STANDARD OPERATING PROCEDURE (SOP)
GS02 Staff Organisation and Training, version 04

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1. PURPOSE
This Standard Operating Procedure (SOP) defines the TFS policy for training and development of TFS staff and describes the procedures for completing and documenting this training.

2. SCOPE
These procedures apply to all TFS employees. Each employee will receive training appropriate to his or her role in the company.

3. BACKGROUND
ICH GCP guidelines require that appropriately qualified individuals are used at all stages of a trial and that they are adequately trained.

Medical expertise
The sponsor should designate appropriately qualified medical personnel who will be readily available to advise on trial related medical questions or problems. If necessary, outside consultant(s) may be appointed for this purpose.
(Reference: ICH E6 GCP 5.3)

Study Design
The sponsor should utilise qualified individuals (e.g. biostatisticians, clinical pharmacologists, and physicians) as appropriate, throughout all stages of the trial process, from designing the protocol and CRF’s and planning the analyses to analysing and preparing interim and final clinical reports.
(Reference: ICH E6 GCP 5.4.1)

Training
Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).
(Reference: ICH E6 GCP 2.8)

Contract Research Organisation (CRO)
All references to a sponsor in this guideline also apply to a CRO to the extent that a CRO has assumed the trial related duties and functions of a sponsor.
(Reference: ICH E6 GCP 5.2.4)
4. DEFINITIONS

Mentor
A person assigned to support and instruct an employee given new tasks and responsibilities. The mentor should have experience of the tasks and should be appointed by a Manager.

5. RESPONSIBILITY

Line Managers
- Ensuring and documenting that their staff are appropriately qualified and trained, including GCP training
- Ensuring that their staff are trained in, and familiar with, relevant TFS SOPs Preparing an individual induction and training programme for all new employees in their department. Ensuring that sufficient time and opportunity is available for staff training
- Appointing mentors if required
- Ensuring that job descriptions are available for all staff

Project Leaders
- Ensuring that all members of their study team have adequate training, including both TFS and Sponsor-specific SOP training. Arranging and documenting study specific training

Employees
- Ensuring that their CV’s and Training Records are updated as and when required

Training Department
- Providing SOP training and other training as and when required
- Maintaining records of all training provided (in TFS Academy)

Human Resources Department (or equivalent)
- Maintaining a training file for each employee organised according to “Contents Training File”

6. CURRICULUM VITAE and TRAINING RECORD

A signed and dated CV and Training Record written using the appropriate TFS template will be obtained by the HR department from all employees. A copy should be sent to the Quality Assurance/Training department, electronically, within one month of commencing employment.

Employees are responsible for updating their CVs and Training Records as soon as information changes, for example after participating in a training course.
7. TRAINING

7.1 Annual Review of Competency

Individual training needs and requirements should be reviewed at least once a year by Line Managers, together with each employee, and actions taken to ensure that ICH and TFS requirements, both SOP training and other training, are fulfilled. For all operational staff this should be documented using the “Annual Checklist – Training Requirements”.

7.2 Required Training Activities

All employees should perform appropriate TFS training courses as defined in the TFS Internal Training Requirements. The mandatory courses should be completed as defined in TFS Internal Training Requirements. All new employees will participate in the following TFS training modules as soon as possible after beginning their employment:

- Good Clinical Practice (GCP)
- (GCP update training should be performed every three years)

Furthermore,
- Monitoring, basic, for employees such as CRAs, sCRAs, CRMs – This course is mandatory even if similar training has been obtained before employment at TFS.

Line Managers are responsible for ensuring and documenting that operational staff have adequate training and experience to conduct the tasks required by their function. For example, new CRAs should conduct a number of co-monitoring visits together with more experienced personnel, who should provide documented approval of the CRA as suitable for this function. Alternatively, for more experienced new CRAs with previous documented experience written approval of monitoring competence can be given by Line Managers, on the annual checklist. This should also be documented in the Training Record (“on-the-job” training).

Review of an employee’s experience should be in accordance with the corresponding experience needed for each function.

7.3 Required SOP and Policy Training

Employees should perform appropriate SOP training according to “SOP Training Requirements list”. This training is mainly performed using the e-learning platform TFS Academy. Employees are not permitted to work on studies where TFS SOPs are used until they have received relevant SOP training and passed the tests.

Employees will participate in relevant training sessions for new and updated SOPs as soon as possible after the release of new versions.

TFS employees using client’s SOPs in their daily work have to read and pass a test in TFS Academy for TFS SOP GS Staff organisation and training and read TFS SOP IT E-mail at a minimum.
TFS Policies should also be read and tested as required.

7.4 TFS People
Employees in working in TFS People should, in addition to training courses provided by the client, perform the following training:

- Good Clinical Practice. This course is required unless a reputable GCP course (minimum 1 day) has been attended within the last 3 years. This should be approved by TFSQA.
- Monitoring, basic (if relevant to the role - unless an equivalent training course has been attended previously or the client is to provide training. This should be approved by TFSQA SOPs.
- GS SOP Staff organisation and training and IT SOP E-mail (at a minimum)

The above mandatory training will be dependant on the employee’s previous working experience and background as well as which assignment the employee is assigned for.

Additional training will be based on the Internal Training Requirement and the yearly updated individual development plan, evaluated in relation to the assignment for the employee.

7.5 Project Specific Training
All project and/or study specific training performed should be documented on the Project Specific Training Log. On this form the following information must be documented: type of training, (name and version date of the documents, if applicable), information as to whether provided by trainer or self-study and the date when training was performed. The document should be filed in the Study Master file.

7.6 Mentor Programme
When necessary, a mentor should be designated for TFS employees given new tasks and/or responsibilities which they have not previously performed. The mentor should give support and instructions to the employee and should keep the Line Manager informed of their progress. Examples of tasks where a mentor should be appointed could be:

- Site selection
- Study Initiation
- Monitoring
- Close Out Visit
- Application to Ethics Committee
- Application to Regulatory Authorities
- Protocol writing
- Report writing
7.7 Conducting new tasks
New employees, or employees designated new tasks, should be evaluated to ensure that they have the required knowledge and skills to perform the task before the employee is allowed to do the assigned task on his/her own. This assessment can be conducted by Line Managers or mentors. Approval for conducting new tasks should be documented on the annual training checklist.
**Standard Operating Procedure**

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<tr>
<th>Version No</th>
<th>Effective Date</th>
<th>Brief Description of Change</th>
<th>New training required</th>
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<td>01</td>
<td>1 February 2002</td>
<td>New SOP</td>
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<tr>
<td>02</td>
<td>1 October 2006</td>
<td>General update to harmonise TFS and CDC SOPs.</td>
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<td>03</td>
<td>24 July 2009</td>
<td>Revised regarding training requirements, QA and annual review</td>
<td>Yes</td>
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<td>04</td>
<td>1 December 2014</td>
<td>Revised regarding GCP training requirements</td>
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**EXTENSION WITHOUT CHANGES**

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<th>QA Approval</th>
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