ZDRAVLJE
A FRONTIER BIOPHARMA COMPANY

ZDRAVLJE AD LESKOVAC
VLAJKOVA 199, 16000 LESKOVAC
BULEVAR MILUTINA MILANKOVIĆA 23, 11 000 BEOGRAD
info@zdravlje.co.rs
zdravlje.co.rs
+381 60 790 2200
PIB(TIN):100330231
MAT.BR.(REG.NO.):07204817

Minimum Required Elements of EHS

Objectives and Implementation Plans according to SOP-EHS-000016 General and specific EHS objectives and targets and programs for achieving these objectives and targets

Category	Expectations/Objectives	Area	Activity/Title	Objective/Goal/	KPI	Action item/Description	Responsible/Owner	Start date	Deadline	CAPEX dependent
Compliance										
	EHS Compliance with all local regulatory requirements and other (EU, GMP, ISO 14001:2015 and ISO 45001:2018 standards) requirement	Local legal compliance	Using local system for legislative changes tracking - implement all new legal requirements in EHS system	Fully compliance to the environment, safety and health regulations and laws. New H&S Law (Official Journal 35/23) - to be in compliance New Law for waste management (Official Journal 35/23) - to be in compliance	100% Implementation of legal requirements on time . No NOV or Fines during regulatory inspections	Utilizing Officinal Journals www.pravno-informacioni-sistem.rs check all changes in legislation and initiate local activities and developing Program in order to be in compliance.	Mgr EHS , EHS Associate, Responsible person for Fire and Security, Purchasing supervisor All relevant managers	Q2	Q4	no
		Compliance with compliance calendar and TWD	Continue with tracking of activities in compliance calendars and update on monthly basis	100% compliance with activities scheduled in compliance calendar	100% of activities finished on time	Continual Upgrading Facility compliance calendar and implementation new requirements . On time activities in TWD	All	Q1	Q4	no
		Compliance with European legislative	Implementation of requirement related to IPPC Permit	Zdravlje facility to get IPPC Permit	Get IPPC	Starting procedure for IPPC - Team for preparing documentation - Preparing documentation for IPPC	EHS and Team	to be decided	to be decided	no
		Internal EHS audit of contractors and all department	EHS internal audit -	Conduct EHS internal audit according to adopted Plan for 2024	more than 90% CAPAs from internal audit to be closed	Internal verification performing by internal forces in order to verify compliance with Zdravlje EHSMS	EHS and Team	Apr-24	Q4 2024	No
		Incident reporting	Continue to improve the timeliness and quality of investigations of EHS incidents and non-conformities	Enhance level of incidents & non-conformities investigation	100% on time reporting	Continue to improve the timeliness and quality of investigations of EHS incidents and non-conformities : - Participation in EHS learning team - On Time reporting to EHS and to local authorities - Communication and notification of incidents according to local procedures and regulations Lesson learned communication of Zdravlje incidents to local team	Mgr EHS/ EHS Associate	Jan-24	Q1 - Q4	no
	Local Objective		New regulation regarding Pressurized vessels	Pressurized vessels	100% compliance	Review regulation Training and testing for License	Engineering Director	Q1	Q4	No
		Waste water- compliance with local requirement	Implementation of improvement plans related to waste water compliance	Reducing environmental impact due to waste water discharge	No NOV , citations or Fines	Installation oil separator for atmospheric water - on going	Engineering Director	2022	2024	Yes
						Continue to make analysis of parameters of waste water quality : - Frequently checking of waste water quality/ quarterly -Weekly checking of pH of waste water - Cleaning of waste water pool and disposal of waste from it. -Daily checking of waste water flow rate - Calibration of flowmeter - Checking of integrity of Equalization pool and connected piping systems (Once per 5 years)	Mgr EHS	2022	2024	No
		Emergency situations	Plan in case of chemical accidents	Organize Exercise with external Emergency team according to Plan in case of chemical accidents License for local team to prepare our own plan was received	No NOV , citations or Fines	Organize Exercise with external Emergency team according to Plan in case of chemical accidents License is received	EHS manager	Q2	Q2	No
			Risk assessment and Plan for rescue and protection	Risk assessment completing and making Plan for rescue and protection	No NOV , citations or Fines	Contact relevant authorities, Preparation of documentation ,and approval for prepared plan were done . Conduct training and apply for License for RA and Plan in the Future	EHS manager	2022	2025	No
Risk										
	Continue to develop facility risk registers/Risk mapping and risk mitigation plan.			Update EHS Risk Registries and create control plan for each high risk	Zero TRIR	Define actions from EHS Risk register/ map in order to decrease either the severity or the probability of one or two risks each quarter so that all are improved by end 2024. Reduce risks during non routine work at height -fence around roofs (OSD and Medicina) , technical spaces. Chimney IH monitoring - new products (OEB 3)	Mgr EHS	Q1	Q1- Q4	No
	Complete full implementation of the high risk work and process safety management Standards comprising the Process Safety Series at TGO locations, specifically: o Process Safety Management o Fire and Explosion Prevention o Fire Protection and Emergency Egress	Process safety and Fire protection	implementation of the high risk work and process safety management Standards comprising the Process Safety Series	ZERO MATERIAL EHS EVENTS	Zero PSE	HAZOP study for non production area (e.g. Steam Boiling Room) Fire and explosion safety - training for all employees	Engineering Director, Production director EHS manager Responsible person for Fire and Security		2024	No
	Complete full implementation of contractor management programs accordance with SOP Contractor Management.	Contractor Safety	Improvement of Contractor safety management program - IFM part	Improve Contractor safety program - IFM contractors on site in compliance with local and corporate requirements	Zero Contractors incidents	• EHS involvement in Contractors pre selection before starting activities on site • Safety trainings for contractors with testing • Regular inspection of contractors activities on site • Regular/annual checking of EHS documentation for all contractors on site	EHS manager, facility and Maintenance coordinator. Engineering Director	Q1	Q4	no
	property loss prevention program - risk reduction	audit findings	Work on Category 1 recommendation	Reduce risk identified related sprinkler system	Reduce risks	Collecting possible solutions for sprinkler system project (automatic sprinkler protection in the warehouses and other areas with combustible occupancies. Design and install the systems in accordance with NFPA 13 and local standards). Decision to be made after further status of project	Engineering Director	TBD	TBD	yes
			work on Human Element recommendations that should be easy/quick fixes	Fix all Human Element recommendations from Insurance company audit	Reduce risk identified during audits. No repeated findings during the next audit	Thermal scanning on electrical systems to be finished in on yearly basis Conduct annual transformer oil analysis including dielectric strength and dissolved gas analysis (DGA). Further details on oil analysis and DGA are available from and the following links http://www.machinerylubrication.com/Read/282/transformer-oil-analysis https://en.wikipedia.org/wiki/Dissolved_gas_analysis Consider the use of anti static bags for charging low MIE powders or hybrid mixtures	Engineering Director	Q1	Q4	No
	Verify effectiveness of controls for all medium risks by quantitative IH sampling for OHC 4 materials	Industrial hygiene	Complete Quantitative IH assessment for new APIs	Evaluate and improve existing controls to prevent employee exposure to potent compounds	No health events or illnesses regarding to exposure of employees	• According to available resources conduct quantitative measurement of employees exposure- continue IH monitoring Identify possible Engineering solution	EHS manager,	Q1	Q1- Q4	no
	Continue to implement actions to prevent serious environmental spill events(Level 3-5).	Prevention of Soil , underground and surface water contamination	Conducting measures on prevention spillage according to internal list of places where spillage could happened	Implementation engineering and administrative measures in order to prevent serious environmental spillage (RA list is made)	No environmental spill events (Level 3-5)	Conducting internal administrative measures according to local SOPs and local inventory of possible space's where spillage could happened - Monthly inspection of possible places of spillages and leaking by Securitas and according to check list	All responsible managers / Securitas	Q1	Q1- Q4	no
	Regular checking programmed effectiveness for five EHS Standards governing high risk work activities, specifically: o Safe Work Permits o Confined Spaces o Electrical Safety o Control of Hazardous Energy o Fall Prevention and Protection		Continue to improve the safety of High Risk Work activities performed by Zdravlje employees and contractors	Improve safety during performing high risk activities (Work at height, Control of hazardous energy , Confined space, Electrical safety)	zero incident during performing HRW	TOLOT SOP upgrade and three year training with testing for employees	Engineering Director /Electricity engineer	Q1	Q3	no
						Work at height programmed : - providing additional equipment for work at height (harnesses/ fence around roof on OSD, ...) - Two year Training for employees who work at height - work at height on chimney _ installation of additional equipment - further decision - postponed	Engineering Director /EHS	Q1	Q1- Q4	Partially yes - fence around OSD - TBD
Systems										
	Achieve 100% full implementation of EHS Management System Ensure accurate and timely reporting	EHS Management system _ Environmental and Product Stewardship STDs	Environmental and Product Stewardship STDs Installation . Goals: 100% installation, **TRANSFORMATIONAL OBJECTIVE**	100% installation of Environmental and Product Stewardship SOPs	100% Installation on time Environmental SOPs	For "Zdravlje" standards perform gap analysis and ensure compliance with local SOPs for the following "Zdravlje" standards and related specifications. o Emissions Management o Soil, Groundwater and Surface Water Protection o Energy Conservation and Management o Water Conservation and Management o Waste Minimization and Management o Environmentally Responsible Packaging o Community Impact and Engagement o Chemical Management and Hazard Communication o Dangerous Goods Classification and Transportation implement actions to ensure effective and on-time closure of EHS CAPA	EHS manager and responsible persons (competent person and authors of relevant SOPs.)	2022	Q4 2024	no
					Contracts that cover Environmental activities on Hazardous waste management	Upgrade contract for disposal of hazardous waste - >New or extension of existing	EHS manager	Q3	Q3	no
Sustainability										
	Ensure timely and accurate submission of environmental footprint data required to NRIZ	Environmental	Annual reporting of Environmental Footprint data for Zdravlje site	On time reporting Environmental footprint data	100% reporting on time	During the Environmental Footprint Campaign enter all needed information NRIZ – Complete Annual Footprint report for 2024 Reporting according to local authorities by 31st March 2024	Mgr EHS	Q1	31st March	no
	Continue to identify and implement opportunities to reduce the use of natural resources and minimize waste		Establish annual facility targets to support environmental goals and identify and implement environmental footprint improvement opportunities	Improving environmental performance	1% improving Environmental goals according to previous year (waste, energy, water)	Continue to collect all data on the monthly basis (energy consumption, Heavy fuel oil consumption, hazardous waste, non-hazardous waste, water, waste water, solvents...)	Mgr EHS	Q1	Q4	no
		Water conservation and management	Complete baseline Water Balances and take subsequent actions in accordance with SOP Water Conservation and Management. **TRANSFORMATIONAL OBJECTIVE**	Rational of potable water consumption **Reduce total water withdrawal by 5% between 2024 and 2030 in production site (Leskovac) that is in areas projected to be in water stress by 2030**	Complete Water Balance 1% Annual Reduction in water withdrawal per units produced at sites projected to be subject to water stress by 2030	Form Water Balance team	Mgr EHS	Q1	Q4	no
						Nominate a Water Champion	Water Balance Team (WBT)	Q1	Q4	no
						Identifying water supplier, Users and discharges	WBT	Q1	Q4	no
						Data collection	WBT	Q1	Q4	no
						Create Water Balance	WBT	Q1	Q4	no
						Water Balance +/- 10 % Closed ?	WBT	Q1	Q4	no
						Refine Water Balance if not 90 %	WBT	Q1	Q4	no
						Identify Water conservation opportunities	WBT	Q1	Q4	no
						Open CAPAs	Mgr EHS	Q1	Q4	no
						Monitoring of water consumptions on monthly basic in OSD , Entacapone Regular checking and maintenance of flow meter for potable water with local suppling organization	Facility coordinator	Jan-23	Q4	no
		Air emission	Reduction of air emissions	Air emission reduction (VOC)	Improve results from air emission monitoring by reducing organic solvent consumption	Finding the best solution and choose technology without organic solvents in order to reduce VOC emissions	Whole team	Q1	2025	Yes
			Reduction of air emissions . Reduce Zdravlje`s absolute Scope 1 and 2 GHG emissions by **20% between 2024 and 2030** to support effort to limit the global temperature increase	Air emission reduction (VOC) and NOx and SO2 on Steam Boiler **Reduce Zdravlje`s absolute Scope 1 and 2 GHG emissions by 20% between 2024 and 2030** to support effort to limit the global temperature increase	Improve results from air emission monitoring by 1 % annually	**Gasification project Is on going . Letter of intention was signed**	Engineering Director and team	Feb-23	2025	Yes
		Waste water	Implementation of improvement plans related to waste water compliance	elimination atmospheric water contamination by grease or oil	Not NOV or fines	Installation of Oil Grease separator for atmospheric water	Facility coordinator	1/31/18	Q1 2025	Yes
		Energy saving	Energy saving plan and respecting SOP	Reduction of energy and natural resources consumption **Increase energy efficiency by 10% and increase the total proportion of energy purchased or generated from renewable sources to 20% between 2024 and 2030**	1% improvements in energy consumption comparing to previous year (Fuel oil and electrical energy) **20% reduction by 2030**	**Project for gasification- replacing Have Fuel Oil oil with natural gas .** **Solar panel project - to be started with company Resalta**	Engineering Director and team	Q1	Q2 2025	yes
						Energy saving manager - regular tracking of energy consumption and reporting to authority Locally tracking actions from energy saving audits .	Engineering Director/	Q1	Q4	no
		Waste reduction	Reduction of non hazardous and hazardous waste	Reduction waste **Increase the proportion of recycled and responsibly sourced materials by 10% between 2024 and 2030**	1 % recycled or responsibly sourced materials used in production process (by weight)	New characterization of waste and contract with PWW to dispose non hazardous waste (placebo, non hazardous raw material s...)	EHS manager /	January2020	continual project	no
		Waste management	Compliance with legal and requirements in waste management	Full compliance with legal and requirements in waste management	Without non compliances in waste handling	Upgrade Waste management Plan - according to new law once per three year New waste contract (hazardous waste)	Mgr EHS	Q2	Q4	No
	Continue to reduce environmental impact from use of products	Products End of Live	Continue to minimize waste generated from Zdravlje operations and minimize the environmental impact of its disposal Mitigate the environmental impact of pharmaceutical ingredients from "Zdravlje" operations	Increase % of recyclable packaging materials , Recycling of wooden pallets	**1% reduction in waste generated per units produced**	Reviewing possibilities for implementation recyclable packaging materials , Recycling of wooden pallets by returning from customer Continue to met national goals for recycling of packaging materials (by contractor Eko Star Pack)	EHS /Q/Production	Q1	2025	No
Stewardship	Minimize EHS impact of used APIs and chemicals	Chemical Management	Support chemical hazard communication improvement and standardization projects	Laboratory safety Plan - upgrade	No health events, illnesses or injuries caused by chemicals, APIs or environmental spillages	Preparation/updating of Laboratory Safety Plan (reviewing once per year)	Quality control manager	Q1	Q2	no
				Continue with implementation of GHS standard on local level		Continue with farther implementation of CLP labels for imported substances (Using new SDS/label)	Chemical advisor	Q1	Q1 - Q4	no
				Improvement of knowledge regarding management of chemicals		Training for all personnel from laboratories about update Laboratory safety plan and Laboratory Risk assessment (once per four year)	Quality control manager /EHS Manager	Q1	Q4	no
				Ensure IH information is available for all new APIs Reducing Health risks during the work with potent chemicals and new APIs		Regular updating of OEB list for APIs used in Zdravlje according to the new IH knowledge in order to protect employees from extremely exposure	Mgr EHS	Q1	Q1 - Q4	no
				Preparation and providing SDS for all APIs and products		Preparation SDSs for all APIs and Finished products	EHS	Q1	2025	
Culture	Continue to build EHS knowledge and capabilities of all facility personnel and integrate into their personal development plans, as appropriate. Ensure on-time completion of all regulatory and company required EHS training. Continue to support efforts to standardize the EHS experience. Share learnings from significant EHS events across Zdravlje		Continue to execute improvement initiatives linked to the site EHS culture maturity assessment	Improve EHS culture	No critical safety rules broken, No punishment for braking EHS rules	Safety committee meeting	HR managers/ all managers	Q1	Q1-Q4	no
						GEMBA walk once per month and monthly EHS inspections	GM and all managers	Q1	Q1-Q4	no
						Continue with program "One page lesson and Lesson Learned . Continue with local program Lesson Learned and weekly communication and discussion of EHS safety performances	EHS manager and all managers	Q1	Q1-Q4	no
						Support "good observation" program and EHS initiatives in this program	EHS manager /all managers	Q1	Q1-Q4	no
		Training	Continue to build EHS knowledge and capabilities of all facility personnel and ensure on-time completion of all regulatory and company-required EHS training	Increasing awareness and knowledge of employees regarding the topics connected with Environmental aspects and all H&S risks during performing activities, processes and services	100% EHS training attended by employees on time and 95% successfully pass exam	Regular annual H&S training and checking of knowledge for employees that perform High Risk Work activities;	Mgr EHS	Q1	Q1 - Q4	no
						Regular once per three year H&S training and checking of knowledge for all contractors on site	Mgr EHS	Q1	Q3	no
						Regular refresh trainings for all EHS related internal SOPs and all SOPs that are undergo on three years reviewing	All relevant managers	Q2	Q1-Q4	no
						Perform annual training for Labs people according to upgraded Laboratory Safety plan and according to RA (Once per four year)	QC manager/EHS manager	Q1	Q4	no
						Forklift training (three year) - for employees from Warehouses	Warehouse manager	Q1	Q4	no
			Share learnings from significant EHS events across "Zdravlje"	Actively participate in Lesson learned program in order to prevent repeating of similar incidents	No repeated /reoccurrence of similar incident on local level	Prepare Lesson learned slide in case of incident on site . Share Lessons from other sites with Zdravlje employees	Mgr EHS/EHS Associate	Q1	Q1 - Q4	no
Performance	Use Internal Scorecard to drive performance improvements	EHS scorecard	Ensure accurate and timely reporting of EHS information regarding Water consumption El. Energy consumption Heavy Fuel Oil consumption	Monitoring of EHS performances in order to reach out continual improvement at least 1% per year	100% reporting on time 100% meet all KPIs target	Regular monthly reporting EHS data	Mgr EHS/EHS Associate	Q1	Q1 - Q4	no
	Customer Health and Safety	Quality performance	Ensure products quality according to Q Policy	Continual development, manufacturing and sales of Zdravlje safe , efficient and quality pharmaceutical products	Without products recall	Performing all aspects of Zdravlje business on a foundation of quality, innovation and excellence so that the safety , efficiency and quality of our products improve the quality of health and life in the community	Whole team	Q1	continually	
	Identify and implement relevant site-level leading indicators of EHS performance **(OPERATIONAL OBJECTIVES)**	EHS Performance indicators	Establish local KPIs that support continuous improvement	Reduce TRIR comparing with previous year	TRIR 0,9	Conduct AOP Plan 2024 - especially in Risks Category Implement measures defined High Risks Standards and locally implemented by local SOP	Mgr EHS/EHS Associate	Q1	Q1 - Q4	no
				CAPAs closure according to scheduled timeline	80% CAPAs Closure on time	Monthly tracking all CAPAs Support responsible persons for closing CAPAs on time	Mgr EHS/EHS Associate	Q1	Q1 - Q4	no
				No PSE	PSER 0, 015	Implement all measures defined during ATEX compliance project . Usage of new vessels for solvent preparation Implementation all requirements from three Standards comprising the Process Safety Series	Mgr EHS/EHS Associate	Q1	Q1 - Q4	no
				Continue to improve safety culture and encourage employees to report Good Observations	1 GO per employees (Rate of GO at least 40)	Internal tracking of Good observations and related CAPAs Held monthly council with representatives responsible for closing actions from Gos. Regularly inform employees about GOs status.- by weekly reporting of performances or by EHS committee	Mgr EHS/EHS Associate	Q1	Q1 - Q4	no
				Improve closing GO actions	80 % closed Gos SIFp (10-20 % of all Gos)	Monthly Good Observations council with CAPAs responsible people in order to close GOs actions	Mgr EHS/EHS Associate	Q1	Q1 - Q4	no