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Vendor Sustainability Due Diligence and Risk Management

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SCOPE

This Standard Operating Procedure (SOP) supports Camurus' vendor sustainability due diligence and risk management framework and provides guidance on managing sustainability risks within Camurus' supply chain. This SOP should be read in conjunction with Camurus' Vendor Code of Conduct (3), Anti-Corruption Policy (4), Code of Conduct (5) and procedures listed in section 10.

This SOP applies to all vendors in R&D (including non-clinical and clinical research) and commercial production (including vendors of constituent components) as well as transport and distribution vendors from whom Camurus procures products or services to a value of more than SEK 500,000 total contract value per annum.

Procedures for engaging vendors and Third-Party Intermediaries (TP Intermediaries), compliantly under GxP frameworks and anti-corruption, and compliance risk management of TP intermediaries are not in the scope of this SOP, and are covered in the following SOPs:

- Vendor management (6)
- Clinical Outsourcing (7)
- Supplier and Customer Qualifications for marketed products (8)
- Anti-Corruption & Compliance Risk Management of TP Intermediaries. (9)

Where there are national or international laws, regulations or codes of practice and other approved internal policies and procedures, the strictest provisions always apply.

FLOWCHART

Process for vendor sustainability due diligence and risk management:

Vendor engagement form initiation for in scope vendors (by Engagement Owner)

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Registration in digital vendor sustainability management platform (by Director Sustainability)

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Initial risk rating based on basic company information (by platform)

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Vendor sustainability due diligence and risk assessment. Send standard questionnaires¹ through platform (by Sustainability Department)

Due diligence and risk assessment outcome

Recommendation to Engagement Owner (by Director Sustainability)

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Contracting and if applicable, qualification (by Engagement Owner in collaboration with Legal Counsel)

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Monitoring and follow up actions (by Director Sustainability)

 $^{^1}$ *Human rights and labor standards, anti-corruption, business ethics & leadership, and environmental questionnaires



ROLES AND RESPONSIBILITIES

Role	Responsibility and Obligations
Engagement Owner (or contract owner)	 Initiating the procurement of goods or services based on a legitimate business need and aligned with Camurus' strategic objectives, and for vendors thereby request vendor sustainability due diligence and risk assessment from Director Sustainability Working with Legal Counsel and other stakeholders to negotiate and agree a contract with vendors when applicable, by considering any recommendations for risk mitigation, as a result of the vendor sustainability due diligence and risk assessment Supporting Director Sustainability in performing vendor sustainability due diligence and risk management Working with key stakeholders when there is a need to renew or terminate the relationship with a vendor Ensures to address any requirements to perform GxP and/or anticorruption and compliance risk management of TP Intermediaries if applicable in accordance with the relevant Camurus' policies and procedures
Line Manager	Designating the relevant Engagement Owner from his/her/their team or function through appropriate delegation or may otherwise self-perform the role as an Engagement Owner
Legal Counsel	 Supporting due diligence and risk assessment Ensuring that Camurus agreements and contract templates include necessary safeguard clauses to mitigate sustainability risks Supporting negotiations e.g., on contractual terms with vendors Supporting compliance monitoring
Director Sustainability	 Collaborating with Compliance Officer/Global Head of Compliance concerning vendor categorization and necessary due diligence and risk assessments including monitoring and follow up actions Performing vendor sustainability due diligence and risk management Supporting sustainability related discussions Collaborating with Legal Counsel and Compliance Officer/Global Head of Compliance to consider the necessary clauses to be included in the contract to mitigate the sustainability risk(s) identified Ensuring that monitoring activities and follow up is performed on a periodic basis Reporting vendor sustainability due diligence and risk management outcome to Camurus' Executive Management Team and Board
Sustainability Department	Perform risk rating and monitoring of vendors



Role	Responsibility and Obligations
Compliance Officer (CO)/Global Head of Compliance	Collaborating with Director Sustainability concerning necessary due diligence and risk assessments including monitoring and follow up actions.

PROCEDURE

Identification and planning

- 1. Engagement Owner initiates the procurement for new products/services when there is a legitimate business need.
- 2. Engagement Owner fills in the Vendor Engagement Form (TEM-0276), available in Word: File/New/Sustainability and sends the request to Director Sustainability

Vendor sustainability due diligence and risk assessment

Based on a request from Engagement Owner, Director Sustainability starts vendor sustainability due diligence and risk assessment process. The purpose of vendor sustainability due diligence and risk assessment is to assess, monitor and follow up vendors' compliance with the Camurus' vendor code of conduct (4).

The following types of sustainability risks are to be considered in Camurus' vendor sustainability due diligence and risk assessment:

- Human rights abuses
- Labor rights abuses including risk for modern slavery and child labor
- Poor and dangerous work environment
- Corruption
- Adverse environmental impact
- Lack of sustainability governance

Vendor sustainability due diligence and risk assessments must be conducted in Camurus' digital vendor sustainability management platform and carried out as following:

Level 1 - Brief initial risk rating: Vendors are automatically risk rated at a basic level (regarding the sustainability topics human rights, anti-corruption, and water use).

Level 2 - Vendor sustainability due diligence and risk assessment: The digital vendor sustainability management platform provides a range of due diligence questionnaires within the field of sustainability. Key questionnaires regarding human rights and labor standards, anti-corruption, business ethics & leadership, and environmental must be sent to all vendors.

Based on vendors' answers to the questionnaires, the Sustainability Department carries out a second extended risk rating in the digital vendor sustainability management platform. Vendors are categorized according to 4 risk levels (low, medium, high and extreme risk).

Director Sustainability gives a recommendation to Engagement Owner based on the due diligence and risk assessment results. If the vendor is classified as a high or extreme risk vendor from a sustainability point of view the recommendation must include risk mitigating measures (such as continued dialogue, periodic performance monitoring meetings, on-site compliance visits, desk top



audits, remediation or joint development projects like training etc.) or in the worst case a requirement to refrain from contracting. Any risk mitigating measures will be implemented by the Sustainability Department in collaboration with the vendor. If needed Director Sustainability can request support from Engagement owner or CO/Global Head of Compliance.

The due diligence and risk management process described above must follow Table 1 below.

Table 1:

Due diligence and risk management options (including monitoring options)	High and extreme risk	Medium risk	Low risk	Responsibility
Providing Camurus' "Vendor Code of Conduct" or verifying that the vendor's own Code of Conduct is compliant with Camurus' Code of Conduct.	Required	Required	Required	Director Sustainability
Sending standard due diligence questionnaires within the digital vendor sustainability management platform	Required	Required	Required	Director Sustainability
Refreshing standard due diligence questionnaires to confirm status and improvements	Required - annually and before renewal of contract	Required - every three years and before renewal	Required - every four years and before renewal	Director Sustainability
Attending periodic performance monitoring meetings between Camurus and vendor	Required - annually	Recommended	NA	Director Sustainability
Desk top audits and/or on-site visits	Recommended (at least once in the first three years of the relationship)	NA	NA	Director Sustainability
Joint development projects e.g., training etc.	Recommended	NA	NA	Director Sustainability

Key:

- Required It is mandatory to perform this due diligence and risk management option
- Recommended It is recommended to perform this due diligence and risk management. Optout will be decided by Director Sustainability
- Optional This due diligence and risk management option is optional
- NA This risk management option is not applicable

Contracting

- Unless any severe lack of sustainability performance resulting in refraining from contracting,
 Engagement Owner, after dialogue with Director Sustainability, works with Legal Counsel to
 agree on a contract with the vendor by considering required risk mitigating measures resulting
 from the due diligence and risk assessment
- Engagement Owner will negotiate contract terms with the vendor, with support from CO/Global Head of Compliance, Director Sustainability, and Legal Counsel as applicable
- Whichever form of contract is selected, Legal Counsel reviews the final draft to ensure appropriate contractual clauses and amendments are included. Legal Counsel will consider the outcome of vendor sustainability due diligence and risk management to understand the level of risk as well as the vendor's ability to mitigate risks



Monitoring and management

- Director Sustainability is responsible for monitoring and management of the vendor's sustainability performance according to Table 1 in section 4.2. If needed, Director Sustainability can request support from Engagement Owner or CO/Global Head of Compliance
- At times, Engagement Owner may decide to terminate the contract prematurely due to e.g., poor performance. Engagement Owner should discuss the transition process and any potential risks the transition could cause with applicable functions, including Director Sustainability and CO/Global Head of Compliance
- If Engagement Owner recommends to renew/continue activities with an existing vendor at the
 time of contract expiry, Director Sustainability must review the latest risk rating and the
 outcome of monitoring to confirm existing compliance with Camurus' Vendor Code of Conduct
 and if necessary, refresh the vendor sustainability due diligence and risk assessment before
 renegotiating and renewing the contract

ABBREVIATIONS AND DEFINITIONS

For Camurus global definitions, see INS-0358 (11).

CAM	Camurus
СО	Compliance Officer
GxP	"Good x Practice", see definition in INS-0358 (11).
Healthcare stakeholder	See definition in INS-0358 (11).
Public Official (or Governmental Official)	See definition in INS-0358 (11).
SOP	Standard Operating Procedure
Third Party Intermediary ("TP Intermediary")	Any external party, whether an individual or an entity which is appointed by Camurus to represent Camurus in a particular matter and to whom Camurus provides money, goods or other assets. A TP Intermediary includes any external party, who interacts with healthcare stakeholders or Public Officials on Camurus behalf, including re-selling Camurus products to the relevant end-customer (e.g. to a pharmacy, hospital, clinic, healthcare region or healthcare organization).
R&D	Research and Development

REFERENCES

- 3. Camurus Vendor Code of Conduct
- 4. GUI-0022 Anti-Corruption Policy
- 5. GUI-0016 Code of Conduct
- 6. SOP-0049 Vendor management
- 7. SOP-0018 Clinical Outsourcing
- 8. SOP-0111 Supplier and Customer Qualifications for marketed products
- 9. SOP-0150 Anti-Corruption and Compliance Risk Management of Third Party Intermediaries
- 10. INS-0079 Quality Manual Pharma Legislation and Guidelines
- 11. INS-0358 Camurus global definitions