**SASAI – Shared Audit and Supplier Assessment Initiative**

Version 1.5 (Mar 2021) ©EARL

|  |  |  |  |
| --- | --- | --- | --- |
| Legal entity in English: |  | | |
| Department name in English: |  | | |
| Legal entity full address / department (if different from the institution): | Street name and number, City, Post code, Country | | |
| Invoice address (if different from institution/department): | Street name and number, City, Post code, Country | | |
| Legal entity city of registration and registration number: | [city of commercial court registry] no.[registration number] | | |
| VAT Number: |  | | |
| Legally authorized person to sign contract for the audit report(s) purchasing (name / email / telephone): | Full name  email  telephone  Position/Title | | |
| Primary contact for the audit report purchasing (name / email / telephone): | Full name  email  telephone  Position/Title | | |
| Invoice contact person (name / email / telephone): | Full name  email  telephone  Position/Title | | |
| Select the SASAI audit reports you would like to purchase.  **Note**: cost is net in Euros and without VAT included. The Austrian VAT is 20%, and it has to be paid by all non-EU entities, all EU non-entrepreneur entities and all Austrian entities. | **Supplier: ABX**  Please note that ABX reviews all audit report orders and approves only those that have been previously purchased from ABX. | | |
| €700.00 |  | ABX\_General\_GMP\_Part purchased alone |
| €999.00 |  | ABX\_General\_GMP\_Part and all of the individual product reports noted below purchased all together |
| €600.00 |  | ABX\_General\_GMP\_Part and any one of the individual product reports noted below purchased together |
| Individual ABX product reports: | | |
| €75.00 |  | ABX\_Mannose\_Triflate\_Bulk\* |
| €75.00 |  | ABX\_Hardware\_Kit\_for\_the GE TRACERlab® MX Synthesizer for [18F]F-PSMA\* |
| €50.00 |  | ABX\_Reagent-Hardware\_Kit\_for\_[68Ga]Ga-PSMA-11\* |
| €100.00 |  | ABX\_Precursor for [68Ga]Ga-PSMA-11 |
| €50.00 |  | ABX\_Sterile\_closed\_glass\_vials |
| €75.00 |  | ABX\_Precursor\_for\_FET |
| Total (net): | €Sum the total cost and include it here | | |
| Signature of the legally authorized person to sign an agreement for the audit report(s) purchasing: |  | | |
| List companies and their products you would be interested to be audited by SASAI in the future: |  | | |

*\*Descriptions for individual product reports to be found on page 2*

Precursor for 2-[18F]FDG (Mannose Triflate bulk)

“The Mannose Triflate bulk was audited at the example of batch TATM-180917233-1 (pharmaceutical grade quality). Production flow starting from raw material handling via intermediates through to final dispatch has been reviewed. Quality control of raw materials and finished products was included in the review as well. Stability testing has also been reviewed.”

Hardware kit for [18F]F-PSMA

“The Hardware kit for [18F]F-PSMA was audited at the example for the GE TRACERlab® MX Synthesizer. Production flow starting from raw material handling through to final dispatch has been reviewed. Quality control of raw materials and finished products was included in the review as well.”

Reagent/Hardware kit for [68Ga]Ga-PSMA-11

“The Reagent/Hardware kit for [68Ga]Ga-PSMA-11 was audited at the example for the Scintomics GRP Synthesizer. Production flow starting from raw material handling through to final dispatch has been reviewed. Quality control of raw materials and finished products was included in the review as well.”

Precursor for [68Ga]Ga-PSMA-11

“The precursor for [68Ga]Ga-PSMA-11 was audited at the example of batch PSMA-06-19011501. Production flow starting from raw material handling via intermediates through to final dispatch has been reviewed. Quality control of raw materials and finished products was included in the review as well. Stability testing has also been reviewed.”

Sterile closed glass vials

“The sterile closed glass vials were audited at the example of batch EV-190527001-01. Production flow starting from raw material handling through to final dispatch has been reviewed. Quality control of raw materials and finished products was included in the review as well.”

Precursor for [18F]FET

“The precursor for [18F]FET (TET = L-tyrosine) was audited at the example of batch TET-190513702. Production flow starting from raw material handling via intermediates through to final dispatch has been reviewed. Quality control of raw materials and finished products was included in the review as well.”