiveness of the management system to ensure your organization is capable to achieve specified objectives and meet applicable statutory, regulatory and contractual requirements.

In DNV GL we believe our audits should not focus solely on compliance with requirements but also stimulate progress and improvements. Through our audit methodology we tailor the audit to your company's needs. The aim is to help improve your management system in order to achieve the intended outcomes and build sustainable business performance over time.

DNV GL

Driven by our purpose of safeguarding life, property and the environment, DNV GL enables organizations to advance the safety and sustainability of their business. DNV GL is a leading provider of classification, certification, verification and training services. With our origins stretching back to 1864, our reach today is global. Operating in more than 100 countries, our 16,000 professionals are dedicated to helping our customers make the world safer, smarter and greener.

As a world-leading certification body, DNV GL helps businesses assure the performance of their organizations, products, people, facilities and supply chains through certification, verification, assessment, and training services.

We also deliver deep insight and pragmatic support to major companies enabling them to build effective sustainability strategies. Partnering with our customers, we build sustainable business performance and create stakeholder trust.

General information

Scope of certification

Authoritycenter for stock and logistic, among these packing, storage, handling/shipping and risk control of temperature sensitive materials within pharmaceutical industry.

Key changes affecting the management system since last audit

- There are no major changes since last audit

Statement of confidentiality

The contents of this report, including any notes and checklists completed during the audit will be treated in strictest confidence, and will not be disclosed to any third party without the written consent of the customer, except as required by the appropriate accreditation authorities.

Accredited unit

Name of the accredited legal entity	DNV GL Business Assurance Denmark A/S
Address of the accredited legal entity	Tuborg Parkvej 8, DK-2900 Hellerup, Denmark

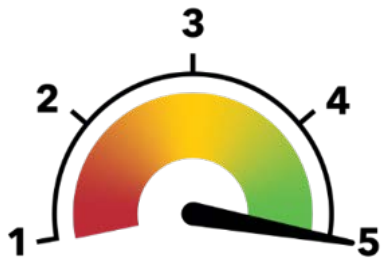
Disclaimer

A management system audit is based on verification of a sample of available information. Consequently there is an element of uncertainty reflected in the audit findings. An absence of nonconformities does not mean that they do not exist in audited and/or other areas. Prior to awarding or renewing certification this report is also subject to an independent DNV GL internal review which may affect the report content and conclusions.

Focus Area results

Focus Area 1

Styring af underleverandører



Low DEGREE OF CONTROL High

Positive indications

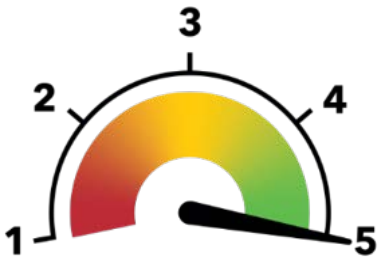
- Der er et godt overblik, dels omkring formalia omkring underleverandørers kompetencer, dels omkring styringen bag og kritterier for udvælgelse af leverandører.

Main areas for improvement

- Intet at bemærke,

Focus Area 2

Rengøringsprocedurer



Low DEGREE OF CONTROL High

Positive indications

- Rengøringsprocedurer vurderes velkendte, opdaterede og tilpassede til eksisterende kundesegment.

Other results

Key points observed during the audit not included in the Focus Areas.

Positive indications

- Ledelsesmæssig godt overblik over 'rigets' tilstand hos Combipack,
- Der forsøges en effektiv intern kommunikation
- Kort magtdistance

Main areas for improvement

- Der er ikke oplagte forbedringsmål, dog kan kommende planlagte generationsskifte evt. opprioriteres,
- Virksomheden er sårbar over kun at have primært en vigtig kunden (NN)

Audit findings and compliance status

Number of nonconformities identified during this audit	**0**
Number of category 1 (major) nonconformities:	0
Number of category 2 (minor) nonconformities:	0
Number of observations identified during this audit	**1**
Number of opportunities for improvement identified during this audit	**1**
The status of corrective actions for nonconformities from previous audit was reviewed.	
Number of nonconformities still not closed from previous audits	**0**

Notes:
1) For details of nonconformities, observations and opportunities for improvement, see list of findings.
2) See definitions of findings in Annex B.

Conclusion

- Auditprogrammet blev fulgt uden væsentlige ændringer.
- Ingen afvigelser blev identificeret under audit og certificeringen er fortsat gyldig.
- Der er jævnfør det positive resultat ikke behov for follow-up.

Next audit

Proposed date: 04-Sep-2017

Focus Area (suggested):

- Implementering af 2015 udgaver af ISO 9001 og 14001.

Annex A - Auditor statements

Verified elements of the standard	Objective evidence and result
Effektivitet af processerne for ledelsesevaluering og intern audit	Intern audit, dateret 29-04-2016 er fundet dækkende for dels system dels standard. Ledelsens genenmgang, dateret 23-5-2016 fundet dækeknde for begeg standarder, - begge område med god dybde i genenmgang og dokumentation.
Effektivitet af processerne for håndtering af kunde- og/eller interessentklager, inklusiv effektivitet af identificerede og implementerede korrigerende handlinger	Professionnel tilgang til at arbejde med afvigelser og reklamationer.
Ledelsessystemet er opdateret i overensstemmelse med ændringer i organisationen.	ok, dateret 12-09-2016
Effektivitet af processen med etablering af mål, planlægning af handlinger og evaluering af fremdrift og resultater	Processerne støtter godt omkring kerneydelsen af virksomheden, men det forventes, at der arbejdes med mere operationelle mål fremover.
Effektivitet af ledelsessystemet til sikring af, at organisationen er kapabel til overholdelse af relevante lov-, myndigheds- og kontraktkrav	Professionel tilgang til overblik og til sikring af evt. implementeringskrav opfyldes i ledelsessystemet.
Effektiv styring af brug af certificeringslogo og reference til certificeringen	Der skal fremsendes ny logoer fra DNV GL til Compipack,

Annex B - Handling of findings

Definition of findings

Major nonconformity (Category 1):

- The absence of one or more required system elements or a situation which raises significant doubt that products or services will meet specified requirements.
- A group of category 2 nonconformities indicating inadequate implementation or effectiveness of the system relevant to an element of the standard.
- A category 2 nonconformity that is persistent (or not corrected as agreed by the organization) will be up-graded to category 1.

Minor nonconformity (Category 2):
A lapse of either discipline or control during the implementation of system/procedural requirements, which does not indicate a system breakdown or raise doubt that products or services will meet requirements. Overall system requirement is defined, implemented and effective.

Observation
An observation is not a nonconformity, but something that could lead to a nonconformity, if allowed to continue uncorrected; or an existing condition without adequate supporting evidence to verify that it constitutes a nonconformity.

Opportunity for improvement
Opportunities for improvement relates to areas and/or processes of the organization which may meet the minimum requirement of the standard, but which could be improved.

Conditions for handling of nonconformities

The standard deadline to respond to nonconformities is max. 90 days. Within this timeframe the following is expected to be performed by the organization:

- Immediate action(s) to eliminate the nonconforming situation (if relevant for the nonconformity)
- Root cause analysis to identify corrective actions to prevent recurrence of the nonconformity
- Implement corrective actions and verify the effectiveness of action(s)
- Fill in the pertinent part of the “List of Findings” and submit to DNV GL’s Team Leader with relevant supporting documentation as evidence (when applicable)

Within the maximum timeframe and as a prerequisite before a certificate can be issued the following conditions apply:

- Major nonconformities: Evidence of root cause analysis and effectively implemented corrections and corrective actions shall be provided.
- Minor nonconformities: Preferred and normal status is the same as for major nonconformities, however, DNV GL's Team Leader may also accept a plan for implementing identified corrective actions. The implementation of planned actions will at latest be verified during next audit.

Response deadline for re-certification
Where the certificate expires within the 90 day period a shorter deadline will be set to ensure proper follow-up and renewal of the certificate within the expiry date. This is to provide for the continual validity of certification. If the expiry date is exceeded without the process being finalised, the current certificate is not allowed to be extended and will be regarded suspended until renewal of the certificate.

There is no obligation to investigate or respond formally to an observations or opportunity for improvement. However, to support an effective certification process DNV GL recommends that observations are also considered and responded to by the organization.

DNV GL will normally perform an on-site follow-up when major nonconformities are issued. For minor nonconformities follow-up is normally performed as a desk review based on received documentation.

Insufficient responses to nonconformities or lack of corrective actions may result in suspension or withdrawal of a certificate.

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