**ΑΝΑΣΚΟΠΗΣΗ**

ΤΟΥ

**Ε**ΝΟΠΟΙΗΜΕΝΟΥ **Σ**ΥΣΤΗΜΑΤΟΣ

**Δ**ΙΑΧΕΙΡΙΣΗΣ **Π**ΟΙΟΤΗΤΑΣ

**2019**

**31/03/2020**

**ΑΤΖΕΝΤΑ – AGENDA**

| **1.** | **Συμμετέχοντες / Υπογραφές Έγκρισης –**  **Persons Attended / Approval Signatures** | |
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|  | **Μετέχοντες** | **Υπογραφή** |
|  | **Τσέτη Ιουλία**  Πρόεδρος Διοικητικού Συμβουλίου /  Διευθύνουσα Σύμβουλος / Διευθύντρια Marketing |  |
|  | **Τσέτη Ειρήνη**  Διευθύντρια Οικονομικών |  |
|  | **Αρχοντίκης Αθανάσιος**  Διευθυντής Εργοστασιακών Λειτουργιών |  |
|  | **Λιόκαλου Μαρία**  Διευθυντής Διασφάλισης Ποιότητας, Περιβάλλοντος, Υγείας & Ασφάλειας |  |
|  | **Πιπερούδης Γεώργιος**  Διευθυντής Παραγωγής,  Υπεύθυνος Αποθηκών |  |
|  | **Κίντζιος Σπυρίδων**  Διευθυντής Επιχειρηματικής Ανάπτυξης |  |
|  | **Κωστόπουλος Γιώργος**  Yπεύθυνος Ανθρωπίνου Δυναμικού |  |
|  | **Θεοδώρου Μάρκος -** Διευθυντής Πωλήσεων |  |
|  | **Πέτσας Λευτέρης**  Προϊστάμενος Χρηματοοικονομικού Σχεδιασμού, Πληροφόρησης και Προγραμματισμού |  |
|  | **Πανταζή Μαρίκα**  Προϊσταμένη Παραγγελιοληψίας |  |
|  | **Σπίγκος Γιώργος**  Διευθυντής Πωλήσεων Εξωτερικού |  |
|  | **Σουμέλας Γεώργιος-Στέφανος**  Προϊστάμενος Κλινικών Μελετών,  Προϊστάμενος Ρυθμιστικών Υποθέσεων |  |
|  | **Παρασκευοπούλου Άννα**  Προϊσταμένη Ποιοτικού Ελέγχου |  |
|  | **Μπίζας Άκης -** Διευθυντής Πληροφορικής |  |
|  | **Παλπανάς Γεώργιος**  Διευθυντής Τεχνικών Υπηρεσιών |  |
|  | **Φαρμάκης Μάριος**  Διευθυντής Προμηθειών |  |
|  | **Σακελλαρίου Ευαγγελία**  Προϊστάμενος Έρευνας και Ανάπτυξης Νέων Προϊόντων (ΠΕΑΠ) |  |
|  | **Ανδριόπουλος Αθανάσιος**  Yπεύθυνος Επικύρωσης |  |

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| **2.** | **Περιεχόμενα Ατζέντας –**  **Agenda Contents** | |
| 1 | Συμμετέχοντες / Υπογραφές Έγκρισης | Persons Attended / Approval Signatures |
| 2 | Περιεχόμενα Ατζέντας | Agenda Contents |
| 3 | Πρόοδος υλοποίησης ενεργειών από την προηγούμενη Ανασκόπηση της Διοίκησης | Status of Actions from Previous Management Review |
| 4 | Aλλαγές σε εξωτερικές και εσωτερικές παραμέτρους που αφορούν το ΕΣΔΠ (Νομοθεσία, Κανονισμούς, Πρότυπα, Λήξεις Συμβάσεων) | Changes in external and internal issues that are relevant to the IQMS (Laws, Regulations, Standards, Contract Expirations) |
| 5 | Πληροφορίες σχετικά με τις επιδόσεις και την αποτελεσματικότητα του ΕΣΔΠ | Information on the performance and effectiveness of IQMS |
| 6 | Μη Συμμορφώσεις και Διορθωτικές – Προληπτικές Ενέργειες | Non-Conformities and Corrective – Preventive Actions (CAPAS) |
| 7 | Αποτελέσματα παρακολούθησης και μέτρησης | Monitoring and measuring results |
| 8 | Αποτελέσματα Επιθεωρήσεων | Audit Results |
| 9 | Έλεγχος συμμόρφωσης με εφαρμοστέες νέες ή αναθεωρημένες κανονιστικές απαιτήσεις | Compliance to applicable new or revised regulatory requirements |
| 10 | Ικανοποίηση Πελατών και αναπληροφόρηση από τα σχετικά ενδιαφερόμενα μέρη | Customer Satisfaction and feedback from relevant interested parties |
| 11 | Αποτίμηση Στόχων Ποιότητας, Περιβάλλοντος & Ενέργειας - Δείκτες | Quality and Environmental Objectives evaluation - ΚPIs |
| 12 | Επιδόσεις διεργασιών και συμμόρφωσης προϊόντων και υπηρεσιών | Process performance and conformity of products and services |
| 13 | Επιδόσεις Εξωτερικών Παρόχων – Aξιολόγηση Προμηθευτών & Συνεργατών | Performance of External Providers – Supplier & Vendor Evaluation |
| 14 | Επάρκεια Πόρων   1. Προσωπικό 2. Εξοπλισμός / Μηχανήματα 3. Εγκαταστάσεις | Adequacy of Resources   1. Personnel 2. Equipment / Machinery 3. Facilities |
| 15 | Αξιολόγηση εκπαίδευσης προσωπικού | Staff training assessment |
| 16 | Διαχείριση κινδύνου - Απειλές και Ευκαιρίες | Risk Management – Risks and opportunities |
| 17 | Αναφορές σε Κανονιστικές ή Ελεγκτικές Αρχές | Reporting to Regulatory Authorities - |
| 18 | Η εξέλιξη των Προγραμμάτων Διαχείρισης Περιβάλλοντος & Ενέργειας | Progress of Environmental Programs |
| 19 | Ασκήσεις ετοιμότητας για τα Σχέδια Έκτακτης Ανάγκης | Review of drills for Emergency Plans |
| 20 | Έλεγχος των Περιβαλλοντικών Πλευρών/Θεμάτων | Review of Environmental Aspects |
| 21 | Ανακύκλωση / Διαχείριση αποβλήτων | Recycling / Environmental waste management |
| 22 | Ευκαιρίες για βελτίωση | Opportunities for improvement |
| 23 | Αποτελέσματα Ανασκόπησης από τη Διοίκηση (Ευκαιρίες για βελτίωση, ανάγκη για αλλαγές στο ΕΣΔΠ, ανάγκες σε πόρους) | Management Review Outputs (Opportunities for improvement, any need for changes to the IQMS, resource needs) |

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| **3.** | **Πρόοδος υλοποίησης ενεργειών από την προηγούμενη Ανασκόπηση –**  **Status of Actions from Previous Management Review** |
|  | **2019 - Year of the Environment:**   * Top Management decided to designate 2019 as the Year of the Environment. In this way, environmental awareness training and the awakening of the ecological sensitivity of staff was increased with a view to promoting recycling and special training was given to address with leak chemicals and toxic raw materials to all relevant staff of the Group. * With the aim to achieve the continuous improvement of the Environmental Management System, the Company monitors all the legislative requirements, follows an Environmental Policy which is imposed to all its suppliers and subcontractors, implements innovative Environmental Management Plans through the moto " U & I Green " actions, has an active participation and support for national and international environmental actions, such as UN Global Compact, and a Corporate Sustainability Strategy to ensure environmental sustainability and its committment to the environmental and sustainable development. * In addition, through the "U & I Safe" logo, the Company implements its commitment to ensuring the Health and Safety of Group employees by attaching anti-slip films to slippery surfaces, by placing guard rails to protect staff, etc. * On the above basis, lots of Environmental Awards were achieved in all OFET Group and a new Energy Audit was implemented in all UNI-PHARMA’s Facilities in late 2019, with the aim to achieve reduction in energy sources and minimize the Company’s energy footprint. |

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| **4.** | **Αλλαγές σε εξωτερικές και εσωτερικές παραμέτρους που αφορούν το ΕΣΔΠ Changes in external and internal issues that are relevant to the IQMS** | | |
|  | **Significant External Changes:**   1. Novel Coronavirus disease COVID-19 (COVID-19): In December 2019, a novel coronavirus (COVID 19) was detected in patients in Wuhan, Hubei Province, China. It is a contagious newly identified virus, with incubation period of 14 days, which has caused an increase transmission globally and a lock-down in all the Countries affected on a global basis. On 30 January 2020, the World Health Organization (WHO) declared the outbreak of the novel coronavirus a public health emergency of international concern. There are no therapeutics and vaccines available and there is presumably no pre-existing immunity in the population. UNI-PHRMA has conducted an Emergency Response Plan and a Contingency Plan to address the new virus with preparedness. 2. Serialization project – a unique product identification of all products produced in the Company. A contract was signed with LAETUS in order to achieve a unique product code GTIN for all products distributed in the European market, according to Regulation (EU) 161/2015. 3. GDPR – new requirement for the protection of confidentiality and data privacy which poses risks and opportunities to the Company. The Code of Conduct and Ethics was updated to cover this requirement and new Privacy Policy was issued. 4. Activation of Audit Trail in HPLC Analyses to achieve traceability in all chemical analyses.   **Significant Internal Changes in 2019:**  1. In order to achieve the continuous improvement of the Company’s Integrated Quality & Environmental Management System, a new certification of ISO 13485:2016 was achieved in 2019.  2. The upgrade of Customer Satisfaction Research was completed by end of 2019.  2. The Project for the conversion of the Integrated Quality & Environmental Management System in an electronic or hybrid system is ongoing. An agreement with I-team was signed in late 2019, in order to install Document Management System for the proper management of all IQMS Documents.  4. A new Pharmacovigilance Agreement was signed with PHARMASSIST on 23th of July 2019, in order to receive outsourcing pharmacovigilance services.  5. A new Materiovigilance Agreement was signed with PHARMASSIT also on 20th December 2020, with the aim to receive outsourcing materiovigilance services.  6. A re-costruction was performed in the HR Department and a new HR Manager was hired on January 2020. Connection of effectiveness of training with evaluation of personnel is under review.  The Company’s Certificates status is as follows: | | |
| **IQMS** | **Πιστοποιητικό**  **Certificate** | **Κατάσταση**  **Status** | **Παρατηρήσεις**  **Comments** |
|  | 1. EuGMP | Valid until **19/05/2020** | ΟΚ |
|  | 1. ISO 9001:2015 | Valid until **30/05/2022** | ΟΚ |
|  | 1. ISO 14001:2015 | Valid until **30/05/2022** | ΟΚ |
|  | 1. ISO 13485:2016 | Valid until **30/05/2022** | ΟΚ |
|  | 1. Απόφαση ΔΥ8δ/1348 – Διακίνηση Ιατροτεχνολογικών Προϊόντων Class I | Valid until **27/02/2022** | ΟΚ |

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| **5.** | **Πληροφορίες σχετικά με τις επιδόσεις και την αποτελεσματικότητα του ΕΣΔΠ –**  **Information on the performance and effectiveness of the IQMS** |
|  | * **A new Integrated Quality & Environmental Manual was issued, according to the new requirements of the new ISO 9001:2015, ISO 14001:2015, ISO 13485:2016 & ISO 50001:2018.** * **A new Energy Policy was issued on May 2019, in order to comply with ISO 50001:2018.** * **A new Organization Chart was issued on May 2019, to reflect the new departments of Energy Management and Validation.** * The review of Company’s Policies, Manual and Organization Chart is presented in the table below.  |  |  |  |  | | --- | --- | --- | --- | |  | **Πολιτικές της Εταιρείας, Εγχειρίδιο, Οργανόγραμμα –**  **Review of Company’s Policies, Manual and Organization Chart** | | | |  | **Έγγραφο**  **Document** | **Έκδοση - Ημ/νία Έκδοσης**  **Issue date** | **Παρατηρήσεις**  **Comments** | | **1.** | Integrated Quality & Environmental Manual | 4.2 – 15/05/2019 | Valid | | **2.** | Quality Policy | 4.0 – 01/03/2018 | Valid | | **3.** | Environmental Policy | 3.0 – June 2016 | Valid | | **4.** | Energy Policy | 3.0 – May 2019 | Valid | | **5.** | Organizational Structure | 5.0 - 15/05/2019 | Valid | |
|  | In 2019, OFET Group received the following **Awards**:   * **Διεθνής Πιστοποίηση Επιχειρηματικής Αριστείας, EFQM Recognized for Excellence – 5 stars INTERMED** * Investors in People International Certification 2018 OFET * European Business Ethics Certification (EBEN GR) OFET * Platinum EBEN CSR Distinction * Τιμητική Διάκριση για τη συνέπεια στην Επιχειρηματική Αριστεία, ΕΕΔΕ OFET * **Diamond of the Greek Economy Award 2018 – INTERMED** * Salus Index Award 2018 – Uni-pharma * Αριστεία Φαρμακευτικής Αγοράς, CSR Platinum Award 2018 * Best in Pharmacy Awards, Gold, Silver, Bronze 2018 * Healthcare Business Awards Silver, Bronze 2018 * Waste and Recycling Awards 2018 (3 awards) * Environmental Awards 2018 (3 awards) * **Innovation Poster Award Herbofix Capsules – InterMed 2018.** * Salus Index Award 2019 – Ιntermed * **Active Business Creative Greece Awards** * **ECOPOLIS, Environmental Award** * **Health and Safety Awards, OFET - 1 silver, 1 bronze & 1 gold award 2019.** * **Manufacturing Excellence Awards 2019 – 1 silver and 1 bronze.** * **Energy Mastering Awards 2019 – 4 Gold And a Silver Award & Company of the Year.** * **RESPONSIBLE MANAGEMENT EXCELLENCE AWARDS BY EBEN.** * **SALUS INDEX 2019.** |

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| **6.** | **Μη Συμμορφώσεις και Διορθωτικές – Προληπτικές Ενέργειες**  **Non-Conformities and Corrective – Preventive Actions** |
|  | The Corrective – Preventive Actions related to the Non-Conformities detected for 2019 were:   * **Total** : **72** * **Completed : 52 (72.2%)** * **On Progress : 8 (11.1%)** * **On Progress/Delayed : 12 (16.7%)**   τhe Non-Conformities detected for 2019 analyzed per department are presented in the following diagram. |

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| **7.** | **Αποτελέσματα παρακολούθησης & μέτρησης –**  **Monitoring and measuring results** |
|  | The Key Performance Indicators per department, along with the monitoring and measuring results, are attached to the Management Review of IQMS. |

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| **8.** | **Αποτελέσματα Επιθεωρήσεων –**  **Audit Results** |
| **8 a.** | **Εσωτερικές Επιθεωρήσεις –**  **Internal Audits** |
|  | * Two Internal Audits have taken place in June 2019 & December 2019 (rescheduled for Jan-2020). * The deviations are handled through the Company’s CAPA plan. |
| **8 b.** | **Εξωτερικές επιθεωρήσεις (ISO, ΕΟΦ, Συνεργάτες/Προμηθευτές) –**  **External Audits (ISO, Regulatory Authorities, Suppliers/Partners)** |
|  | * In 2019, 2 External Audits have taken place from Bureau Veritas at 16/05/2019 and at 06/12/2019-09/12/2019. Zero findings were detected on the 1st Audit and 2 Observations and 1 Minor Non-Conformity were detected on the 2nd Audit. * Lloyd’s Register also performed 2 External Audits at 13/02/2019 with 3 Minor Non-Conformities and at 06/12/2019 with 5 findings: 2 Minor Non-Conformities, 1 Observation, 2 Opportunities for Improvement (OFIs). The 1st External Audit resulted in issuing the new certificate of ISO 13485:2016 and of Decision ΔΥ8δ/1348 for the distribution of Medical Devices. * Greek Regulatory Authorities performed an Audit on new PFS Line (Pre-Filled Syringes) on 19th of September 2019 with 4 findings. * At **17 - 20/06/2019 an External Audit has taken place by the Russian Foreign Medicines Authorities** in order to assess the facilities for compliance with the requirements of the Russian Good Manufacturing Practice Rules. 30 Non-Conformities were noted (1 Critical, 17 Essential / Major & 12 Insignificant / Minor) and are handled through the Company’s CAPA Plan. * An extra Energy Audit was implemented in late 2019 and was completed at 20th March 2020 by “ΣΑΜΑΡΑΣ & ΣΥΝΕΡΓΑΤΕΣ», according to ISO 50001:2018 and was submitted to the Ministry of Environment and Climate Change. |

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| **9.** | **Έλεγχος συμμόρφωσης με εφαρμοστέες νέες ή αναθεωρημένες κανονιστικές απαιτήσεις –**  **Compliance to applicable new or revised regulatory requirements** |
|  | * The Ministry of the Environment and Energy now obliges all public and private waste management bodies to register in the new electronic database of the Electronic Waste Register (HMA). The operation of this Registry is determined by the Joint Ministerial Decision 43942/4026/2016 (Β '2992) "Organization and operation of the Electronic Waste Registry (HMA), in accordance with the provisions of article 42 of Law 4042/2012 ( A '24) as applicable. * In addition, the Ministry of Environment and Energy requires the registration also in the National Waste Producer Register (Ε.Μ.Π.Α.). More specifically, according to Government Gazette 2454/2016, as of 01/01/2016, it is a legal obligation for all Producers operating in Greece as follows: * A) The registration of all producers in the National Waste Generation Register (NWGR) * B) Submission of the Clearance Announcement of Packaging Amounts for the Year 2018 to an Alternative Management System (i.e. SED, such as Reverse Recycling S.A.), as part of the Alternative Packaging Management of the respective producer. * C) Electronic submission to the National Waste Producers Register of this Declaration by product type, with information on the quantities of packaging or other products that each producer has made available on the Greek market in the previous calendar year. * D) Electronic submission of the Annual Waste Production Report to the Ministry of Environment with information on the quantities of all waste produced by the producer and the quantities recycled, managed, transported for destruction abroad, temporarily stored for final disposal mood, etc. * The Company has been register in the new electronic database of the Electronic Waste Register (HMA) and also in the National Waste Producer Register (Ε.Μ.Π.Α.). on time and has submitted the Annual Waste Production Report and the Annual Quantity Declaration for recycling packaging on March 2019. * New legislation regarding energy management and energy audits was issued on 2018, according to the EU Energy Efficiency Directive 2012/22/EC. * A new Law regarding the protection of data privacy was issued on 2019: Law 4624/2019 “Authority for the Protection of Personal Data, measures of application of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals against the processing of personal data and incorporation into national legislation of Directive (EU) 2016 / 680 of the European Parliament and of the Council of 27 April 2016 and other provisions”. |

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| **10.** | **Ικανοποίηση Πελατών και αναπληροφόρηση από τα σχετικά Ενδιαφερόμενα Μέρη –**  **Customer Satisfaction and feedback from relevant interested parties** |
|  | 1. Παράπονα πελατών – Customer Complaints 2. **Customer complaints:**  | **Α/Α Νο Παραπόνου No of Complaint** | **Ημερ/νία λήψης**  **Complaint receipt Date** | **Σύντομη Περιγραφή του παραπόνου**  **Short Description of Complaint** | | --- | --- | --- | | 1 | 07/01/2019 | **CARDIOSALT 17-05**  Το προϊόν είναι κρυσταλλωμένο | | 11 | 18/02/2019 | **Hemafer Chewable tablets**  Το προϊόν δεν έχει την επιθυμητή γεύση | | 24 | 10/04/2019 | **Blocatens tablets 10 mg/tab 19-002**  To προϊόν έχει διαφορετικό σχήμα, υπάρχει πιθανότητα να μπει λάθος δισκίο σε λάθος συσκευασία | | 33 | 27/05/2019 | **B12 fix orodispersible tablets 19-02**  Το προϊόν διαλύεται γρηγορότερα σε σχέση με πριν | | 51 | 12/09/2019 | Δύο κουτιά **Thiamazole 5mg**, 100tabs με lot 18-005 και exp. 08-2023 βρέθηκαν άδεια κατά την παραλαβή στο φαρμακείο | | 53 | 24/09/2019 | Ένα κουτί **Thiamazole 5mg** με lot 18-004 βρέθηκε χωρίς lot και exp. | | 56 | 02/10/2019 | Απουσία batch number και expiry date σε 2 κουτιά Apotel 10mg/ml 10 Poche 100ml των παρτίδων 19-003 και 19-004 που διατέθηκαν στο Μαρόκο. |   In 2019, 7 **customer complaints** were recorded and handled according to SOP 13.02 – Complaint Management. **All of them were successfully handled. The aforementioned complaints had no previous history.**   1. **Pharmacovigillance**   The total number of Adverse Effects reported during the year 2019 (period covered: January 2019 to December 2019), is presented below.   * During the 1st semester of 2019, **ten (10) Spontaneous Adverse Effects were recorded from interested parties (Patients and Healthcare Professionals), one (1) Follow-up Report, along with thirty eight (38) Initial reports from National Competent Authorities (via EVWΕΒ).** * During the 2nd semester of 2019, and in particular during the period **23/07/2019 – 31/12/2019, when Pharmassist was QPPV: twenty one (21) Spontaneous Adverse Effects were recorded from literature review, twenty (20) Spontaneous Adverse Effects from Healthcare Professionals/ Patients/ Other Companies, out of which 1 is a follow-up Report, 71 Adverse Effects Reports from National Competent Authorities (via EVWEB) out of which 1 is a Follow-up Report.**      1. **MD- Cosmetovigillance**   More specifically, during the 1st semester of the year 2019 there were;   * **Three (3) Adverse Effects Reports** regarding the **FOOD SUPPLEMENTS** of **UNI-PHARMA**, none of which are classified as SERIOUS, therefore no further actions have been taken. * **NO Adverse Effects Report** regarding the **MEDICAL DEVICES**, **COSMETICS** and **BIOCIDAL PRODUCTS** of **UNI-PHARMA**.   During 2nd semester of the year 2019 there were:   * **NO Adverse Effects Reports** regarding the **FOOD SUPPLEMENTS, COSMETIC PRODUCTS**, **MEDICAL DEVICES**, and **BIOCIDAL PRODUCTS** of **UNI-PHARMA S.A**.   Customer Satisfaction Assessments   1. Παράπονα Περιβαλλοντικά – Environmental Complains   There is no environmental complaint registered.   1. Παράπονα εσωτερικά – Internal Complains   There is no internal complaint registered.   1. Πληροφόρηση από τρίτους – Other external party feedback   Concerning the feedback from the Company’s interested parties, a Customer Satisfaction Survey was performed with the use of specific Questionnaires which were sent directly through email to all the distribution channels (i.e. Doctors, Pharmacists, Pharmaceutical Warehouses). All these customers had previously given their consent for the use of their personal data. In particular, they had accepted and agreed that their personal data will be processed and stored exclusively for the purposes of the Company’s Customer Satisfaction Survey and in accordance with the provisions of Law 4624/2019 (GDPR).  The KPIs related with the satisfaction of clients 2019 are presented in the section below. |
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| **11.** | **Αποτίμηση Στόχων Ποιότητας & Περιβάλλοντος - Δείκτες**  **Quality and Environmental Objectives Evaluation - KPIs** |
|  | The Key Performance Indicators are attached to the Review. The evaluation of the results versus the objectives is presented below per department.  ***Evaluation of results – QA Department***  Product quality - Complaints  The result of 0.15 was satisfactory and well below the performance standard/bench, for the third consecutive year. The objective for 2020 is thus tightened to 0.3.  IQMS upgrade  The result was 20%, worse than the previous year. It is considered that the specific KPI is no longer suitable, as it refers to all of the IQMS documents, regardless of whether they need to be revised or not. The KPI for 2020 is thus modified to “% of reviewed documents of IQMS / total documents nearing expiry”, to better reflect IQMS maintenance needs. The objective remains the same for 2020, at 100%.  Internal Audit findings/ Number of Audits  The result (2.63) is slightly higher than 2018. The aim for 2020 is set to 0 (no findings), to provide an impetus for even better compliance to standards and regulations.  Individual Key Performance Indicators versus Targets regarding Internal Audit Findings per department are set at 0 (i.e. no findings), for each subcategory/ department (QA KPIs 4-12).  External Audit findings / Number of Audited department/process  The result (5.09) is over the objective and higher than previous years. Thus, the objective remains the same for 2020, as set at 2. However, the Key Performance Indicator will be modified for 2020 to reflect the External Audit Findings per number of Audits.  % Not in time completed CAPAs/ Completed CAPAs  The result, 24.1%, is over the performance standard/ bench (20.00) and comparable to previous years. It is because of the nature of the audit observations received during the year, as most of them required time-consuming modifications on processes. Thus, the performance standard for 2020 remains the same, at 20.00%.  Recalls   * 1 recall was performed on 22/10/2019 concerning the product ZOLIDEN F.C. Tabs., Lot. 19-001, due to its content in nitrosamines. * 1 recall was performed on 18/02/2020 regarding the product APOTEL TABS EFF., Lot. 19-006 & 19-009, due to alleged weight variations in the tablets.   Change Management Success - lead time  The result (60%) remains close to target (65%) and is the same as the previous year. As it is considered within reach, it is suggested to maintain the same objective for 2020.  Change Management Success - Deployment Efficiency  The result (95%) is well above the performance standard (80%) for the third consecutive year. It is thus suggested to change the objective for 2020 to 95%.  Change Management Overall Success  The result (78%) is well above the performance standard (65%) for the third consecutive year. It is thus suggested to change the objective for 2020 to 80%.  Overall, the KPIs related to change management indicate that the Company’s approach is effective.  ***Evaluation of results – EHS Department***  Evaluation of Environmental Key Performance Indicators vs Targets for 2019  The Environmental Key Performance Indicators (KPI’s) of UNI-PHARMA S.A. for 2019 are within the Environmental Targets and more specifically the consumption of Natural Resources (especially the energy and Natural Gas consumption) per unit produced decreased, as planned, in order to ensure the protection of the environment.  The evaluation of Environmental Indicators for 2019 is set out below.   1. Water consumption per unit produced was increased compared to 2018 by 11% and still remains far below the Environmental Target of 2 ml/bt. Therefore, the Environmental Target will be set at 1 ml/bt for 2020. 2. Electricity consumption per unit produced was slightly increased, by 9% compared to 2018, due to the electricity consumed during the revamping project of UNI 1. However, it needs to be decreased to reach the Environmental Target of 0,150 KWh/bt and therefore new staff trainings will be performed to increase the staff environmental awareness regarding the electricity consumption. 3. Consumption of Natural Gas per unit produced was increased, by 21%, compared to 2018, due to the revamping project of UNI 1, but still remains within the environmental target of 0.005 Nm3 / bt. 4. The percentage of recycled waste to total waste disposed decreased by 16%, but still remains above the Environmental Target of 25%, as a result of increase of the environmental consciousness of the staff. 5. The percentage of recycled waste per unit produced was reduced, by 19% compared to 2018, due to the increase in production. Indeed, this percentage has fallen sharply below the target of 1 gram per unit produced due to the Group's systematic actions and initiatives related to integrated recycling (ie the sorting of solid non-hazardous waste at source and recycling by type of waste). 6. The Satisfaction of staff from the Company’s Environmental Management increased by 1% compared to 2018, but still remains below the target of 90%. New staff trainings will be performed to increase the staff environmental awareness. 7. The liquid waste disposed per unit produced was reduced, as planned, compared to 2018 and even exceeded the target of 1g / bt, due to the Group's systematic actions and initiatives related to the rational management of hazardous waste. 8. The percentage of Out Of Specification waste to total waste was also reduced by 17% compared to 2018, due to the increase in the production and thus in the waste generated. However, this percentage still needs further growth to reach the target. Further staff training will be carried out with a view to informing about recycling, awareness of the workers' ecological consciousness, and the initiatives and synergies that need to be developed to protect the environment. 9. The cost of discarded raw materials expired or found to be out of specification in the warehouse was 0, since no raw materials were discarded during 2019. 10. The percentage of discarded packaging materials per total recycled waste slightly increased by 1% compared to 2018, due to the increase in recycled waste as a result of the Group's systematic actions and initiatives related to the recycling. 11. The contributory benefit of discarded packaging materials that expired or found to be out of specification in the warehouse decreased, by 47% compared to 2018, due to the Group's systematic actions and initiatives related to integrated recycling (ie sorting of solid non-hazardous waste at source and recycling by type of waste), against the Group's rewarding benefit. 12. The cost of disposing of hazardous waste decreased compared to 2018, as planned.   ***Human Resources - HR***  In 2019 the company continued, the OFET Academy program that entailed all the training provided to employees with training programs led by a pool of capable internal trainers. The majority of trainings were short and frequent, in order to keep everyone alert and active in learning.  Unfortunately due to the re-organizational changes at the HR Department many external trainings were postponed and for the same reason the employee satisfaction survey did not take place too. Our target is to run the survey for 2019 as soon as the coronavirus (COVID-19) outbreak in Greece is over (June 2020).  In 2019, the number of employees kept growing overcoming 1,6:1 (for every termination of employment 1,6 people are hired). Our target for the upcoming years is to reach 2:1 ratio.  Finally, regarding absences, they are still low, proving our people’s commitment overcoming the projected target of 2 days per employee.  ***Τμήμα Παραγωγής – Production department***  A part of Productio KPIs has shown a slight (not important) decrease compared to the last year’s values due to the procedure of adjusting the production processes. New separate KPIs were developed especially for the Medical Devices per pharmaceutical forms produced in the factory, such as sticks and ampoules.  ***Ποιοτικός Έλεγχος (QC)***  For the 2019, quality control has succeeded the targets for all fields except the % expired lots or OOS / total 0 %.  Only 2 excipients of the total 1291 imports were out of specification. The   raw materials  are under investigation and there is no cost for the company.  For 2019 the objectives of the department are as follows:  % lots NOT rejected / total 100 %  % lots NOT rejected / total 99.6 %  % lots NOT rejected / total 99.86 %  % lots NOT rejected / total 100 %  % expired lots or OOS / total 0.15 %  ***Research & Development (R&D)***  Performance for 2018 (R&D Personnel: 7)  R&D Department consists of 7 employees and has achieved 5 from 9 total goals for 2018.  The new projects of non-pharmaceutical developments are increased, while, the corresponding projects of pharmaceutical developments remained stable within the target.  The number of submissions for new Dossiers of pharmaceutical products through both National and DCP procedures is decreased for 2018, while, there is a noteworthy increase in the official communication and in official variations/updates of already submitted Dossiers, through National and DCP procedures.  There is a significant increase in the number of new patent applications submitted in 2018, while, the number of official communications as regards the already submitted patent applications and oppositions is also increased.  Furthermore, the R&D Department has an active role in National and European Research Projects. In particularly, R&D Department of Uni-Pharma S.A. participates in the following Research Projects:   * “Ιnnovative multifunctional biomimetic micro-/nanofibrous scaffolds for the treatment of periodontitis” (NANOSCAPE) relates to the development of tri-layer hybrid multifunctional, biocompatible and biodegradable electrospun barrier membranes that will enhance bone and periodontal ligament regeneration, preventing epithelial cells growth and protecting the surrounding environment from anaerobic bacterial pathogens. Uni-Pharma S.A. participates from the beginning of the project which has a starting date on 28.06.2018. * “Bioactive compounds from Olea europaea: investigation and application in food, cosmetic and pharmaceutical industry” (OLIVE-NET) in the frame of Marie Skłodowska-Curie Actions and the “Research and Innovation Staff Exchange (RISE) Call: H2020-MSCA-RISE-2016” with a starting date of 01.03.2017 and closing date of 28.02.2020. * “Preclinical development and commercial exploitation of Autotaxin inhibitors, a novel pharmaceutical target in the pathogenesis of pulmonary fibrosis and chronic inflammation” with the acronym “ATX” and a starting date of 28.06.2018. In the frame of working package 4 (WP4) Uni-Pharma S.A. designed the IP strategy and performed a deep search in the prior art as regards novel autotaxin inhibitors. * “Structural studies of intrinsically disordered proteins towards the development of formulations for market-oriented pharmaceutical products” in the frame of the project “Instruct-Ultra Work Package 4 – Call 2” in the “Horizon 2020 Infrastructures Development Call” and in collaboration with National Hellenic Research Foundation. This project relates to the structure analysis of intrinsically disordered at molecular level, as active pharmaceutical ingredient carriers that may lead to the development of protein and polysaccharide containing formulations for market-oriented pharmaceutical products.   Targets for 2019 (R&D Personnel: 7)  Target 1: # Dossier Development Projects in progress / # people - 27  Target 2: # Dossier Update Projects / # people - 20  Target 3: # New Dossier Submitted National Procedure / # people - 2  Target 4: # New Dossier Submitted DCP Procedure / # people - 5  Target 5: # New Projects under Research and Development/ # people - 10  Target 6: # New Projects non pharma under Research and Development/ # people - 10  Target 7: # New Projects non pharma Submitted/ # people - 10  Target 8: # of patents submitted - 3  Target 9: # of answers in patents – 15  Uni-Pharma S.A. R&D Department will be also involved in two additional research projects within 2019:   * Η ερευνητική πρόταση με τίτλο: “Encapsulation of Chromophores by Self-assembled Hydrogels with Biomedical Applications” (EPHESIAN) and a starting date 18.07.2018. Uni-Pharma S.A. is involved on the 7th month of the project.. * The research project entitled: “Development of innovative pharmaceutical and cosmeceutical products from industrial hemp (Cannabis sativa L.)” with the acronym “CannabisMed” and a starting date 06.09.2018. The “CannabisMed” project aims to produce innovative, high added value products from industrial hemp using mainly cannabidiol (CBD) as an active ingredient. Uni-Pharma S.A. is involved on the 6th month of the project.   ***Sales***  **Evaluation of Key Performance Indicators (KPI’s) for Sales Department for 2019**  1.      For 2019 the Efficiency Index of the National Total Marketing - Sales Team remained  high, 631,9% v 672,8% last year.  2.     That comes as a result of a 9,1% increase in  the total promotional products income values and a 16,2% increase  in the total promotional  cost.  3.     The increase of total  promotional cost is mainly due to the increase of the cost by 18,5% in 2019 of the extended TV advertisements for newly launched OTC products.  4.     The Efficiency Index per AREA is not valid because there were many changes in the wholesales repartition throughout the whole country in 2019.  **Target 2020:** 1. It is already a very high Efficiency Index, and for this reason its stabilization for 2020 has to be considered reasonable.    ***International Sales***  **REVIEW 2019**  Target for revenue growth for 2019: 40%  Actual growth for 2019: 54%  Target achieved due to successful participation in tenders, growth in existing markets and new market launches.  Target for New DAs for 2019 was 4  Actual new contracts 4  This is due to successful participation of UNIPHARMA in International Exhibitions.  Additional SKUs entered into Distribution Agreements target for 2019 8  Actual new SKUs is 9  This is due to successful participation of UNIPHARMA in International Exhibitions  Target for New prospects for 2018 was 15  Actual discussion for new projects 18  This is due to successful participation of UNIPHARMA in International Exhibitions and B2B meetings.  Target for % deviation of Actual Vs Planned Budget for 2017 was 20%  Actual deviation 26%  Same as No1  TARGET 2020  Further to 2017 UPH continues to invest in its growth by participating in INTERNATIONAL EXHIBITIONS (5) , B2B meetings and Greek delegations all over the world, making new developments and increasing its staff which creates an optimistic environment for the future, leading to the below targets for 2020:  Growth% / 25%  Distribution agr / 3  Additional SKUs / 6  Prospects id / 12  Actual vs budget % / 15%  Satisf of Int clients / 89%  ***Regulatory Affairs***   * Evaluation of KPIs   As it can be seen, the department’s Productivity and Effectiveness remains high, for pharmaceutical products as well as for non-pharmaceutical products.  In 2019 there was a change in the KPIs as a result of a new collaboration with a Third Party Service Provider, i.e. Pharmassist. Thus, all Vigilance related KPIs (7-14) have been removed, since Pharmassist has taken over the role of Vigilance for Uni-Pharma for both pharmaceutical and non-pharmaceutical products.  It is also suggested to add a new KPI for 2020 regarding the Compliance to submission of safety variations triggered by PRAC or other Competent Authorities.  For all other indicators it is suggested to maintain the target at the same level.  ***BD Metrics Performance Review 2018 (Metrics Recorded In 2019)***  The key metric for immediate growth stemming from international markets -number of on-going projects (Accounts)- marked a value of 24, exceeding the target. Following the established approaches (existing business network referrals, exhibitions and partnering events) identifying and acquiring new accounts through the network continued to prove being the most effective. This year there were also more agents engaged, as the availability of human resources in the International Business Function to follow up with all leads had been identified from the previous year as being the rate limiting step for business growth.    Regarding the ‘’New Agreements made/ live projects" metric, current performance was recorded at 25%, still higher than the targeted 20%, although slightly lower than last year; however, as the number of ongoing projects rose, practically the actual number of New Agreements remained the same. During this period as well, the focus of the Dept. was diverted to the development of existing accounts via cross-selling (expansion of the scope of collaboration), as well as to the establishment of new accounts.    With regards to the financial performance of the Business Development Function, the key efficiency metrics that have been selected, are the present value of anticipated revenue from new accounts in a 5year projection and the development of total revenues in foreign markets from new accounts per year, expressed as a percentage of total revenues.    In 2018 the first KPI, NPV of Growth Revenue was calculated at € 26.980mio, as opposed to the targeted € 33.27mio, while the 2nd KPI, the overall International Business Growth Index (to total Revenue) was 5.5%, outperforming the targeted 5.3%.  The dynamic growth of the International Markets is attributed to the growth of the VN account and the activation of many new accounts, which combined with the steady high volumes of the Francophone Africa and Iraq accounts overcame the handicap of continuous absence from the Iranian market due to protectionism banning imports on pharmaceutical products when there are locally produced alternatives.    Finally, as to the effectiveness of partnering negotiations and the parallel processing of commercial agreements, the targets have been set up with assumptions based on historical data.  The figure for Average Draft Finalization lead time was further improved by one less week, while the Average Agreement Conclusion lead time remained at the same level, which is already set at 4 weeks Vs the originally targeted 12 weeks.  ***Corporate Social Responsibility***   1. Science on the Go – An extremely innovative educational activity, on the axis of CSR Strategy for Science and the New Generation, is the Mobile Science Laboratory of the Tseti Pharmaceutical Enterprise Group "Science on the Go". The mobile workshop, in collaboration with educational institutions, travels to Greece, educating students of Medicine and Pharmacy and bringing even closer to the consumer, the product of uninterrupted research and development. 2. An important anthropocentric action is the "APOSTOLI ZOIS" which in collaboration with the Hellenic Endocrinological Society, implements free information and preventive thyroid examinations in areas of the Barren Line and the province. The Mission of Life also cooperates with local Dental Associations for preventive examinations and information on oral health issues. 3. OFET Academy   OTEF Academy is the umbrella under which all educational programs and other educational activities organized by the Group are hosted not only on behalf of its staff but also on behalf of third parties (eg customers, partners, students, etc.).  Mission of our ACADEMY is to provide practical training, experiential workshops and other educational activities on and off the job activities that promote applied knowledge and contribute to the interconnection of knowledge with professional and personal development and development.  ACADEMY has a vision: it is to contribute to upgrading the qualifications of our executives and staff, to cultivate a culture of lasting learning and to prepare the executives of tomorrow. To do the business, that is, the corporate value of Learning (T.E.Learning. E.I.A.).  ***IT***  Key Performance Indicators (KPI's) for 2019   1. Satisfaction from intranet in 2019 compared to 2018 has increased by 0.3% and is significantly above the target by 4.3% 2. Satisfaction from internet and email in 2019 compared to 2018 has remained stable and at 1.6% above the target. 3. Satisfaction from IT intervention in critical system break-downs or other situations in 2019 compared to 2018 has increased by 1% and has equalized the target at 91%.   2019 Target Review:   1. It was a high target, however we managed to increase the rate or keep it stable in each of the three indicators, so we consider 2019 as a successful year. 2. In the 3rd indicator, we achieved to equalize the rate difference from the target, as our goal was, for the previous year.   Target 2020:   1. In the context of continuing staff training and new technological capabilities, and despite the already high levels of satisfaction we have been able to achieve, we believe that we can successfully achieve both our minimum goal of maintaining our rates and basic goal to increase the indicators by 1%   ***Finance***  The Company’s financial results have not been finalized yet, as we await the results from the file we submitted for clearing clawback with investments for the fiscal year 2019. |

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| **12.** | **Επιδόσεις διεργασιών και συμμόρφωσης προϊόντων και υπηρεσιών –**  **Process performance and conformity of products and services** |
|  | The process performance and conformity of products for 2019 is as follows:   * Non conforming products for 2019: - * Non conforming starting materials for 2019: - * Non conforming packaging materials for 2019: - * Product recalls for 2019: 1 – ZOLIDEN Lot: 19-001, due to UQUIFA’s API, ranitidine. |

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| **13.** | **Επιδόσεις Εξωτερικών Παρόχων - Αξιολόγηση Προμηθευτών & Συνεργατών –**  **Performance of External Providers - Supplier & Vendor Evaluation** |
|  | The evaluations of Suppliers takes place in the 1st trimester of each year.  All Suppliers and Vendors’ evaluations for 2019 were successfully completed. |

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| **14.** | **Eπάρκεια Πόρων** –  **Adequacy of Resources** |
|  | 1. Προσωπικό – Personnel   In 2019, **57 new employees were recruited.**   |  |  | | --- | --- | | **Department** | **Headcount** | | Creative | 1 | | Legal | 3 | | Production | 29 | | QA | 1 | | QC | 7 | | Regulatory Affairs | 1 | | RnD | 2 | | Sales | 10 | | Validation & Engineering | 3 | | **Γενικό Άθροισμα** | **57** |  1. **Equipment / Machinery**   UNI-PHARMA – 1   * The renovation of the historic factory was completed at the end of 2019. However, in some sections a further upgrade is perfomed in parts (as in injectables, suppositories, etc.).   UNI-PHARMA – 2   * The receiving of the main equipment of the unit has already taken place as well as its setting on specific areas. Moreover, receipt of the main part of the rest of the equipment has already taken place. * New equipment was received (such as a new Bags Line was installed).  1. **Facilities**   UNI-1   * Revamping of UNI-1 facilities has already began. Completion schedule of the revamping processes was scheduled for the end of May of 2019.  | **FLOOR** | **DEADLINE** | **STATUS** | | --- | --- | --- | | **3rd Floor** | **Up to 31/05/2018** | **Completed** | | **2nd Floor** | **Up to 31/05/2018** | **Completed** | | **1st Floor** | **Up to 30/06/2018** | **Completed** | | **Ground Floor** | **Up to 31/05/2019** | **100% completed** | | **Basement** | **Up to 31/05/2019** | **100% completed** | |

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| **15.** | **Aξιολόγηση εκπαίδευσης προσωπικού –**  **Staff training assessment** |
|  | Training program of 2019 was not totally met, basically because some trainings did not take place, due to work overload, training withdrawing by the institutions etc.  A new training program of 2020 was issued on 31/03/2020. |

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| **16.** | **Διαχείριση κινδύνου – Ρίσκα και ευκαιρίες**  **Risk Management – Risks and Opportunities** |
|  | Η αποτελεσματικότητα των ενεργειών που αναλαμβάνονται για την αντιμετώπιση απειλών και αξιοποίηση ευκαιριών σε όλο τον κύκλο ζωής των προϊόντων της Εταιρείας, παρατίθεται κατωτέρω:  Τhe effectiveness of actions taken to address risks and opportunities throughout the life cycle of the Company's products, is set out below:   |  |  |  | | --- | --- | --- | | **Τομέας**  **Sector** | **Κίνδυνος**  **Risk** | **Ενέργειες διαχείρισης (πρόληψη / αντιμετώπιση)/**  **Risk Management actions (preventing/ addressing)** | | **Διασφάλιση Ποιότητας**  **Quality Assurance** | **Μη συμμόρφωση με απαιτήσεις νέων προτύπων ISO 9001:2015, ISO 14001:2015 & ISO 13485:2016 & GMPs**  **Non-compliance with new ISO 9001: 2015, ISO 14001: 2015 & ISO 13485: 2016 & GMPs requirements** | * Προσέγγιση με βάση τη διακινδύνευση για τον έλεγχο των κατάλληλων διεργασιών που απαιτούνται για το ΕΣΔΠ / Risk based approach to ensure the control of the appropriate processes needed for the IQMS. * Τεκμηρίωση αλλαγών στις διεργασίες, βάσει Λ.Δ. 16.04 / Documentation of changes according to SOP 16.04. * Παρακολούθηση, διατήρηση και έλεγχο των διεργασιών που εκτελούνται με εξωτερική ανάθεση / Monitoring, maintaining and controlling outsourced processes. * Επικύρωση εφαρμογής λογισμικού ERP – SAP για υπολογιστές που χρησιμοποιούνται για το ΕΣΔΠ / SAP Validation for all the PCs used for the IQMS implementation | | **Διασφάλιση Ποιότητας**  **Quality Assurance** | **Μη συμμόρφωση με απαιτήσεις τεκμηρίωσης**  **Non-compliance with documentation requirements** | * “QA Walk” - Έλεγχος αρχείων παραγωγής εντός των απαιτήσεων ελέγχου του εγγράφου. / “QA Walk” - Control of production records within the document control requirements. * Τεκμηρίωση για την προστασία εμπιστευτικών πληροφοριών για την υγεία / Documentation related to protection of confidential health information. * Τεκμηρίωση σχετικά με την προστασία για φθορά και απώλεια εγγράφων (Λ.Δ. 20.06) / Documentation related to deterioration and loss of documents. | | **Διασφάλιση Ποιότητας**  **Quality Assurance** | **Μη επαρκής χειρισμός παραπόνων**  **Inappropriate complaints handling** | * Λήψη ανατροφοδότησης από τις δραστηριότητες κατά την παραγωγή και κατά τη φάση μετά την παραγωγή. / Receiving feedback from production and post-production activities. * Σύστημα καταγραφής & χειρισμός παραπόνων με διερεύνηση της βαθύτερης αιτίας και αιτιολόγηση στον πελάτη (Λ.Δ. 13.02) / Complaint handling system with investigation of the root cause analysis and justification to the client (SOP 13.02). * Χρήση αναπληροφόρησης στις διεργασίες διαχείρισης της διακινδύνευσης προκειμένου να παρακολουθούνται και να διατηρούνται οι απαιτήσεις του προϊόντος. / Use feedback in risk management processes in order to monitor and maintain the product requirements. | | **Διασφάλιση Ποιότητας**  **Quality Assurance** | **Μη επαρκής έλεγχος μη συμμορφούμενου προϊόντος**  **Inappropriate control of non-conforming product** | * Διερεύνηση βαθύτερης αιτίας κάποιου μη συμμορφούμενου υλικού ή προϊόντος, που βρίσκεται εκτός προδιαγραφών και αιτιολόγηση για περαιτέρω ενέργειες και αποφάσεις. / Investigation of a root cause analysis of a non-conforming material or product found to be Out of Specification and justification for further actions and decisions. * Διαχωρισμός απαιτήσεων για μη συμμορφώσεις που ανιχνεύονται σε όλο τον κύκλο ζωής των προϊόντων (πριν από την παράδοση στον πελάτη, μετά την παράδοση στον πελάτη και κατά την επανεπεξεργασία του προιόντος). / Separated requirements for non-conformities detected during the whole life cycle of products (before delivery, after delivery and during reprocessing). * Τήρηση αρχείων ανάκλησης, εικονικής ανάκλησης και αρχείων που σχετίζονται με την έκδοση συμβουλευτικών ανακοινώσεων. / Maintenance of records of recalls, virtual recalls (mock-recalls) and files related to the publication of advisory notices. | |  | **Λήψη μη κατάλληλων διορθωτικών ενεργειών**  **Taking inappropriate corrective actions** | * Προσθήκη Διερεύνησης βαθύτερης αιτίας εντοπισμού μη συμμόρφωσης και αιτιολόγηση. / Addition of investigation of a root cause analysis of non-compliance detection and justificaion. * Ανάληψη διορθωτικών ενεργειών χωρίς αδικαιολόγητή καθυστέρηση. / Taking corrective action without undue delay. * Επικύρωση, μέσω του Εντύπου ΕΝ 11.01.01, ότι οι Διορθωτικές & Προληπτικές Ενέργειες που αναλαμβάνονται δεν έχουν δυσμενή επίδραση στην ποιότητα και την ασφάλεια του προϊόντος. / Validation, through the Form F 11.01.01, that Corrective & Preventive Actions undertaken do not have an adverse effect on the quality and safety of the product. | | **Tμήμα Οικονομικών Υποθέσεων**  **Financial Department** | **Κίνδυνος επισφαλών χρεών**  **Bad Debt Risk** | * Συμβόλαιο ασφάλισης Πιστώσεων στην Ηeuler Hermes - Έχουμε ασφαλίσει τα ανοιχτά υπόλοιπα των πελατών μας στην Euler Hermes με ρήτρα επιστροφής ασφαλίστρων. Ο συνολικός ασφαλιστέος τζίρος είναι 45εκ. ευρώ. Ήδη το 2019 γλυτώσαμε από μια επισφάλεια της τάξης των 200 χιλ. ευρώ και έχουμε συνολικά 4 φακέλους ζημιών ανοιχτούς για αξία 50χιλ ευρώ. * Εργαλείο BD με αξιολογηση του αξιοχρεου των εν δυναμει πελατων. * Διεθνης συναργασιες ασφαλιστικων για αξιολογηση ξενων πελατων. * Real time ενημέρωση εστω και για δήλωση καθυστερησης απο προμηθευτη του πελάτη μας. * Συνεχης ανάλυση χρηματοιοκονομικών μεγεθων απο ασφαλιστικές . * Uni-pharma Global Credit Ratings Grade 4 ( 1-9 ). * Credit Insurance Contract at Heuler Hermes - We have insured the open balances of our customers at Euler Hermes with a premium refund clause. The total insurable turnover is 45Κ. Euro. Already in 2019 we escaped an uncertainty of the order of 200 thousand Euros and we have a total of 4 loss files open for a value of 50 thousand euros. * BD tool with evaluation of the potential of potential customers. * International insurance transactions for the evaluation of foreign clients. * Real time update even for a statement of delay from our customer's supplier. * Continuous analysis of financial figures by insurance companies. * Uni-pharma Global Credit Ratings Grade 4 (1-9) | | **Tμήμα Οικονομικών Υποθέσεων**  **Financial Department** | **Κίνδυνος επιτοκίου**  **Ιnterest Rate Risk** | * Όλα τα δάνεια μας είναι συνδεδεμένα με το 3Μ Euribor (+ spread) το οποίο καθόλη τη διάρκεια του έτους ήταν αρνητικό ( -0,25% έως -0,4%). Με τα νέα δεδομένα η ΕΚΤ δεν αναμένεται να κάνει αύξηση επιτοκίων στο άμεσο μέλλον προκειμένου να διατηρηθεί το χαμηλό κόστος δανεισμού για τις επιχειρήσεις ως μοχλός για την ανάπτυξη. Συνεπώς θεωρούμε ότι δεν θα έχουμε καμία αύξηση επιτοκίων για τουλάχιστον 2-3 χρόνια. Σε περίπτωση αύξησης των επιτοκίων, υπάρχουν τεχνικές hedging όπως συβολάια SWAPS είτε να εισέλθουμε στην αγορά παραγωγών. * All our loans are linked to the 3M Euribor (+ spread) which throughout the year was negative (-0.25% to -0.4%). With the new data, the ECB is not expected to raise interest rates in the near future in order to maintain low borrowing costs for businesses as a lever for growth. Therefore, we believe that we will not have any increase in interest rates for at least 2-3 years. In the event of an increase in interest rates, there are hedging techniques, such as SWAPS invoices or entering the producer market. | | **Tμήμα Οικονομικών Υποθέσεων**  **Financial Department** | **Κίνδυνος Συναλλάγματος**  **Foreing Ex. Risk** | * Η εταιρεία εισπράττει περίπου 5% του τζίρου της σε ξένο νόμισμα και συγκεκριμένα σε αμερικάνικο δολάριο $. Η τεχνική που εφαρμόζεται για την αντιστάθμιση του συναλλαγματικού κίνδυνου είναι η χρησιμοποίηση του ξένου νομίσματος για πληρωμές υποχρεώσεων επίσης σε δολάριο με την αντιστοίχιση τους χρονικά, μέθοδος netting & lagging. Επιπλέον, αν η έκθεση μας στο μέλλον αυξηθεί και δεν μπορεί να καλυφθεί με την παραπάνω μέθοδο τότε μπορούμε να εφαρμόσουμε εργαλεία αντιστάθμισης κινδύνου μέσω των τραπεζών (Money Market Hedge), καθώς επίσης μπορούμε να εισέλθουμε στην αγορά παραγώγων με συμβόλαιο μελλοντικής εκπλήρωσης, όπως forwards & options σε ξένο νόμισμα. * The Company earns about 5% of its turnover in foreign currency, specifically in US dollars. The technique used to offset the foreign exchange risk is to use the foreign currency to pay liabilities also in dollars by matching them in time, netting & lagging method. In addition, if our exposure increases in the future and cannot be covered by the above method, then we can charge money market hedge tools, as well as we can enter the derivatives market with a futures contract such as forwards & options in foreign currency. | | **Έρευνα και Ανάπτυξη**  **Research and development** | **- Mη επαρκής σχεδιασμός και ανάπτυξη νέων προϊόντων**  **Inappropriate design and development of new products**  **- Ανεπαρκής έρευνα αναφορικά με διπλώματα ευρεσιτεχνίας / Inappropriate research for patent**  **- Ανεπαρκής έρευνα αναφορικά με το προϊόν αναφοράς/Inappropriate research for the reference product**  **- Μη σωστή προτεραιοποίηση των υπό ανάπτυξη προϊόντων/ No specified priorities for the research and development** | * Προγραμματισμός – Επαλήθευση και έλεγχος του σχεδιασμού νέων προιόντων / Development - planning and control of design and development of new products * Τήρηση αρχείων επαλήθευσης και επικύρωσης. / Maintenance of verification and validation files. * Σωστή έρευνα γύρω από το προιόν αναφοράς με πλήρη έλεγχο των φυσικοχημικών ιδιοτήτων του. / Reference product full control * Έλεγχος διπλωμάτων ευρεσιτεχνίας με σωστό και συστηματικό τρόπο στα πρώτα στάδια την έναρξη ανάπτυξης / Research of patents as a priority in the first stages of the development. | | **Έρευνα και Ανάπτυξη**  **Research and development** | **Ακατάλληλες αλλαγές στο Σχεδιασμό και Ανάπτυξη νέων προϊόντων**  **Inappropriate changes in the Design and development of new products** | * Έλεγχος των αλλαγών στο Σχεδιασμό και Ανάπτυξη νέων προϊόντων / Control of Design and development changes. * Αποτίμηση της επίδρασης της αλλαγής στα προϊόντα, στις λειτουργικές διαδικασίες της Εταιρείας και στις διεργασίες υλοποίησης των προϊόντων / Evaluation of the change effect on products, on the Company’s Standard Operating Procedures and on the product realization processes. | | **Εφοδιαστική Αλυσίδα**  **Supply Chain** | **Mη κατάλληλη αξιολόγηση προμηθευτών & συνεργατών**  **Inappropriate Suppliers and Vendors assessment** | * Αυστηρά κριτήρια επιλογής προμηθευτών στην επίδραση των επιδόσεων του προμηθευτή στην ποιότητα του προιόντος / Strict supplier selection criteria on the effect of supplier performance on the product quality * Έλεγχος διακινδύνευσης που σχετίζεται με το προιόν / Risk assessment associated with the product. * Παρακολούθηση και επαναποτίμηση των προμηθευτών και ενέργειες που πρέπει να αναλαμβάνονται όταν οι απαιτήσεις ποιότητας δεν ικανοποιούνται. / Monitoring and re-evaluation of suppliers and actions to be taken when quality requirements are not met. * Απόρριψη προμηθευτή με χαμηλή ποιότητα προιόντος/ Rejection of a low-quality Supplier * Έλεγχος ικανοποίησης εφαρμοστέων κανονιστικών απαιτήσεων για το προιόν. / Control of product meeting applicable regulatory requirements. * Ειδοποίηση πελάτη σε περίπτωση σημαντικής αλλαγής στο προϊόν./ Notification of the client in case of significant changes in the product. * Σύναψη Σύμβασης Ποιότητας με τους Προμηθευτές Δραστικών Ουσιών με ρητές προδιαγραφές ποιότητας. / Conclusion of Quality Technical Agreements with Suppliers of Active Substances with explicit quality standards. * Logistics Policy. | | **Μηχανολογικός εξοπλισμός**  **Mechanical equipment** | **Βλάβες στο μηχανολογικό εξοπλισμό**  **Damage to mechanical equipment** | * Προληπτική συντήρηση / Preventive maintenance * Ετήσια συντήρηση όλων των μηχανημάτων / Annual maintenance of all equipment. * Επικύρωση μηχανολογικού εξοπλισμού κατά την εγκατάσταση και κατά τη λειτουργία / Validation of mechanical equipment during installation (Installation Qualification) and operation (Operation Qualification). * Επικύρωση απόδοσης μηχανολογικού εξοπλισμού / Performance qualification of mechanical equipment. | | **Προγραμματισμός Παραγωγής / Production Planning** | **Παρά την ικανοποίηση των απαιτήσεων του forecast υπήρξε μη έγκαιρη παράδοση για του τελικού προϊόντος /Untimely delivery of finished product, despite meeting the forecast requirements.** | * Δημιουργία του αποθέματος ασφαλείας και χρήση του ως buffer για την βραχυπρόθεσμη ικανοποίηση της ζήτησης / Safety stock built up to act as a buffer for the short term demand satisfaction. | | **Προγραμματισμός Παραγωγής / Production Planning** | **Απότομη αύξηση της ζήτησης τελικού προϊόντος / Sudden peak of demand in finished product.** | * Δημιουργία αποθέματος ασφαλείας Α’ υλών και υλικών συσκευασίας, και χρήση τους ως buffer για την βραχυπρόθεσμη ικανοποίηση των παραγωγικών απαιτήσεων / Material safety stock built up to act as a buffer for the short term satisfaction of production requirements. | | **Προγραμματισμός Παραγωγής / Production Planning** | **Βραχυπρόθεσμος περιορισμός της διαθεσιμότητας εξοπλισμού για την διεξαγωγή παραγωγικών διαδικασιών/ Short term unavailability of equipment for operational procedure execution.** | * Ύπαρξη εναλλακτικών οδών διεκπεραίωσης των παραγωγικών λειτουργιών (Πολυχρησιμότητα εξοπλισμού) / Existence of alternative paths for the execution of operation procedures (Equipment versatility). | | **Προγραμματισμός Παραγωγής / Production Planning** | **Υπερφόρτωση πόρων σε μία παραγωγική φάση / Over-allocation of resources in a single production phase.** | * Έκδοση και διαρκής ενημέρωση προγράμματος παραγωγής ανά παραγωγική φάση/ Production Plan issuing and constant updating based on production phases. | | **Παραγωγή & Συσκευασία**  **Production & Packaging** | **Χαμηλή ποιότητα παραγόμενων προϊόντων/ Low quality of produced products** | * Προσέγγιση με βάση τη διακινδύνευση για τον έλεγχο των κατάλληλων διεργασιών που απαιτούνται για το ΕΣΔΠ / Risk based approach to ensure the control of the appropriate processes needed for the IQMS. * Προγραμματισμός παραγωγής βάσει Λ.Δ. 08.02 / Production planning based on SOP 08.02. * Ποιοτικός έλεγχος όλων των παραγόμενων προϊόντων σε όλα τα στάδια παραγωγής (πριν την παραγωγή, κατά τη διάρκεια της παραγωγής & στο τέλος της παραγωγής) / Quality control of all products produced at all stages of production (before production, during production - in process quality control and at the end of production) * Παραγωγή όλων των προϊόντων βάσει των Πρωτοκόλλων Παραγωγής / Production of all products based on Protocols * Επικύρωση μεθόδων / Method Validation * Eπικύρωση διεργασιών παραγωγής / Process Validation * Επικύρωση λογισμικού / SAP Validation. * Επικύρωση καθαρισμού / Cleaning Validation. * Αναφορά Ανασκόπησης Ποιότητας Προϊόντων / Product Quality Reviews. * Επαλήθευση προϊόντος / Verification of product. * Δραστηριότητες επαλήθευσης και λήψη κατάλληλων ενεργειών όταν γνωστοποιούνται στον οργανισμό τυχόν αλλαγές στα υλικά ή στον εξοπλισμό. – Ενεργοποίηση διαχείρισης αλλαγών (Λ.Δ. 16.04) / Verification activities and actions taken when the organization becomes aware of any changes to the materials or the equipment (SOP 16.04). | | **Παραγωγή & Συσκευασία**  **Production & Packaging** | **Διασταυρούμενη επιμόλυνση**  **Cross- contamination** | * Προσέγγιση με βάση τη διακινδύνευση στις διαδικασίες παραγωγής & συσκευασίας / Risk based approach to ensure the control of the appropriate processes needed for the IQMS. * Κατάλληλη υποδομή (ταξινόμηση των χώρων παραγωγής ανά προϊόν και χρήση των air-locks και των αεραγωγών υλικών) για πρόληψη της αστοχίας του προϊόντος και της διασταυρούμενης επιμόλυνσης. / Appropriate infrastructure (classification of areas and use of personnel air locks and material air locks) in order to prevent product mix-up and cross-contamination. * Έλεγχος εργασιακού περιβάλλοντος & χρήση κατάλληλου ιματισμού / Control of working environment & use of appropriate clothing. * Επικύρωση καθαρισμού / Cleaning Validation. | | **Παραγωγή & Συσκευασία**  **Production & Packaging** | **Μη κατάλληλη αποστείρωση στείρων προϊόντων**  **Inappropriate sterilization of products** | * Επικύρωση διεργασιών αποστείρωσης / Validation of processes for sterilization. * Έλεγχος επιμόλυνσης με μικροοργανισμούς και σωματιδιακή ύλη για στείρα προϊόντα για ιατρική χρήση. / Control of cross-contamination with micro-organisms of particulate matter for sterile medical devices. * Παραγωγή στείρων ιατροτεχνολογικών προιόντων με βάση το ISO 14971:2007 – Εφαρμογή της διαχείρισης κινδύνου στα ιατροτεχνολογικά προιόντα / Production of sterile medical devices based on ISO 14971: 2007 - Application of Risk Management to Medical Devices | | **Παραγωγή & Συσκευασία**  **Production & Packaging** | **Παραγωγή μη ταυτοποιημένων προϊόντων**  **Production of unidentified products** | * Μοναδική ταυτοποίηση προϊόντος / Unique product identification – Serialization project * Τεκμηριωμένη διαδικασία για την αναγνώριση του προϊόντος που αφορά την αναγνώριση και την κατάσταση του προϊόντος κατά τη διάρκεια της παραγωγής. / Documented procedure for product identification and regarding identification and product status during production. | | **Ποιοτικός έλεγχος**  **Quality control** | **Χαμηλή ποιότητα χημικών αναλύσεων / Low quality of chemical analyses** | * Αλλαγή και αναβάθμιση του λογισμικού για τα συστήματα των χημικών αναλύσεων HPLC / Change and upgrade software for HPLC. * Ενεργοποίηση του Audit Trail για την ιχνηλασιμότητα των χημικών αναλύσεων / Activate Audit Trail for the traceability of chemical analyses. * Διαφορετικά επίπεδα πρόσβασης (administrator, user) με διαφορετικά δικαιώματα. / Different access levels (administrator, user) with different permissions. * Δυνατότητα πραγματοποίησης Review του Audit Trail μετά τον έλεγχο ολοκλήρωσης των αναλύσεων του προϊόντος. / Audit trail review after completing product analysis controls. | | **Διακίνηση & μεταφορά προϊόντων**  **Products handling & transportation** | **Μη κατάλληλες συνθήκες διατήρησης & μεταφοράς προϊόντων**  **Inappropriate product preservation transport conditions** | * Θερμική χαρτογράφηση θερμοκρασιών & υγρασιών στην αποθήκη ετοίμων προϊόντων. / Temperature warehouse mapping in the finished products warehouse. * Τοποθέτηση κλιματιστικών μονάδων στην αποθήκη ετοίμων προιόντων. / Installation of ventilation systems in the warehouse of finished products * Τοποθέτηση θερμομέτρων & υγρασιομέτρων και καταμέτρηση υγρασίας και θερμοκρασίας σύμφωνα με το Worst Case Scenario. / Installation of thermometers & humidity meters and measurement of humidity and temperature according to Worst Case Scenario. * Σύναψη σύμβασης με μεταφορική εταιρεία (3PL) πιστοποιημένη για μεταφορά φαρμακευτικών και ιατροτεχνολογικών προϊόντων. / Conclusion of a contract with a transport company (3PL) certified for the transport of pharmaceuticals and medical devices. | | **Εκπαίδευση**  **Training** | **Χαμηλή ποιότητα εσωτερικών εκπαιδεύσεων Low quality of internal trainings** | * Ορισμός συντονιστών ανά κατηγορία εκπαίδευσης για γενική εποπτεία των προγραμμάτων/ Allocation of coordinators per training category for general supervision of training programs * Έλεγχος εκπαιδευτικού υλικού πριν την υλοποίηση/ Check of training materials prior implementation * Επιλογή εσωτερικών εκπαιδευτών με σημαντική τεχνογνωσία στο αντικείμενο εκπαίδευσης/ Internal Trainer selection criteria – expertise in the training subject * Συμμετοχή του HR στις εκπαιδεύσεις για αξιολόγηση των διδακτικών δεξιοτήτων των εσωτερικών εκπαιδευτών/ participation of HR to training programs for assessing the teaching skills of internal trainers * Μέτρηση της ικανοποίησης των συμμετεχόντων και ενημέρωση των εσωτερικών εκπαιδευτών για διορθωτικά μέτρα, αν απαιτείται/ Satisfaction measurement of participants and update of internal trainers for corrective measures, if required * Ενεργοποίηση της διαδικασίας των CAPAs αν η ικανοποίηση των συμμετεχόντων είναι <60%/ Activating CAPAs if satisfaction rate is <60% * Εξασφάλιση κατάλληλων υποδομών (αίθουσα, προβολικό, κλπ) ανά εκπαιδευτικό πρόγραμμα/ • Ensuring the appropriate training infrastructure (venue, data display etc.) per training program. | | **Εκπαίδευση**  **Training** | **Χαμηλή ποιότητα εξωτερικών εκπαιδεύσεων Low quality of external trainings** | * Ορισμός συντονιστών ανά κατηγορία εκπαίδευσης για γενική εποπτεία των προγραμμάτων/ Allocation of coordinators per training category for general supervision of training programs * Επιλογή παρόχων με σημαντική τεχνογνωσία και αποδεδειγμένη ποιότητα/ Selecting Training institutions and trainers with considerable expertise and proven quality. * Μέτρηση της ικανοποίησης των συμμετεχόντων και διερεύνηση σχετικών παραπόνων/ Satisfaction measurement of participants and investigation of related complaints. * Πριν τη διεξαγωγή της εκπαίδευσης, συνάντηση και επικοινωνία -όπου δύναται- με παρόχους εκπαίδευσης για τη διασφάλιση κατανόησης των αναγκών και των εκπαιδευτικών στόχων/ Prior the training meetings and/or communication – where possible – with external trainers to ensure understanding of training need and objectives. * Ενεργοποίηση της διαδικασίας των CAPAs αν η ικανοποίηση των συμμετεχόντων είναι <60%/ Activating CAPAs if satisfaction rate is <60% | | **Εκπαίδευση**  **Training** | **Χαμηλός βαθμός συμμετοχής**  **Low participation rate** | * Υποχρεωτικότητα συμμετοχής/ Mandatory participation * Επανάληψη διεξαγωγής με βάση τις βάρδιες/ Shift wise repetitive trainings | | **Εκπαίδευση**  **Training** | **Μη επίτευξη μαθησιακών στόχων**  **Non-attainment of learning objectives** | * Γραπτές εξετάσεις για έλεγχο της απόκτησης γνώσεων/ written exams proving knowledge acquirement * Επανάληψη της εκπαίδευσης ομαδικά ή και ατομικά, αν απαιτείται/ Repetition of training as a group or individually when required * Τακτική επανάληψη (ετήσια) σημαντικών εκπαιδεύσεων (π.χ. GMP, Υγεία & Ασφάλεια κα.)/ Regular repetition (annualy) of important trainings (e.g. GMP, Health Safety etc) * Σύνδεση θεωρίας με πράξη από την καθημερινότητα της εργασίας στον Όμιλο/ Linking theory with practice from day to day routine in the Group * Επαν-εκπαίδευση μετά από μακροχρόνια απουσία / Re training in cases of long-term employee absence | | **Εκπαίδευση**  **Training** | **Χαμηλός βαθμός διάχυσης της γνώσης**  **Low rate of knowledge sharing** | * Υποχρεωτική εκπαίδευση συναδέλφων μετά από τη συμμετοχή σε σημαντικό πρόγραμμα εκτός εταιρείας / Mandatory colleague training after an important outsource training * Τήρηση εκπαιδευτικού υλικού από το HR και κοινοποίηση στο intranet/ Outsource training material record keeping in the company intranet * Τεκμηρίωση μέσω διεργασιών καθιέρωσης επαγγελματικής επάρκειας, παροχής απαιτούμενης κατάρτισης και διασφάλισης της ενημέρωσης του προσωπικού./ Documentation processes of establishing competence, providing needed training and ensuring awareness of personnel. | | **Πρόσληψης Υποδοχής και Αποχώρησης του Προσωπικού**  **Recruitment, Induction & Exit Process** | **Ελλιπείς γνώσεις και δεξιότητες νεοπροσληφθέντα**  **Lack of knowledge and Skills of newcomers** | * Interviews από πολλαπλά επίπεδα/ multiple level interview * Συστάσεις/ Recommendations * Πιστοποιήσεις / τυπικά προσόντα/ Certifications/qualifications | | **Πρόσληψης Υποδοχής και Αποχώρησης του Προσωπικού**  **Recruitment, Induction & Exit Process** | **Αργή προσαρμογή**  **Slow adjustment** | * Συστηματική παρακολούθηση της προσαρμογής από τον προϊστάμενο και το HR – coaching κατά το α 3μηνο/ Systematic monitoring of the adjustment of the supervisor and HR – coaching during a 3 month period * Ενεργή συμμετοχή του HR στο induction – active HR participation to the induction process * Εκπαίδευση στον Κανονισμό Εργασίας και τις εσωτερικές πολιτικές – Internal Regulation and policies training | | **Πρόσληψης Υποδοχής και Αποχώρησης του Προσωπικού**  **Recruitment, Induction & Exit Process** | **Σύντομη αποχώρηση**  **Quick exit** | * Ειλικρινή interviews με πλήρη και αξιόπιστη περιγραφή της θέσης και της εταιρείας/ honest interviews with reliable job and company description and requirements * Ανταγωνιστικοί όροι συνεργασίας/ Competitive terms of employment * Τήρηση αρχείου βιογραφικών με εναλλακτικές επιλογές/ CV and interview record keeping for direct alternative actions * Exit interviews από το HR και λήψη διορθωτικών μέτρων ανάλογα με τα αποτελέσματα των exit/HR Exit interviews and CAPAs adjusted to exit results | | **IT** | **Μη κατάλληλη εφαρμογή Λογισμικού**  **Inappropriate use of Software** | * Επικύρωση εφαρμογής λογισμικού ERP – SAP για υπολογιστές που χρησιμοποιούνται για το ΕΣΔΠ / SAP Validation for all the PCs used for the IQMS implementation * Τεκμηρίωση σχετικά με την προστασία για φθορά και απώλεια εγγράφων (Λ.Δ. 20.06) / Documentation related to deterioration and loss of documents. | | **IT** | **Παραβίαση προσωπικών δεδομένων**  **Personal Data breach** | * GDPR - Πολιτική Απορρήτου και προστασίας προσωπικών δεδομένων – GDPR - Privacy Policy and personal data protection. * Προστασία προσωπικών δεδομένων υποψηφίων εργαζομένων / Job Applicants’ Data Protection Policy * Προστασία προσωπικών δεδομένων Επαγγελματιών Υγείας / Health Professionals’ Data Protection Policy. * Τεκμηρίωση για την προστασία εμπιστευτικών πληροφοριών για την υγεία / Documentation related to protection of confidential health information. | | **IT** | **Κίνδυνος Πληροφοριακών Συστημάτων**  **Information Systems Risk** | * Disaster Site για εξασφάλιση Business Continuity. Down time < 1 ώρα για restore back και full operations. Back up data delay disaster site- control data center < 30 minutes. * Disaster Site to ensure Business Continuity. Down time <1 hour for restore back and full operations. Back up data delay disaster site- control data center <30 minutes. | | **Ρυθμιστικές Υποθέσεις/**  **Φαρμακοεπαγρύπνηση**  **Regulatory Affairs/**  **Pharmacovigilance** | **Μη επαρκής αντιμετώπιση θεμάτων που σχετίζονται με την ασφάλεια ενός προς έγκριση προϊόντος**  **Insufficient handling of issues related to the safety of under approval product** | * Κατάθεση κατά την αρχική έγκριση προϊόντος ενός Risk Management Plan με τις ενέργειες που κάνει η εταιρεία (αν χρειάζονται) για να προληφθούν προβλήματα στους ασθενείς / Submission of a RMP during the registration procedure of a product with actions taken by the company (if needed) to prevent safety issues for patients. | | **Ρυθμιστικές Υποθέσεις/**  **Φαρμακοεπαγρύπνηση**  **Regulatory Affairs/**  **Pharmacovigilance** | **Μη συμμόρφωση με χρονοδιαγράμματα καταγραφής, αναφοράς και καταχώρησης στην Ευρωπαϊκή βάση δεδομένων Eudravigilance των ανεπιθύμητων ενεργειών – κίνδυνος αλληλογραφίας από Αρχές, προστίμου ή ακόμα και ανάκλησης Άδειας Κυκλοφορίας**  **Non-compliance with handling and reporting in the Eudravigilance European database of adverse reactions – Risk of deficiency letter risk, fine, or even revocation of a Marketing Authorization** | * Τήρηση αυστηρών χρονοδιαγραμμάτων, εβδομαδιαίος έλεγχος της Eudravigilance, τήρηση δεικτών/ Keeping tight timelines, check of Eudravigilance on a weekly basis, compliance with specific indicators | | **Ρυθμιστικές Υποθέσεις/**  **Κλινικές μελέτες**  **Regulatory Affairs/**  **Clinical trials** | **Ολοκλήρωση μελετών εκτός χρονοδιαγραμμάτων – κίνδυνος καθυστέρησης στην έγκριση προϊόντων με κανονιστικές αλλά και εμπορικές επιπτώσεις**  **Completion of trials out of the agreed timetable - risk of delay in regulatory approval of products with regulatory and commercial implications** | * Συνεχής παρακολούθηση της πορείας των μελετών-επιτήρηση μελετών, τήρηση δεικτών/ Continuous monitoring of study progress, compliance with indicators * Σε περίπτωση που δεν είναι εφικτή η ολοκλήρωση μιας μελέτης εντός του συμφωνημένου χρονοδιαγράμματος, υπάρχει μέριμνα να ανανεώνονται εγκαίρως τα ασφαλιστήρια συμβόλαια και οι συμβάσεις, ούτως ώστε να μην τίθεται εν κινδύνω η ομαλή διεξαγωγή της μελέτης/ In case that it is not possible to complete a study within the agreed timetable, care must be taken to ensure that insurance and contracts are renewed in a timely manner so as not to jeopardize the smooth running of the study | | **Ρυθμιστικές Υποθέσεις**  **Regulatory Affairs** | **Κίνδυνος μη ορθής λήψης του φαρμάκου από τον ασθενή και λήψης σχετικών παραπόνων για την εταιρεία λόγω ελλιπούς αναγνωσιμότητας Φύλλου Οδηγιών, ενημερωτικών φυλλαδίων και Συσκευασίας**  **Risk of improper drug administration by the patient and receipt of complaints due to inadequate readability of the leaflet, brochures and labelling** | * Κατάθεση κατά την αρχική έγκριση μίας μελέτης (readability test) της αναγνωσιμότητας του προτεινόμενου φύλλου οδηγιών από γκρουπ ασθενών διαφόρων ηλικιών και διαφορετικού μορφωτικού επιπέδου, ούτως ώστε να προβλεφθεί αν το φύλλο οδηγιών είναι ευανάγνωστο και κατανοητό/ Submission during registration procedure of a readability test of the proposed package leaflet from a group of patients of different ages and different levels of education to test whether the package leaflet is legible and comprehensible * Τελικός έλεγχος των κειμένων των ενημερωτικών φυλλαδίων, των φύλλων οδηγιών και της επισήμανσης (μακέτες) σε συνεργασία με το Σχεδιαστικό, πριν να εκτυπωθούν και βγουν στην αγορά/ Final check of the texts of the brochures, patient leaflets and labelling (mock-ups)s in collaboration with Creative department before printing and marketing | | **Ρυθμιστικές Υποθέσεις**  **Regulatory Affairs** | **Κίνδυνος μη έγκρισης προϊόντος λόγω καθυστερημένης απάντησης αλληλογραφιών από Αρχές**  **Risk of non-approval of products due to delayed response to deficiency letters from the Authorities** | * Τήρηση και παρακολούθηση Αρχείου excel/ Maintaining an monitoring of respective excel file | | **Ρυθμιστικές Υποθέσεις**  **Regulatory Affairs** | **Κίνδυνος εσφαλμένης εφαρμογής τροποποιήσεων**  **Risk of inappropriate implementation of variations** | * Το Τμήμα ελέγχει πριν την εφαρμογή μίας τροποποίησης αν είναι τύπου IA, IB ή II. Στην πρώτη περίπτωση η τροποποίηση πρέπει να έχει γνωστοποιηθεί στις Αρχές μέσα σε ένα έτος από την ημερομηνία που εφαρμόστηκε στην εταιρεία, ενώ στις άλλες περιπτώσεις δεν μπορεί να εφαρμοστεί αν δεν έχει εγκριθεί πρώτα από τις Αρχές/ The Department checks before implementing a variation if it is of type IA, IB or II. In the first case, the variation must be notified to the authorities within one year from the date it was implemented in the company, while in other cases it cannot be implemented if it has not been approved first by the Authorities | | **Περιβάλλον Environment** | **Ρύπανση περιβάλλοντος Μόλυνση υδροφόρου ορίζοντα, εδαφών, αέρια ρύπανση**  **Environmental pollution Contamination of aquifers, soils, air pollution** | * Aνακύκλωση όλων των στερεών μη επικίνδυνων αποβλήτων / Recycling of all solid non-hazardous waste. * Ορθολογική διαχείριση επικίνδυνων φαρμακευτικών αποβλήτων / Rational management of hazardous pharmaceutical waste. * Χρήση απόλυτων φίλτρων HEPA για κατακράτηση σωματιδίων και περιορισμό της αέριας ρύπανσης / Use of absolute HEPA filters for particle retention and limitation of air pollution. * Χρήση ηπιότερων καθαριστικών χωρίς φορμαλδεύδη και γλουταραλδεύδη για αποτροπή της μόλυνσης του υδροφόρου ορίζοντα. / Use of non-formaldehyde and glutaraldehyde cleansers to prevent contamination of aquifers. * Δράσεις “U & I Green” για αύξηση ευαισθητοποίησης προσωπικού / U & I Green" actions to increase staff awareness. * Συνεχής εκπαίδευση προσωπικού / Continuous staff training. | | **Περιβάλλον Environment** | **Επίδραση στη φήμη της Εταιρείας λόγω επιβολής περιβαλλοντικού προστίμου ή**  **περιβαλλοντικού ατυχήματος ή συμβάντος**  **Environmental fine**  **Environmental accident or incident** | * Χρήση Φ.Α. αντί για πετρελαίου στις ατμογεννήτριες / Use of Natural Gas instead of oil in steam generators. * Χρήση νέου μηχανολογικού εξοπλισμού με μικρή περιβαλλοντική επιβάρυνση / Use of new mechanical equipment with low environmental impact * Έλεγχος διαρροής ψυκτικών μέσων από εξουσιοδοτημένο συνεργάτη και υποβολή στο Υπουργείο Περιβάλλοντος / Control of refrigerant leakage by an authorized partner and submission to the Ministry of Environment. * Σύμβαση με φορέα διαχείρισης επικίνδυνων αποβλήτων για ορθολογική διαχείριση επικίνδυνων φαρμακευτικών αποβλήτων / Contract with a hazardous waste management organization for the rational management of hazardous pharmaceutical waste. * Σύμβαση με φορέα διαχείρισης μη επικίνδυνων αποβλήτων για την ανακύκλωση όλων των στερεών μη επικίνδυνων αποβλήτων / Contract with a non-hazardous waste management organization for the recycling of all solid non-hazardous waste. | | **Περιβάλλον Environment** | **Θόρυβος**  **Noise** | * Καταμέτρηση θορύβου στον προαύλιο χώρο του εργοστασίου για μη υπέρβαση των νόμιμων ορίων. / Noise measurement in the yard area of ​​the factory for not exceeding the legal limits. * Μελέτη θορύβου στους χώρους παραγωγής του εργοστασίου. / Noise study at factory production sites. | | **Eνέργεια**  **Energy** | **Αύξηση ενεργειακής κατανάλωσης**  **Increase in energy consumption** | * Δείκτες Ενέργειας / Energy Efficiency Targets * Προγράμματα Ενεργειακής Δράσης / Energy Efficiency Action Plans | | **Υγεία και Ασφάλεια**  **Health and Safety** | **Εργατικά ατυχήματα**  **Accidents at work** | * Χρήση ΜΑΠ (μάσκες, γυαλιά, αντιολισθητικά υποδήματα ασφαλείας κλπ) από όλο το προσωπικό του εργοστασίου / Use of PPE (masks, goggles, anti-slip safety shoes, etc.) by all staff * Τακτικές εκπαιδεύσεις αναφορικά με υγεία και ασφάλεια στον χώρο εργασίας. / Regular trainings on health and safety at work. * Συγκρότηση Ομάδων Πυρασφάλειας και Ασφαλείας. / Establishment of Fire Safety Team and Emergency Response Teams. | | **Υγεία και Ασφάλεια**  **Health and Safety** | **Κορωναιός**  **Coronavirus COVID-19** | * Μέτρα προστασίας κορωναιού – σύνταξη και διανομή σε όλο το προσωπικό.   Coronavirus protection measures – development and distribution to all staff.   * Σύνταξη Contingency Plan από τη Διοίκηση για να διασφαλιστεί ο περιορισμός και ο μετριασμός του COVID-19 στους χώρους εργασίας / Development of Contingency Plan from Top Management to ensure containment and mitigation of COVID-19 in the workplace. * Χρήση ΜΑΠ (μάσκες υψηλής προστασίας FFP2, FFP3, γάντια, αντισηπτικά, κλπ) από όλο το προσωπικό του εργοστασίου / Use of PPE (high-protective masks FFP2, FFP3, gloves, antseptics, etc.) by all staff. * Σύνταξη Σχεδίου Έκτακτης Ανάγκης (ΣΕΑ) και τακτικές εκπαιδεύσεις αναφορικά με υγεία και ασφάλεια στον χώρο εργασίας. / Development of Emergency Response Plan and regular trainings on health and safety at work. * Συγκρότηση Ομάδων Επικοινωνίας & Συντονισμού. / Establishment of Communication Team and Co-ordinationTeam to address the outbreak of COVID-19. | |

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| **17.** | **Αναφορές σε Κανονιστικές ή Ελεγκτικές Αρχές –**  **Reporting to Regulatory Authorities** |
|  | * If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the Organization shall document procedures for providing notification to the appropriated regulatory authorities. * No such case was detected in 2019. |

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| **18.** | **Η εξέλιξη των Προγραμμάτων Διαχείρισης Περιβάλλοντος & Ενέργειας –**  **Progress of Environmental Programs** |
|  | * The Environmental Management Programs launched in January 2017 with the use of red bins exclusively for glass recycling and in July 2017 using brown bins exclusively for wood recycling have been implemented with success during the whole 2018. The collection of the said bins is performed by a specially Licensed non-hazardous Waste Management Company and the recycling of these constitutes a compensatory benefit to the OTEF Group. The above Environmental Programs follow the Environmental Programs of 2016, using a yellow paper press for compressing the volume of paper to be recycled, and using green bins for recycling of plastic that have a large participation of the Company’s staff and already provide a significant contributory benefit to the Company. * New Innovative Environmental Management Program was launched in March 2018 with the use of non-formaldehyde and glutaraldehyde cleansers to prevent contamination of aquifers. The new Environmental Management Program was implemented in the 2nd half of 2018 with success in both production plants with success. * New Energy Efficiency Plans were launched in 2019 with the use of energy counters to achieve a decrease in energy consumption. |

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| **19.** | **Ασκήσεις ετοιμότητας για τα Σχέδια Έκτακτης Ανάγκης –**  **Review of drills for Emergency Plans** |
|  | * The Firefighting Group's exercise / training program for 2019 was implemented according to the Fire Protection Study and Contingency Plans for the installations of UNI-PHARMA. Virtual fire extinguishing and building evacuation exercises took place and it was found that both the Fire Protection Team and the staff responded well and in accordance with the Emergency Contingency Plans.   **Training in Health and Safety Issues**   * Training is being carried out with a detailed presentation to the newly recruited for the proper use of the Personal Protective Equipment and the mechanical equipment, as well as the application of material recycling (paper, plastic, glass, etc.) with the aim of providing adequate information on environmental management applicable to the Group and ensuring the health and safety of the Group's personnel. * Within the framework of the U & I Safe actions, new Εmergency Response Teams ("Safety Teams") were set up in the 2 Group Companies and training and internships will be conducted in these new Group Safety Teams, with the assistance from the Greek Red Cross on 1st and 8th of February 2020 (First Aid Training and First Aid Practice). * In the new training needs program of 2020, new training courses will be included for the environmental consciousness and the awakening of the ecological sensitivity of the personnel as well as specific training for the leakage of chemical substances and toxic raw materials and their treatment to all the relevant personnel of the Group |

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| **19.** | **Έλεγχος των περιβαλλοντικών πλευρών / θεμάτων –**  **Review of Environmental Aspects** |
|  | * A review of the Environmental Issues and Impacts and the replenishment of EN 30.02.01 - Environmental issues was carried out in order to take into account the full operation of the building’s extension, the upgrading of the production and packaging areas of the existing building and the change in the method of assessing the environmental aspects and impacts of the Company's operation, following the issuance of the new Decision Approving Environmental Terms. The revision of these documents took place in the second half of 2019, in order to include also the indirect environmental aspects associated with the transport of products eg from INTRALINK and subcontracting. * In the context of the revamping of the Company's existing plant (UNI 1), which was fully operational in the second half of 2019, the Environmental Objectives were reviewed per product for 2019. * The Operational Process "SOP 30.02 - Environmental Issues ", was updated, with new flow diagrams for the production process of new formulations produced in the new building (ie soft gel, sticks, strips and pouches). |

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| **20.** | **Ανακύκλωση / Διαχείριση αποβλήτων –**  **Recycling / Environmental management of wastes** |
|  | * According to the new Decision Approving Environmental Terms, issued on 30/11/2017, hazardous waste from production processes is safely collected and placed in durable containers, as well as hazardous solid waste, a record of the respective quantities is kept and delivered to POLYECO, a licensed hazardous waste management organization, with which there is a cooperation agreement. * In addition, according to the new Decision Approving Environmental Terms, the Company monitors the quality characteristics of its wastewater discharged into the EYDAP network, which are within the allowed limits set by EYDAP for its installations, through chemical analyzes by a specialized external laboratory. A new Sewer License Renewal of EYDAP was issued on 8th November 2019. |

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| **21.** | **Ευκαιρίες προς βελτίωση –**  **Opportunities for improvement** |
|  | For the year 2019 the following were planned and launched:  1. Review and improve the Key Performance Indicators to achieve a better connection to Company’s strategic goals and provide meaningful information for improvement measures.  2. Evaluation of the company by European Assessors of the European Quality Award EFQM as preparation for accession to the process in spring of 2019.  3. Creation of the OFET Academy for upgrading education, expanding the group of in-house trainers, creating targeted training programs, organized executive development and linking with CSR  4. Better communication internally and externally of CSR actions and expanding of CSR actions.  5. Supply and installation of Document Management System for QA Department to reduce bureaucracy issues.  6. Carry out customer satisfaction surveys (doctors / pharmacists) with the use of a subcontractor (an external company) for more comprehensive and objective results.  7. Review and improve the Εnergy Key Performance Indicators to achieve a better connection to Company’s strategic goals and reduction of energy consumption with better production planning and energy counters. |

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| **22.** | **Αποτελέσματα Ανασκόπησης από την Διοίκηση**  **(Ευκαιρίες για βελτίωση, ανάγκη για αλλαγές στο ΕΣΔΠ, ανάγκη σε πόρους) –**  **Management Review Outputs (Opportunities for improvement, any need for changes to the IQMS, resource needs)** |
|  | Concluding the Review from Management, we conclude that the IQMS is operating smoothly and is constantly upgrading. Sections are periodically reviewed and the problems encountered are solved through the Corrective Action – Preventive Action (CAPA) Plan. Complaints are taken into account and settled accordingly. UNI-PHARMA's Compliance with the Greek Legislation and the Standards it implements is verifiable.  **Decisions for 2020:**  1. Update the Company’s Integrated Quality & Environmental Management System (IQMS), with a new certification of ISO 5001:2018 in 2020, in order to achieve the continuous improvement of IQMS. |