Answering sheet

Environmental Criteria for pharmaceuticals

Please specify if the answers cover the strategy in general or if it's tender product specific:

_____

1. **Are you able and willing on request, to provide information about the API-manufacturing sites for the tender specific products?**

   YES NO

2. Does the company have an environmental risk management strategy in place to minimize environmental impact of manufacturing discharges of APIs?
   YES NO

3. Does the strategy applies to the company's own facilities,
   YES NO N/A

4. to third-party manufacturers of APIs and drug products,
   YES NO N/A

5. and to waste water treatment plants (on-site or off-site) used by the manufacturing plants?
   YES NO

6. Does the environmental risk management strategy includes, where relevant, monitoring or mass balance calculations of discharges (or other equivalent methodologies to estimate discharge levels), and corresponding environmental risk assessments
   YES NO

7. and environmental auditing operations at the manufacturing sites?
   YES NO

8. Please describe your environmental procedures/routines that form the basis for the environmental risk management strategy.

9. Please describe the scope of the strategy (applicability to type of products/substances, geographies/locations, number of steps backwards in the supply chain etc.).

10. If you conduct audits at the manufacturing sites, please describe how environmental auditing is being performed (frequency, internal / external resources, scope, reasons for performing audits etc.).

11. Please describe the consequences of the environmental risk assessments, i.e. examples of actions undertaken when risks have been identified.

Second level (B2): Follow-up/control of supplier during the contract phase

Follow-up/control of contracted suppliers is being based upon the level of requirements and criteria asked in the tender, procurement body's own risk assessments, spot-checks and/or indications that a supplier does not act in compliance to the documents shared during the tender phase.

The company shall then be able to show the following documents, within XX weeks of the request, either during a physical meeting (a "desk-top follow-up") or via submitted documents, depending on which level of evaluation above the company met.

Third level (B3): Audit to verify second level follow-up

An audit may be performed to verify documentation provided in the second phase.