Audit date	21-12-2023
Conclusion	Approved
Reference	ISO 9001:2015
Audited by	Marta Smolarczyk Ewelina Pisarczyk
Audited site	Orion Znakowanie Towarów Sp. z o.o. Nowa 23 55-080 Nowa Wieś Wrocławska Poland

Activities carried out by the company

	Audited
Manufacture of packaging materials	Yes

Introduction

Scope: manufacturing of product label for Fagron Service Northern Europe

The company has been founded in 2001. Orion Sp. z o.o. is spezialized in designing and manufacturing of product labels for many different branch, including pharmaceutical.
The company is located in Nowa Wieś Wrocławska, near to Wrocław (Poland). There are over 90 employees.
The company is ISO 9001:2015 certified and currently they are working on implementation of the food safety quality system management (FSSC 22000). The main audit reason was a complaint, number Fagron: (ID) 16533, 601/2023 regarding to miscrepancies in labesl for Metamizole.

Audited

Name	Position	Email	Phone	Fax
Marek Dziewanowski	Chairman	marek.dziewanowski@orion.wroc.pl		
Kami Zięba	Quality Assurance Manage	kamil.zieba@orion.wroc.pl		
Wojciech Chlebicki	Quality Control Director	wojciech.chlebicki@orion.wroc.pl		
Bartłomiej Biskupski	Sales Manager	bbiskupski@etisoft.com.pl		

GMP/HACCP/ISO certificates

Certificate Type / Number	Certification Body	Date issued	Expiry Date	Scope
ISO 9001:2015 , number: PL 15/0248	SGS	19 Apr 2023	08 Jul 2024	

CEP-COS certificates

Certificate Nr	Date issued	Expiry Date	Product
No items to show...			

FDA letters

Inspection Date	Date issued	Expiry Date	Product(s)
No items to show...			

Written confirmations (Dir 2011/62/EU)

WC Nr.	Authority	Date issued	Expiry Date	Products
No items to show...				

Others

Type of certificate	Date issued	Expiry Date	Scope
No items to show...			

List of deficiencies

Critical deficiencies

None

Major deficiencies

Lack of the proper identification of the missing labels on the last step of the manufacturing process.
In the last step of manufacturing process the whole roll of labels is cutting and rolling to the final tube (accordingly to the customer requirements). In case of a missing labels the empty gaps are filled up manually by operator. During the plant tour it has occured, that there is no proper segregation of spare labels. Also - bin for spare labels is not controlled between manufacturing/cutting of the next batches of products. There is a high possibility, that those deficiencies were a root cause of analysed complaint.

Orion' comment (from the 24/01/2024) : the vision supervised system has been installed on the line. The training for operators has been planned for February 2024.

There is no quality agreement between interested parties.

Minor deficiencies

Excess of manufactured labels is just removed to the regular bin. Labels are not counted or preserving from unwanted using.

Remarks

None

Very good points

The company is going to implement the quality managment system for food safety (FSSC 22000)

Other remarks

It should be considered to organise GMP training (basic rules for labeling) to help contractor understand the customer QMS's requirements.

Labels are ordered through distributor - Etisoft. So the proper supply chain is: Orion-Etisoft-Fagron.

In case of any changes in product' project Orion change their internal product number thus there is no possibility print unproper labels. In case of Fagron - there is just one product number in the Navision system and in case of any changes information is available in the system, but the product number is still the same. To avoid possible misunderstanding it should be consider to add on Fagron' orders Orion's product number.

Summary

The main references of the audit were requirement of ISO 9001:2015. Regarding to mentioned standard there were no non-conformities. Nevertheless it was also important to check, whether there is a chance to proceed according to GMP requirement. Findings can not be treated as a classical non-conformities because of declared audit' references, nevertheless they should be reviewed and solve to avoid future issues.
The main audit reason was complaint number Fagron: (ID) 16533, 601/2023. In the whole role of labels some of empty spares have been fulfilled by wrong labels. There is a very high possibility, that during the audit the auditing team were able to identify the root cause of the complaint.
The manufacturing process is very well documented thus there is no issue with traceability.
Staff has impressive level of knowledge based on accurate education and very solid experience in branch.
Moreover - employees are able to answer on every auditors question, what prooves excellent awareness of flow process and also properly performed of training policy.
Also it is important to state, that manufacturer agreed for audit in very early date and communication with auditee is perfect. Every reply is passed without any delay. Information provided by manufacturer is always very clear, understandable, detailed and precise.
Based on documents and the facility tour the site and facilities were found to be well maintained and in a clean and orderly condition.
Information and documents requested before and during the audit were made available as required.
The manufacturing unit is following ISO 9001:2015 requirements in manufacturing of labels. The manufacturing plant is subjected to regular inspections by the certification bodies and customers.
Manufacturer is willing to improve cooperation with Fagron, therefore it should be consider to organise GMP training for Orion employees. Such training should help to understand the requirements of the customer (Fagron) QMS

Conclusion

The future cooperation is possible only after signing a quality agreement. Due to completely different requirements of implemented QMS (Fagron - GMP, Orion- ISO 9001) there is no possibility to approach to the processes in equal standards. Parties should declare duties and responsibilities of both parts.

Re-audit date Proposed 21-12-2024

Confirmed By	Marta Smolarczyk
Confirmed At	12-03-2024 12:17:23

Audit Attachments

Type
checklista 121282.jpg
checklista 126559.jpg
Etisoft_Kwestionariusz.pdf
Etykiety produktowe.jpg
Etykiety_Metamizol.jpg
Etykiety_Syldenafil.jpg
Formularz poreklamacyjny rek id 16533.pdf
I_R2_1 Kontrola jakości.pdf
Konfekcja _ sztancowanie.xlsx
Mapa procesów Orion.docx
Orion_21.12.2023_Audit agenda_PL.pdf
Orion_ISO 9001_certificate_pl_2023.pdf
Orion_Kwestionariusz.pdf
Orion_Zlecenie produkcyjne_121282.jpg
Orion_Zlecenie produkcyjne_II.jpg
Protokół kontroli jakości.docx
Wykaz dokumentacji systemu zarządzania.docx

Documents provided

Type	Reference Code	Comments
No items to show...		

SOP's provided (or examined)

Type	Reference Code	Comments
No items to show...		

Pictures

No pictures

Business cards

No business cards

Audit checklist

1 - QUALITY MANAGEMENT		
1.1	Is there a Quality Policy in place?	Yes
1.2	Is the policy signed by the top management?	Yes
1.3	Do management reviews consider: Findings of internal audits, recommendations made and corrective actions taken?	Yes
1.4	Do management reviews consider: The overall effectiveness of the system in achieving quality objectives and updating and/or improving the system?	Yes
1.5	Is there a Quality organization independent of production?	Yes
1.6	Are the Quality organization's authorities and responsibilities clearly defined and in writing?	Yes
1.7	Do written procedures exist for notifying responsible management in a timely manner of regulatory inspections, serious GMP, GLP, GDP, ISO 15378 deficiencies, product defects and related action (ex, quality-related complaints, recalls and regulatory actions?)	Yes
1.8	Does a system exist for the holding in quarantine, release or rejection of raw materials, intermediates, packaging and labeling materials?	Yes
1.9	Does the Quality organization review the completed batch production and/or laboratory control records of critical process steps prior to the release the product/data for distribution?	Yes
1.10	Does the Quality organization review and release intermediates and finished products according to an approved specification?	N/A
1.11	Does the Quality organization oversees the investigation and resolution of critical deviations and is the investigation and its conclusions documented?	Yes
1.12	Does the Quality organization review and approve all procedures, specifications and master production instructions?	Yes
1.13	Does the Quality organization approve the use of intermediate and contract manufacturers?	N/A
1.14	Does the Quality organization review and approve validation protocols and reports?	Yes
1.15	Does the Quality organization oversee that quality-related complaints are investigated and resolved?	Yes
1.16	Does the Quality organization ensure that effective systems are used for maintenance and periodic calibration of critical equipment?	Yes
1.17	Does the Quality organization ensure that materials are appropriately tested and results reported?	Yes
1.19	Does the Quality organization oversee the internal audit program?	Yes
1.20	Does the Quality organization ensure that there is corrective and preventive action system in place?	Yes
1.21	Does the Quality organization perform Product Quality Reviews?	No
1.22	Is there a library of relevant regulations on API, excipients, cosmetics or whatever applicable for the activity concerned?	No
1.23	Is a person designated or a source defined to keep the company informed about legislative developments in the area of starting materials for pharmaceuticals, excipients, cosmetic ingredient, packaging manufacturers or whatever applicable?	Yes
1.24	Are responsibilities for assessing the impact of such legislative developments and for proposing actions to comply with these clearly defined?	Yes

Remark 1.19: Date of the last internal audit: 12/06/2023

2 - PERSONNEL		
2.1	Are there an adequate number of personnel qualified by appropriate education training, and/or experience to perform and supervise the production of materials and other products?	Yes
2.2	Are the responsibilities of all personnel engaged in the production specified in writing?	Yes
2.3	Is initial and ongoing training provided?	Yes
2.4	Does the company have a formal training program that includes training of current GMPs, GDPs, GLPs, ISO 15378, HACCP or whatever applicable?	Yes
2.5	Is the performance of training documented?	Yes
2.6	Is a program in place to qualify individuals to conduct training to ensure that qualified individuals conduct training?	Yes
2.7	Does the training program include the training requirements and qualifications for personnel?	Yes
2.8	Does a program exist for the routine evaluation of the competence and capabilities of personnel?	Yes
2.9	Are there procedures in place ensuring good hygiene of the personnel where exposure to materials in open containers may occur (e.g. monitoring of health conditions, wearing of protective clothes, respecting food/drink policy, etc ?	Yes
2.10	Does a written procedure exist that describes the proper apparel (e.g. clean clothing suitable for production activity, protective apparel, etc.) to use during processing?	Yes
2.11	Are smoking, eating, drinking, chewing and the storage of food, restricted to certain designated areas separate for the production areas?	Yes
2.12	Is there a specific qualification required for employees responsible for key activities in Health, Safety and Environment (HSE) and quality?	Yes
2.13	Who makes the decision to release/reject product for sale?	QC
2.14	Who signs the Certificate of Analysis?	QC
2.15	Are contract services providers included in the training program?	N/A

Remark There are 85 employees, around 40 in production department, 3 in quality control. There are 3 shifts.

3 - BUILDINGS AND FACILITIES		
3.1	Are laboratory areas/operations separated from production areas?	No
3.2	Is the facility cleaned and maintained according to written procedure?	Yes
3.3	Were all utilities that could affect product quality qualified relative to its intended use, monitored and do they have documented reports?	Yes
3.4	Are drawings of the utility systems available?	Yes
3.5	Is there a procedure that indicates that all permanently installed pipework is appropriately identified?	N/A
3.6	Are drains provided with an air break or a suitable device to prevent back-siphonage?	Yes
3.7	If the water used in the process of production is treated to achieve a defined quality, is treatment process validated and monitored with appropriate actions limits?	N/A
3.8	Describe the types of water systems used in the production process and those used for cleaning equipment. Are water systems validated?	NA
3.9	Which is the quality of water used in the production? Specify	NA
3.10	Have you established monitoring programs for your water, steam, air and gas systems?	N/A
3.11	If air or inert gas is used for product contact in the production, is it filtered before use?	N/A
3.12	Is there a written procedure for environmental control and air handling systems?	N/A
3.13	Is your production equipment multipurpose or product specific?	Multipurpose
3.14	Are highly sensitizing materials (e.g. penicillins or cephalosporins) or materials of an infectious nature or high pharmacological activity or toxicity (e.g. certain steroids) manufactured at facility?	No
3.15	If yes: Are dedicated production areas for highly sensitizing materials (e.g. penicillins or cephalosporins) available?	N/A
3.16	Are cross contamination potentials minimized?	No
3.17	Do written procedures exist that define the responsibility for sanitation, cleaning schedules, methods, equipment and building cleaning materials?	N/A
3.18	Does a written program exist for the use of rodenticides, insecticides, fungicides, and fumigating agents, cleaning and sanitizing agents to prevent the contamination of equipment, raw materials, packaging/labeling materials, intermediates, food ingredients, cosmetic ingredients, excipients and APIs?	Yes

Remark

4 - PROCESS EQUIPMENT		
4.2	Are schedules and written procedures available for the preventive maintenance of equipment?	Yes
4.3	Is critical production and filling equipment qualified and reports available?	Yes
4.4	Are written procedures established for equipment cleaning and release of equipment for production use?	Yes
4.5	If equipment is assigned to continuous production (dedicated equipment) does a procedure exist that designates equipment to be cleaned at appropriate intervals to prevent build-up and carry-over contaminants?	N/A
4.9	Do you keep use logs, cleaning logs and maintenance logs of equipment?	Yes
4.10	Do written procedures exist for the cleaning of utensils?	Yes
4.11	Are acceptance criteria for residues and the choice of cleaning procedures and agents defined and justified?	Yes
4.12	Is equipment used for the control, weighing, measuring, monitoring and testing of products that is critical for ensuring the quality calibrated to written procedures and an established schedule?	Yes
4.14	Are changes to computerized systems made according to a change procedure and formally authorized, documented and tested?	Yes
4.15	Is a back-up system provided in the event of system breakdowns or failure that would result in the permanent loss of records?	Yes

Remark

5 - DOCUMENTATION AND RECORDS		
5.1	Do written procedures exist for the preparation, review, approval and distribution of all documents related to the production and testing?	No
5.4	Are specifications established and documented for raw materials, intermediates, APIs, cosmetic and food ingredients and labeling and packaging materials?	Yes
5.5	Is acceptance criteria established and documented for in-process controls?	Yes
5.6	Are master approved labels compared to issued labels?	Yes
5.9	Is the batch production record numbered with a unique batch or identification number, dated and signed when issued?	Yes
5.10	Do written procedures exist for the investigation of critical deviations of failure of batches?	Yes
5.12	Are all deviation, investigation and OOS reports reviewed as part of the batch record review before the batch is released?	Yes
5.13	Do you have hard copies of the delivery notes, signed by the receptor:	Yes
5.14	Do you have a SOP for full traceability of the goods received/delivered?	Yes
5.16	Do you have a SOP for document management (e.g. transfer of analytical methods)?	No

Remark

6 - MATERIALS MANAGEMENT		
6.1	Do written procedures exist describing the receipt, identification, quarantine, storage, handling, sampling, testing, and approval or rejection of materials?	Yes
6.3	Is there a system to ensure that all materials purchased meet governmental safety environmental and toxic material regulations?	Yes
6.4	Is each container or grouping of containers of materials examined visually for correct labeling (including correlation between the name used by the supplier and the in-house name, if these are different), container damage, broken seals and evidence of tempering or contamination upon receipt by and before acceptance by QA?	Yes
6.5	Are materials under quarantine until they have been sampled, examined, or tested, as appropriate, and released for use?	Yes
6.7	Do you test all your materials prior to use?	N/A
6.8	Is a system in place to evaluate and approve suppliers?	Yes
6.9	Is there an updated list of approved suppliers?	Yes
6.10	Is there a system in place to audit suppliers?	No
6.11	Are audit of suppliers of raw materials conducted on a regular basis as part of supplier approval and certification program?	No
6.13	Is a complete analysis performed at appropriate intervals and compared with the certificates of analysis with reliability of certificates of analysis checked at regular intervals?	Yes
6.14	Are steps taken to ensure that all non-conforming materials/products are identified and quarantined to prevent their use or release?	Yes
6.15	Is it ensured that the storage temperature is always kept within a defined range and controlled, if necessary for product quality or stability?	N/A
6.17	Do you have written SOP's for cleaning tanks, reservoirs etc	N/A
6.20	Do you have written SOP's for the revision of the MSDS of the products transported?	N/A
6.23	Are non pharmaceutical products stored in the same warehouse?	N/A

Remark 6.8-6.11: Supplier qualification process is performed accordingly to SOP "S1" - Supplier qualification. There are 16 suppliers for raw materials. Each of them is evaluationg once per year. Every supplier must be approved by quality assurance department in the Orion's computer system (customized, dedicated computer system - "Etisek"). There is no possibility to order goods from unapproved supplier. Also - some of orders must be placed on special supplier platform and the order in Etisek system is just a copy of the original order.

7 - PRODUCTION AND IN-PROCESS CONTROLS		
7.10	What do you consider to be a lot or batch?	see below
7.11	What does a typical lot number look like and how can we recognize it as a lot number?	see below
7.12	What is the significance of each element in the lot number?	see below
7.13	Are retained-samples of all production batches kept for future reference?	No
7.14	For how long?	NA
7.15	If product exposure to, or contamination with, lubricants or coolants is possible, are these materials suitable for use in food applications?	N/A
7.16	Is all the equipment in contact with products dedicated or are validated cleaning procedures applied in case of product changes?	N/A
7.17	Is the customer informed when mixed lots are supplied?	N/A
7.18	(if the equipment is not dedicated) Is the equipment only used for Food, Cosmetic, and/or Pharma grade products?	Equipment is multipurpose

Remark 7.10-7.12: Batch number (6 digits) is a production order number. The number is generated by the system (Etisek). The system generates the batch number on a planning step.

8 - PACKAGING AND IDENTIFICATION LABELING		
8.9	If hazardous (e.g. toxic, corrosive) products are present on the site, is there a written procedure for segregations or prevention of cross contamination?	N/A
8.10	Do you follow first in first out (FIFO) principle?	N/A
8.11	Do all product containers bear identification labels with the batch number?	Yes
8.12	Does your labeling indicate the appropriate quality grade? (e.g. USP, NF, EP, reagent grade etc.)	N/A
8.13	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?	N/A
8.14	Is the company able to provide full traceability on product origin?	Yes
8.15	Is the company able to provide full traceability in its own operations?	Yes
8.16	Is the company able to provide full traceability on product destinations? (each shipment?)	Yes
8.17	Are labels applied to containers clear, unambiguous, and permanent fixed?	Yes
8.18	Is it ensured that the following information is provided with each shipment, either on the label or on the COA:	Yes
8.19	Name of the product including grade and amount?	Yes
8.20	Batch number assigned by the original manufacturer or the batch number assigned by the re-packer, if the material has been repacked and re-labeled?	N/A
8.21	The retest date or expiry date and storage conditions (where applicable)	N/A
8.22	Identification of the original manufacturing site and contact details of the supplier?	Yes
8.27	Is the environment of the re-packaging operation clean and dust free?	N/A

Remark

9 - STORAGE AND DISTRIBUTION		
9.1	Are facilities available for the storage of all materials under appropriate conditions (e.g. controlled temperature and humidity when necessary) with records maintained of these conditions if they are critical for the maintenance of material characteristics?	Yes
9.6	Is a system in place by which the distributor of each batch of product can be readily determined to permit its recall?	No
9.8	Are packaging materials used to prevent damage of the materials?	Yes

Remark Labels for Fagron Group are manufactured upon request, there is no product on stock.

10 - LABORATORY CONTROLS		
10.1	Are there written procedures describing sampling, testing, approval, or rejection of materials and recording and storage of laboratory data?	Yes
10.3	Is each parameter stated in the specification tested?	Yes
10.4	Are the material samples taken by QA/QC?	Yes
10.5	Is the microbiological testing performed when required on raw materials, product, water and equipment?	N/A
10.7	Are all out-of-specifications results obtained investigated and documented according to written procedure that includes analysis of the data, assessment of whether a significant problem exists, allocation of the tasks for corrective actions, and conclusions?	Yes
10.8	Are written procedures used for the re-sampling and/or re-testing after OOS results?	Yes
10.9	Is there a procedure for recording laboratories raw data (e.g. worksheets and notebooks)?	Yes
10.10	Are raw data belonging to analytical test reviewed by a second, independent person?	Yes
10.11	Are your analytical instruments qualified?	N/A
10.12	Is there a procedure for the maintenance and calibration of laboratory equipment?	N/A
10.13	Are reagents and standard solutions prepared and labeled following written procedures?	N/A
10.15	Are in-house primary standards established and used?	N/A
10.16	Are secondary reference standards prepared, identified, tested, approved, and stored?	N/A
10.25	Do you perform physical, chemical or microbiological analysis?	N/A
10.26	Do you have temperature and humidity control system?	Yes
10.27	Is instrumentation qualified according to DQ, IQ,OQ and PQ?	N/A
10.28	Are you using an automated information management (e.g. LIMS)?	No
10.29	Is your information system GAMP validated?	N/A
10.30	Do you have a list standards, reagents and materials of the laboratory?	N/A
10.31	Do you have a SOP for the management of reference standards?	N/A
10.32	Do you have a SOP for the preparation and management of working standards?	N/A
10.33	Do you have a SOP for waste management in the laboratory?	N/A
10.34	Do you store analyzed samples after analysis?	No
10.35	Do you have a SOP for Out of Specifications?	Yes

Remark

11 - VALIDATION		
11.1	Is the company's overall policy, intentions, and approach to validation, including the validation of production processes, cleaning procedures, analytical methods, in-process control, test procedures, computerized systems, and persons responsible for design, review, and approval of each validation phase, documented?	No
11.2	Is a written validation protocol established that specifies how validation of a particular process will be conducted?	No

Remark There is no validation plan, as such activity is not a requirement of ISO9001:2015 QMS (audit references)

12 - CHANGE CONTROL	
12.3 Are there written procedures for change control to the process or equipment or systems?	Yes
12.4 Has the potential for critical changes to affect established retest or expiry dates been evaluated?	N/A
12.6 Are customers notified of changes from established production and process control procedures that can affect the quality of the product?	Yes

Remark

13 - REJECTION AND RE-USE OF MATERIALS	
13.1 Is the final disposition of rejected materials recorded?	Yes
13.2 Does an investigation into the reason for nonconformance performed prior to a decision to rework batches that do not conform to established standards or specifications?	Yes

Remark

14 - COMPLAINTS AND RECALLS	
14.1 Are all quality-related complaints, whether received orally or in writing, recorded and investigated according to a written procedure and retained in a designated file?	Yes
14.2 Are complaints reviewed on a timely basis by the Quality unit?	Yes
14.3 Is the action taken in response to each compliant documented?	Yes
14.5 Is there a procedure ensuring all customers and authorities are informed in case of serious or potentially life-threatening situations?	No
14.6 Are records readily available to the designated person responsible for recalls?	N/A
14.7 Is the effectiveness of the recall system evaluated?	N/A

Remark There is no recall system or SOP
SOP for complaints: „Postępowanie reklamacyjne” , ed. 2 approved on 8/09/2022. There is a special panel in "Etisek" system, dedicated for complaints. Only employees of Quality Control Department have access to enter complaint' data to the system.

15 - RETURNED GOODS	
15.1 Are returned products stored separately and appropriately handled according to written procedures?	Yes
15.2 Is there a procedure ensuring that non-conforming materials are prevented from re-introduction into marked unless downgraded or reprocessed?	Yes
15.3 Is there a procedure in place to prevent blending of non-conforming materials with compliant materials?	Yes

Remark

16 - CONTRACT ACTIVITIES	
16.2 Do you evaluate subcontractors periodically?	N/A

Remark There is no contract activities for Orion regarding to manufacturing process, nevertheless it should be marked, that there is a distributor of labels - Etisoft company. Both companies (Orion and Etisoft) belong to the same financial group and have the same owner, but each of the company is completely independend entity. Orders for labels are sending by Fagron to Etisoft and then Etisoft orders the labels at Orion. Usually products are sending to Fagron directly from the manufacturer (Orion) to the Fagron warehouse.