

ShareBiotech TCF Quality Assessment

This questionnaire is a tool for the self assessment of quality management of a Technology Core Facility (TCF).

It should be noted that this questionnaire is not compliant with ISO 9001 certification even if a lot of items were inspired by it.

Domains of expertise TCF:

Year of creation of the TCF:

Staff running the TCF (FTE¹):

Status: Public sector Private sector

Location (country):

Date of form completion:

Optional items:

Name of the facility:

Name and position of the person who completes the sheet:

For each item, please choose: yes, no, in progress or NA (not applicable).

TCF management				
The facility has developed an organizational chart of the facility staff (identifying roles and responsibility)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
The facility has a management committee	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Management/staff/scientific meetings are regularly organized	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Minutes of meetings are recorded and shared internally	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
The facility has a training plan/strategy for staff	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Specific knowledge and know how is formalized in written documents and shared	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Quality management is considered important and is monitored by dedicated staff (the TCF may not have quality certification or the intention to obtain it)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Knowledge of the facility full-costs	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA

¹ Full Time Equivalent

Management of equipment				
Main items of equipment are listed (with the corresponding responsible person defined)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Regular maintenance of equipment is carried out	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Management of consumables is ensured	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Metrology/calibration of equipment is ensured ²	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Protocols and Standard Operating Procedures are documented and implemented	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Tracking and documentation of problems and solutions	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Implementation of solutions	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Responsibility in case of a problem and liability for damage is known by internal and external users (e.g. if a piece of equipment is broken)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Management of samples (for internal and external projects/services)				
Identification and traceability is ensured	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Workflow for sample analysis exists	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Implementation of Material Transfer Agreement ³	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Management of projects/services with <u>external</u> users/clients				
Written commitment of parties (contract for example)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Written terms and conditions for services	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Compliance with written commitments/terms and conditions (e.g. time for delivery)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Rapid communication of problems to client/user and proposal of corrective measures	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
External users/clients can easily access project progress	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Existence and shared use of a project management software (possibly accessible to client/user, but not necessarily)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
On-line reservation and/or tracking	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Formal agreement of TCF acknowledgement by the client/user	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Guarantee of confidentiality	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA

² Pieces of equipment are regularly checked to ensure accuracy and reliability of measurement.

³ A Material Transfer Agreement is a contract that governs the transfer of tangible research materials between two organisations. The MTA defines the rights of the providers and the recipient with respect to the materials and any derivatives (e.g. cells, plasmids, vectors).

Data management				
Record of activities and results (laboratory notebook for example)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Identification, filing and archiving of data	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Anticipation of data storage needs/capacity	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Information management system in place (e.g. LIMS ⁴ software)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Informatics security is ensured (e.g. against hacking, viruses)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Regular assessment of the TCF (internal or external assessment)				
Internal audit/assessment is regularly performed	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
External audit/assessment is regularly performed	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Regular audits of the quality management	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Corrective mechanisms in response to audit/assessment are planned	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA

Client/user satisfaction				
Existence of client/user satisfaction questionnaires	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Efforts to get feedback from users are made (e.g. target number of questionnaires actually completed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Analysis of satisfaction questionnaires	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Shared knowledge of user/client satisfaction (internal dissemination)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Improvements implemented in response to questionnaire analysis	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
External communication				
Existence of external communication tools (e.g. leaflet, website) in own language	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Existence of external communication tools (e.g. leaflet, website) in English	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Existence and use of a graphic identity of the facility	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Marketing strategy				
Existence of a price list (at least internally)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Existence of a differentiated price policy	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Existence of product/service list	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
Official recognition of quality management				
The TCF is part of a broader organization which has an official quality certification	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
The TCF itself (or part of it) is ISO 9001 certified	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
The TCF is GLP/GMP compliant	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA
The TCF has another official quality label	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> In progress	<input type="checkbox"/> NA

⁴ Laboratory Information Management System

Remark: Health and safety are monitored by official regulation, so not relevant here.

The ShareBiotech Quality Charter/questionnaire was created thanks to

ShareBiotech partners' brainstorming

ISO 9001 items

A questionnaire from INSERM (the French National Institute of Health and Medical Research) for laboratory quality management self evaluation

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