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VPRAŠALNIK ZA OCENO ZUNANJEGA PONUDNIKA		
Veljavno od:	Veljavno do:	Šifra: VPR1-VOD-GEN-010
		Verzija: 02
		Število strani: 6
Izdelal: Tine Lavrič	Pregledal: Tina Žmuc	Odobril: Tine Lavrič

NAVODILO ZA IZPOLNJEVANJE VPRAŠALNIKA

- Izpolnite tiste strani vprašalnika, ki zadevajo objekt ocenjevanja.
- Če katero izmed poglavij ali točk standarda, ne zadeva presojeane organizacijske enote, na začetku poglavja ali točke označite ☐ X.
- Če določeno poglavje ni presojano, ga ne označujemo.
- V kolikor se proces izvaja ustrezno, pri posamezni točki vprašalnika označimo ☐ Da.
- V primeru neustreznega procesa pri posamezni točki vprašalnika označimo ☐ Ne.

INSTRUCTIONS FOR COMPLETING THE QUESTIONNAIRE

- The auditor shall complete those pages of a questionnaire, that relate to the object of the audit.
- Complete those pages of a questionnaire, that relate to the object of the assessment.
- If any of the sections or points are not applicable to organization or organization unit, the section or point should be checked ☐ X.
- If a particular section is not part of the assessment, it is not marked.
- If the process complies with the standard requirements, mark at each point of the standard ☐ Yes.
- If the process doesn't comply with the standard requirements, mark at each point of the standard ☐ No.

Komentarji / Comments

Datum / Date:	
Ocenjevalec / Assessor	
Podpis / Signature:	

VPRAŠALNIK ZA OCENO ZUNANJEGA PONUDNIKA	
	Šifra: VPR1-VOD-GEN-010
	Verzija: 02

Ime podjetja / Company Name	
Naslov / Facility Address	
Telefonska št. / Telephone No.	
Vrsta posla / Type of Business	
Področje storitve, ki jo podjetje opravlja ali bo nudilo / Scope of service the company provides or will provide.	

I. Povzetek dosedanjih presoj / Recent Regulatory Audit Summary	☐ X
1. Število presoj v zadnjih dveh letih (datumi, ime agencije). / Number of regulatory agency audits in the last two years (provide dates, agency).	
2. Datum zadnje presoje. / Date of last inspection.	

II. Organizacija in osebje / Organization and Personnel	☐ X
1. Priprnite organizacijsko shemo. / Please attach an organization chart.	☐ Yes ☐ No ☐ X
2. Ali je funkcija Oddelka za zagotavljanje kakovosti (QA) opisana v napisanih postopkih? Če da, priprnite postopek. / Is there a Quality Assurance (QA) function described in written procedures? If yes, attach procedure.	☐ Yes ☐ No ☐ X
3. Ali QA sprosti podatke o testiranju? / Does QA perform release of testing data?	☐ Yes ☐ No ☐ X
4. Število zaposlenih X tej lokaciji. / Number of employees at this site.	
5. Ali imajo vsi zaposleni CV-je in opise delovnih mest v svoji osebni mapi? / Do all employees have CV's and job descriptions on file?	☐ Yes ☐ No ☐ X
6. Ali je program izobraževanja napisan? / Is there a written training program?	☐ Yes ☐ No ☐ X
7. Ali se izvaja letno redno izobraževanje za vse zaposlene, ki delajo v GMP okolju? / Is there an annual compliance training for all employees working in a GMP environment?	☐ Yes ☐ No ☐ X
8. Ali je izobraževanje zaposlenih dokumentirano pred njihovo udeležbo v predpisanih aktivnostih? / Is training of employees documented prior to their participation in regulated activities?	☐ Yes ☐ No ☐ X
9. Ali obstaja dokument za osebno higieno zaposlenih? / Is there a policy on employee hygiene?	☐ Yes ☐ No ☐ X

VPRAŠALNIK ZA OCENO ZUNANJEGA PONUDNIKA	
	Šifra: VPRI-VOD-GEN-010
	Verzija: 02

10. Ali imajo svetovalci zadostno izobrazbo in izkušnje? / Do consultants have sufficient education, training and experience on the subjects for which they are retained?	☐ Yes ☐ No ☐ X
11. Ali imate v podjetju shranjene CVje in kvalifikacije svetovalcev? / Does your company have CVs and qualifications for consultants on file?	☐ Yes ☐ No ☐ X

III. Zgradbe in objekti / Buildings and Facilities	☐ X
1. Priprite tloris objekta. / Please provide a floor plan of the facility.	☐ Yes ☐ No ☐ X
2. Ali obstaja načrt v primeru katastrofe? / Is there a facility disaster plan?	☐ Yes ☐ No ☐ X
3. Ali so zgradbe in objekti, ki se uporabljajo za testiranje produkta primerne velikosti, konstrukcije in lokacije, da se lahko izvajajo primerni postopki, izvaja čiščenje in vzdrževanje? / Are the buildings and facilities used for testing product of appropriate size, construction and location to facilitate cleaning, maintenance and proper operations?	☐ Yes ☐ No ☐ X
4. Ali imajo te zgradbe dovolj primerne prostora za umestitev opreme in materialov tako, da ni možno pomešanje? / Do these buildings have adequate space for placement of equipment and materials to prevent mix-ups?	☐ Yes ☐ No ☐ X
5. So te zgradbe ohranjane v dobrem stanju? / Are these buildings maintained in a good state of repair?	☐ Yes ☐ No ☐ X
6. Ali obstajajo napisani postopki, kateri vključujejo postopek sanitacije in urnike, metode, opremo in materiale, ki bodo uporabljeni? / Are there written procedures for sanitation of the facilities that include schedules, methods, equipment and materials to be used?	☐ Yes ☐ No ☐ X
7. Ali obstaja ustrezna razsvetljava, odplakovalni sistem, sistem za odpadke, sanitarije? / Is there adequate lighting, sewage and refuse disposal, washing and toilet facilities?	☐ Yes ☐ No ☐ X
8. Ali obstaja načrt za zatiranje škodljivcev? / Is there an established Pest Control Program?	☐ Yes ☐ No ☐ X
9. Kakšna voda se uporablja v objektu? / What types of water are used within the facility?	_____
10. Ali je sistem prečiščene vode ali vode boljše kvalitete validiran? / Has the purified or better quality water system been validated?	☐ Yes ☐ No ☐ X
11. Je bil sistem plinov validiran? / Has the process gas system been validated?	☐ Yes ☐ No ☐ X
12. Je bil HVAC sistem validiran? / Has the HVAC system been validated?	☐ Yes ☐ No ☐ X
13. Ali ima objekt rezervno napajanje in če da, navedite sistem. / Does the facility have a backup power system? List systems that are on the backup power system?	☐ Yes ☐ No ☐ X _____
14. Ali obstajajo zaprte kontrole za zelo občutljive materiale? / Are there containment controls for highly sensitizing materials?	☐ Yes ☐ No ☐ X

IV. Oprema / Equipment	☐ X
1. Je vsa večja oprema primerno identificirana? / Are all major equipment and instruments appropriately identified?	☐ Yes ☐ No ☐ X

VPRAŠALNIK ZA OCENO ZUNANJEGA PONUDNIKAŠifra: **VPR1-VOD-GEN-010**Verzija: **02**

IV. Oprema / Equipment	☐ X
2. So vsi kritični deli opreme kvalificirani pred uporabo? / Are critical pieces of equipment qualified prior to use?	☐ Yes ☐ No ☐ X
3. Je oprema umerjena in vključena na koledar umerjanja? / Is equipment calibrated and included in a calibration schedule?	☐ Yes ☐ No ☐ X
4. So standardi za umerjanje v skladu s potrjenimi standardi? / Are calibration standards traceable to certified standards?	☐ Yes ☐ No ☐ X
5. Ali je oprema izdelana za preprečevanje kontaminacije proizvoda zaradi maziv, grelnih tekočin, sredstev za hlajenje in drugih snovi? / Is equipment designed to prevent contamination of product from lubricants, heating fluids, coolants or other substances?	☐ Yes ☐ No ☐ X
6. Ali obstajajo napisani postopki za opremo? Are there written procedures for equipment in place?	☐ Yes ☐ No ☐ X
7. Ali obstajajo napisani postopki za pregled opreme, kvalifikacije, umerjanje, čiščenje in preventivno vzdrževanje? / Are there written procedures for equipment inspection, qualification, calibration, cleaning and preventive maintenance?	☐ Yes ☐ No ☐ X

V. Materiali / Materials	☐ X
1. Ali obstaja napisan postopek za sprejem vhodnega materiala? / Is there written procedures for the acceptance of incoming materials?	☐ Yes ☐ No ☐ X
2. Ali so vhodni materiali ocenjeni s pregledom, testiranjem ali kako drugo metodo, preden se odobrijo in sprostijo? / Are incoming materials evaluated by inspection, testing or other verification activities prior to release?	☐ Yes ☐ No ☐ X
3. So vsi proizvajalci oziroma dobavitelji kvalificirani? / Are all your material manufacturer's or supplier's qualified?	☐ Yes ☐ No ☐ X
4. Ali imate določen prostor za karanteno materiala, sproščen material in zavrnjen material? / Are there designated storage areas for quarantine, release and reject materials?	☐ Yes ☐ No ☐ X
5. Ali so vzorci za hrambo vzeti s produkta in materialov, kot je primerno? / Are retention samples taken of the product and materials, as applicable?	☐ Yes ☐ No ☐ X

VI. Proizvodnja / Production	☐ X
1. Ali obstajajo pisni postopki za spremljanje in nadzor proizvodnih procesov, da se zagotovi skladnost izdelka s specifikacijami? / Are there written procedures for the control and monitoring of production processes to ensure that the product conforms to its specifications?	☐ Yes ☐ No ☐ X
2. Ali proizvodni zapisi zahtevajo dokumentacijo za posamezno uporabljeno opremo? / Do production records require documentation of specific major equipment used?	☐ Yes ☐ No ☐ X
3. Ali so kritični koraki, kot je dodatek materiala in inšpekcije neodvisno preverjeni še s strani druge osebe? / Are critical steps such as addition of materials and inspections independently verified by a second person?	☐ Yes ☐ No ☐ X
4. Ali so vsa proizvodna odstopanja zabeležena in ali so kritična odstopanja raziskana? / Are all production deviations reported and critical deviations investigated?	☐ Yes ☐ No ☐ X
5. Ali so vse spremembe pri procesu ali opremi zabeležene in odobrene s	☐ Yes ☐ No ☐ X

VPRAŠALNIK ZA OCENO ZUNANJEGA PONUDNIKA	
	Šifra: VPR1-VOD-GEN-010
	Verzija: 02

VI. Proizvodnja / Production	☐ X
strani enote, ki skrbi za kakovost? / Are changes to the process or equipment documented and approved by the Quality Unit?	

VII. Kontrolni laboratorij / Laboratory Controls	☐ X
1. Ali obstajajo napisane testne metode in ali so kvalificirane? / Are there written test methods and are they qualified, as applicable?	☐ Yes ☐ No ☐ X
2. Ali obstajajo napisani postopki in/ali protokoli, ki se nanašajo na laboratorijske postopke, vključujoč ravnanje z vzorci, ustvarjanje podatkov in kontrolo? / Are there written procedures and/or protocols that address laboratory operations, including sample handling, data generation and control?	☐ Yes ☐ No ☐ X
3. Ali obstaja postopek za oceno in ravnanje z rezultati izven specifikacij (OOS)? / Is there a process for evaluation and handling of Out-of Specification (OOS) results?	☐ Yes ☐ No ☐ X
4. Se z laboratorijsko opremo ravna tako, kot je to navedeno v poglavju IV. Oprema tega obrazca? / Is laboratory equipment handled per the Equipment section IV of this form?	☐ Yes ☐ No ☐ X
5. Ali so osnovni referenčni standardi pridobljeni od uradno prepoznavnega vira? / Are primary reference standards obtained from an officially recognized source?	☐ Yes ☐ No ☐ X
6. Ali obstaja pisni postopek za ravnanje in nadzor nad reagenti, mediji in pufri? / Is there a written procedure for handling and controlling reagents, media and buffers?	☐ Yes ☐ No ☐ X
7. Če so osnovni standardi pripravljeni v vašem laboratoriju, ali so ustrezno kvalificirani? / If an in-house primary standard is used, has appropriate testing been performed to qualify such standard?	☐ Yes ☐ No ☐ X

VIII. Sistem kakovosti / Quality Systems	☐ X
1. Ali so postopki za upravljanje in hranjenje dokumentov napisani? Have written procedures for records management and retention been generated?	☐ Yes ☐ No ☐ X
2. Ali so vsi dokumenti, povezani s GMP, shranjeni v arhivski sobi in varnostne kopije narejene? / Are all retained GMP records filed in archive storage and backed-up?	☐ Yes ☐ No ☐ X
3. Je dostop do dokumentov kontroliran? / Is access to documents controlled?	☐ Yes ☐ No ☐ X
4. Ali se dokumenti redno pregledujejo in posodablajo v skladu s pisnim postopkom? / Are documents periodically reviewed and updated according to written procedure?	☐ Yes ☐ No ☐ X
5. So bili računalniški sistemi, ki se nanašajo na GMP, validirani? / Have GMP-related computerized systems been validated?	☐ Yes ☐ No ☐ X
6. So notranje presoje izvedene tako, da so izpolnjene tako zakonske kot tudi zahteve podjetja? / Are internal audits conducted to assure that regulatory and company requirements are met?	☐ Yes ☐ No ☐ X
7. Je naročnik obveščen o pregledih regulatornih agencijah na pogodbenem objektu, ki lahko vplivajo na izdelke stranke? / Is the customer notified of regulatory agency inspections at the contract facility where it impacts the	☐ Yes ☐ No ☐ X

VPRAŠALNIK ZA OCENO ZUNANJEGA PONUDNIKA	
	Šifra: VPR1-VOD-GEN-010
	Verzija: 02

VIII. Sistem kakovosti / Quality Systems	☐ X
customer's products?	
8. Ali imate Pogodbenega Serviserje/Dobavitelje ali program zunanjih presoj? / Is there an established Contract Service Provider or external audit program?	☐ Yes ☐ No ☐ X
9. Ali obstajajo napisani postopki o sprejemu, pregledu in oceni pritožb (ne glede na to, ali je pritožba ustna, elektronska ali pisna)? / Are there procedures in place describing the process for receipt, review and evaluation of complaints (whether oral, electronic or written)?	☐ Yes ☐ No ☐ X
10. Ali obstajajo postopki za nadzor nad spremembami vseh vrst dokumentov? / Are there procedures to control the change to all document types?	☐ Yes ☐ No ☐ X
11. Ali program za nadzor sprememb vključuje spremembe procesov, opreme in programov? / Does the change control program include process, equipment and software changes?	☐ Yes ☐ No ☐ X
12. Ali oddelek za zagotavljanje kakovosti odobri vse spremembe dokumentov, opreme, materialov in objektov? / Does the quality unit approve all changes to documents, equipment, product, materials and facilities, as applicable?	☐ Yes ☐ No ☐ X
13. Ali obstajajo napisani postopki za upravljanje korektivnih in preventivnih ukrepov? / Are there written procedures for the management of corrective and preventive actions?	☐ Yes ☐ No ☐ X
14. Ali obstajajo napisani postopki za upravljanje odstopanj, raziskav? / Are there written procedures for the management of deviations and investigations?	☐ Yes ☐ No ☐ X
15. Ali obstaja postopek, ki opisuje odpoklic aktivnosti? / Is there a procedure that describes product recall activities?	☐ Yes ☐ No ☐ X

IX. Pošiljanje produkta in distribucija / Product Shipping and Distribution	☐ X
1. Ali obstajajo napisani postopki za pošiljanje produktov za distribucijo? / Are there written procedures on the shipping of product for distribution?	☐ Yes ☐ No ☐ X
2. Ali so produkti primerno shranjeni v pošiljki? / Are products shipped per appropriate storage conditions?	☐ Yes ☐ No ☐ X
3. Ali se da pošiljkam slediti? / Are product shipments tracked to ensure traceability of product?	☐ Yes ☐ No ☐ X