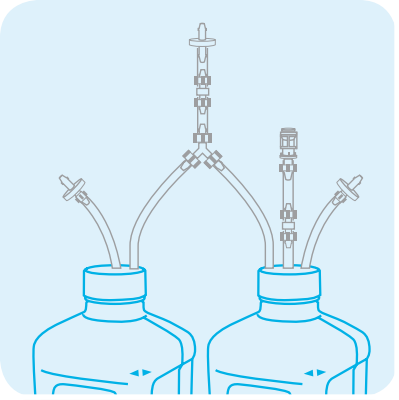
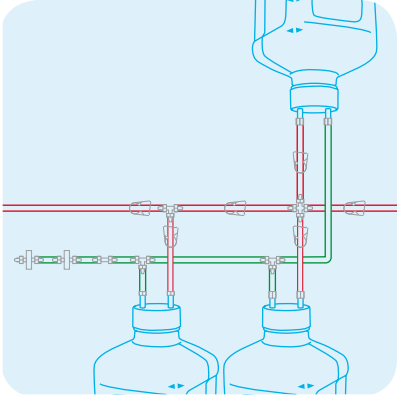
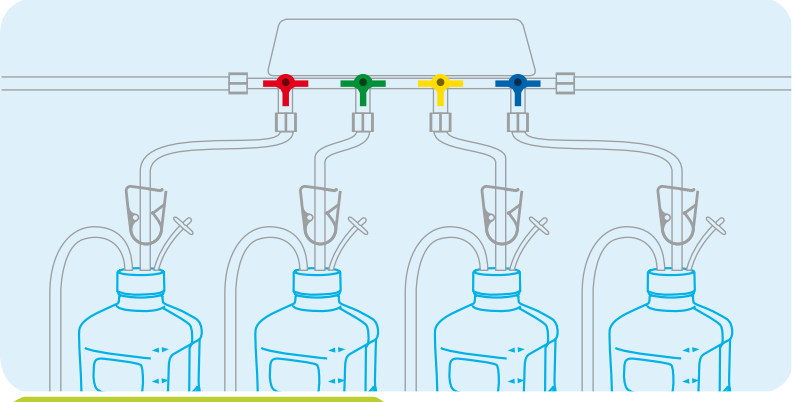
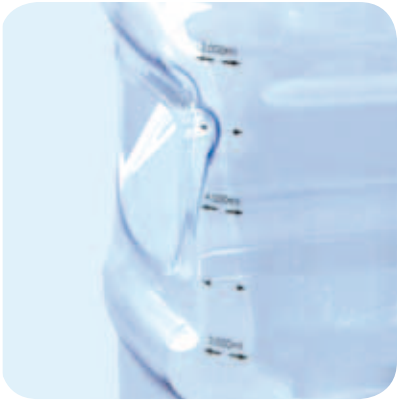




OCTOPUS
ASSEMBLIES





Turnkey solutions for your process requirements

Octopus Assemblies are custom designed assemblies manufactured to meet your specific requirements in a three stage process.

DISPOSABLE BIOREACTORS

SAMPLING ASSEMBLIES

SAMPLING MANIFOLDS

ADDITION ASSEMBLIES

FILLING BELL ASSEMBLIES

BIOREACTOR KITS

CHROMATOGRAPHY SKID KITS

TUBING ASSEMBLIES

GL 45 CAP ASSEMBLIES

83MM CAP ASSEMBLIES

FRACTIONATION RIGS

2-4 PORT BOTTLE / CARBOY ASSEMBLIES

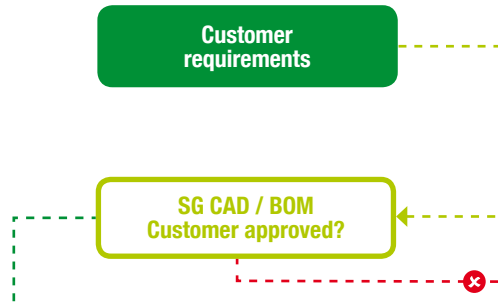
SPECIFICATION & DESIGN

The design phase to develop a new Octopus assembly is operated under an ISO 9001:2008 quality system. This is a fully interactive process between you and Cellon. During this phase the assembly is designed, the materials selected and the in process testing requirements and post assembly processing requirements are determined.

You are supplied with detailed diagrams and bills of materials (CAD/BOMs) as prototype (PR) versions for project review/approval. All changes are recorded and samples can be made available for testing. Following evaluation, the CAD can be further modified. Once the PR CAD is accepted /approved the PR CAD is converted to a "SG" (Specified graphic diagram) CAD issue 1. Once the SG CAD is issued, the design is locked and future changes can only be made via our documented change control procedure. Changes documented through this process are recorded and indicated by an increase in the issue number of the CAD.

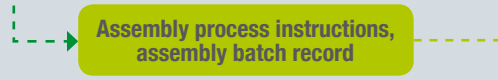
PHASE 1 |

SPECIFICATION & DESIGN



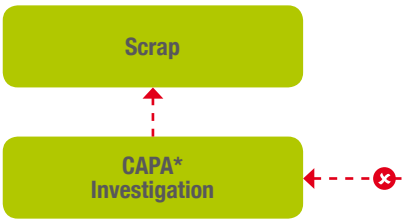
PHASE 2 |

MANUFACTURE



PHASE 3 |

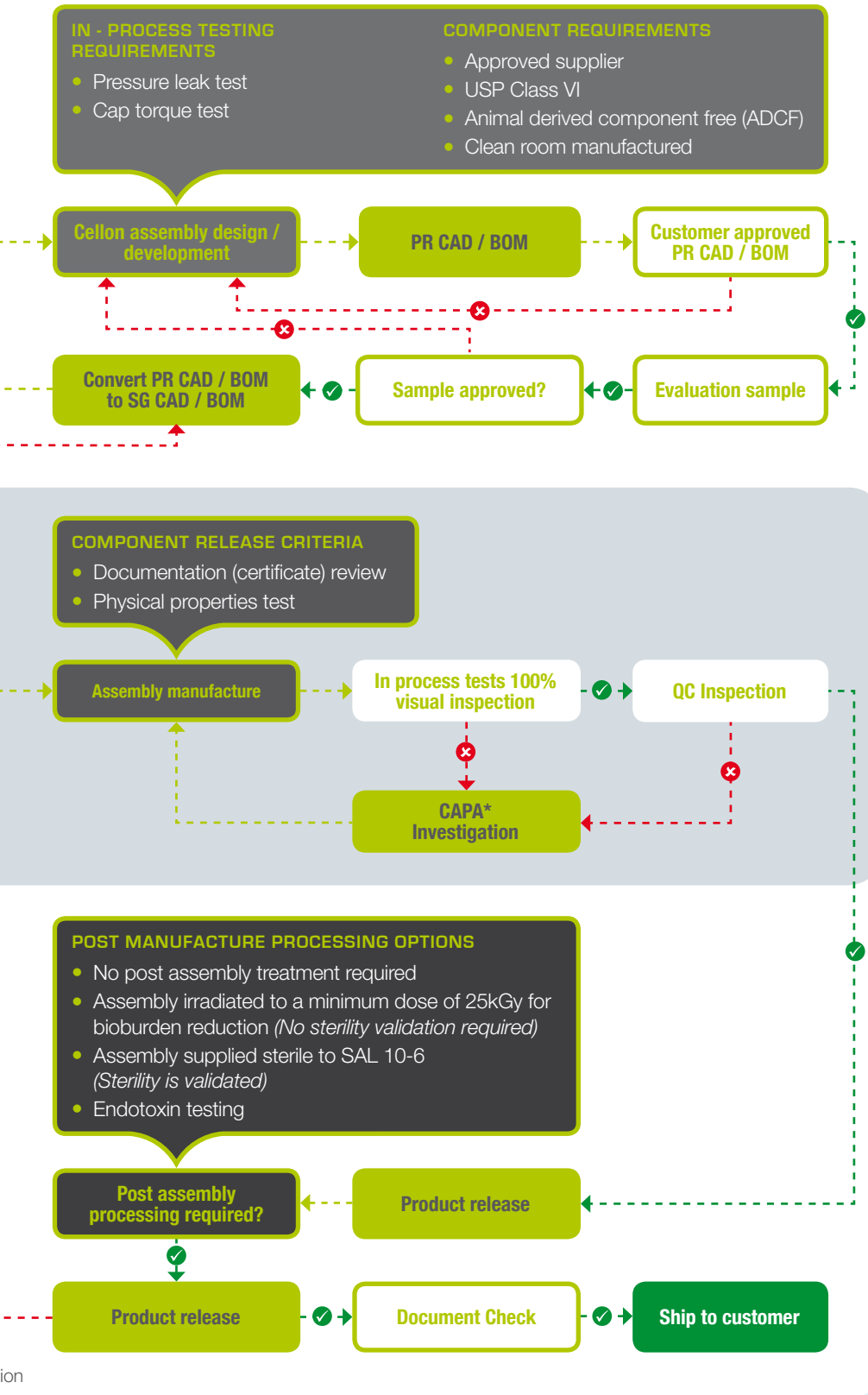
POST MANUFACTURE PROCESSING



* CAPA: Corrective action / Preventative act

POST MANUFACTURE PROCESSING

You determine the level and type of post manufacture processing carried out on each specific assembly, based on the intended use of the assembly within your facility. Cellon subcontracts post manufacture processing to approved independent service providers depending on what processing is required.



MANUFACTURE

Manufacture of Octopus assemblies, and final packaging, is carried out within an ISO 14644-1 Class 7 cleanroom facility operated under ISO 9001:2008 and ISO 13485:2003 quality systems

ASSEMBLY PROCESS

Assembly process instructions (APIs) are produced from SG CAD specifications approved by you. In addition to the API, an assembly batch record (ABR) is produced which details the specific test requirements for the assembly.

The ABR is also used to record the batch details of all components used in the assembly and to record any test result data. All documents are controlled via a controlled documents procedure.

Approved component parts are counted into the clean room in the number required and the assemblies are built according to the API. Each assembly is visually checked by a second clean room technician and tested as defined in the API and ABR. Quality control personnel perform additional visual inspection on a specified number of assemblies before releasing the batch to final packaging. The completed ABR and all associated documents are then combined to form a "job pack" which is submitted to the quality department for review. Only after QC approval of the job pack is the product released.

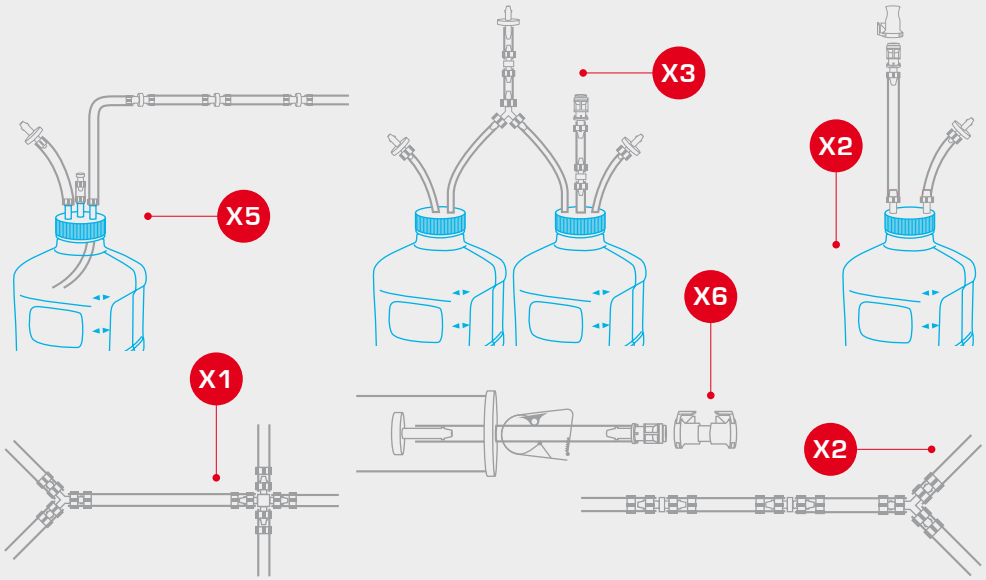
DOCUMENT CONTROL

The document control system ensures only current documents are used for reference, traceability and recording of test results during manufacture. Document changes are controlled via a change control system which requires your approval before any change can be implemented. Obsolete documents are stored electronically allowing easy retrieval in the event of a customer requesting an "obsolete" part or any information relating to that part.

BIOREACTOR & CHROMATO-GRAPHY KITS

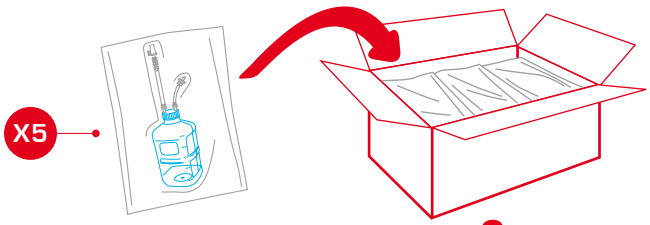
BIOREACTOR OR FERMENTER

ALL THE ASSEMBLIES YOU NEED FOR ONE BIOREACTOR RUN



Individually wrapped and ready to use in one kit box

ONE BIOREACTOR - ONE RUN = ONE BIOREACTOR KIT



Supplied ready to use

SAVE TIME & MONEY

CELLON

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