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| **Chemicals (and Consumables)** |
| Page | <https://arna.cpplgmp.com/#/master/chemical> |
| Reference Documents | SOP-203-11 Quality Control Laboratory Inward Good System ProcedureFM-196-29 Approved QC Chemical and Consumable ListELB-054 QC Laboratory Goods Inwards RegisterELB-098 QC Laboratory Chemical LogELB-069 Reagent Preparation LogSOP-087-19 General Laboratory Procedure |
| Chemical Master Comments/Requirements | \*\*Please confirm if the “Chemical Master” will be the equivalent to our current “List of Approved Chemicals” as currently documented in Section 1 of FM-186.\*\*The Chemical Master will need the following fields for entry of a new chemical:* Chemical Name
* Supplier (or Vendor if this is more consistent terminology)
* Manufacturer
* Size, with units (multiple sizes should be able to be entered)
* Product Code (multiple product codes should be able to be entered for different product sizes)
* Comments
* File upload for SDS (**S**afety **D**ata **S**heet, not mandatory)
* Grade and CAS No. are okay to have but should not be mandatory to enter
* Approval History (i.e. for a new chemical this may include approved after shown suitable during method validation)
* Entered by
* Approval Status (Approved, Approved for Development Use, Not Approved) (restricted to QC Supervisor or delegate)
* Approved by (restricted to QC Supervisor or delegate)

\*\*Note that a particular chemical may have more than one approved supplier and software will need to accommodate this.\*\*The approval of the chemical may be better as a separate workflow. I.e. an analyst enters the chemical details and then a task is forwarded to the QC Supervisor or delegate for approval.The Chemical Master needs to have an option to update / discontinue a particular chemical approval (i.e. for situations where product code changes). The reason for the update will need to recorded in the “Approval History” and re-approved by the QC Supervisor.  |
| Consumables Master Requirements | A “Consumables Master” will need to be created as the equivalent to our current “List of Approved General Consumables” as detailed in Section 2 of FM-186. This could also include consumables for inhalation, instrumentation and environmental monitoring as detailed in Sections 3, 4 and 5 with a drop down for “Consumable Type”.The Consumables Master will need the following fields for entry of a new consumable:* Product Name
* Supplier (or Vendor if this is more consistent terminology)
* Manufacturer (non-mandatory field)
* Pack size (with units, e.g. each, per carton, (set of))
* Product Code
* Related Equipment (non-mandatory field)
* Comments
* Approval History (i.e. for a new chemical this may include approved after shown suitable during method validation)
* Entered by
* Approval Status (Approved, Approved for Development Use, Not Approved) (restricted to QC Supervisor or delegate)
* Approved by (restricted to QC Supervisor or delegate)

\*\*Note that consumables may have more than one approved supplier and software will need to accommodate this.\*\*The approval of the consumable may be better as a separate workflow. I.e. an analyst enters the consumable details and then a task is forwarded to the QC Supervisor or delegate for approval.The Consumables Master needs to have an option to update / discontinue a particular consumable approval (i.e. for situations where product code changes). The reason for the update will need to recorded in the “Approval History” and re-approved by the QC Supervisor. |
| Chemicals and Consumables Stock Management | <https://arna.cpplgmp.com/#/qc/chemical/stock>When a Master for a Chemical or Consumable is created, is there a task/action to set a minimum stock level or re-order interval which would trigger an action to order or re-order the item? |
| Chemicals and Consumables Receipt | <https://arna.cpplgmp.com/#/qc/chemical>Receipt of chemicals and consumables from the delivery courier is performed by warehouse staff in accordance with routine procedures for receipt of goods. After chemicals and consumables are received and accepted in good condition, laboratory staff are advised and stock is moved to laboratory quarantine or solvent store quarantine. Laboratory staff then check items match the approved chemicals and consumables log and approve/label items for use.\*\*We don’t routinely weigh incoming chemicals. We rely on the manufacturer’s labelled quantity. “Weighing of Chemicals” is not required.\*\*<https://arna.cpplgmp.com/#/qc/chemical/receiving>For Receipt of Chemicals/Consumables into the QC Laboratory we need the following fields:* Supplier (or Vendor)
* Purchase Order Number
* Chemical/Consumable Name
* (Chemical/Consumable Number)
* Supplier Item Code (or Part Number)
* Date Received
* Amount received (with units e.g. items, L, g, kg etc)
* Condition acceptable?
* Approved for Use?
* Batch Number (mandatory for chemicals, but non-mandatory for consumables/parts)
* Expiry (mandatory for chemicals, but non-mandatory for consumables/parts)
* Upload of CofA (non-mandatory)
* Date Labelled?

If an item is received and is not approved for use, the supplier would need to be contacted and the item returned or destroyed depending on the supplier’s instructions. This should be handled by the purchasing department. Is there a workflow for rejected items already as part of the warehouse module?  |
| General Comment | Is there functionality for staff to request and item to be ordered? i.e. if they use the last of an item or if some additional testing is planned. Where possible, we like to group items to be ordered from a particular supplier to reduce delivery costs so we currently have a log for requests for items to be purchased. |