Regulatory training – good practice guidance

This paper has been developed by the UKCRC Regulatory and Governance Training Coordination Group. It outlines suggested quality criteria for regulatory training offered as part of a Continued Professional Development (CPD) programme. These criteria are designed to support those developing, delivering or commissioning regulatory training.

Targeted
Training should be specifically tailored to the needs of staff with particular research roles and interests. Targeting may be broad (wide variety of roles and staff groups) or narrow. Training providers should ensure that all training is advertised and promoted to the appropriate target group.

Relevant
Regulatory training must be relevant to specific target groups. Relevance should be judged by the target group themselves, and informed by professional groups, recognised research competencies, employers, study sponsors and organisations hosting research. Training should address what the target group needs to know in order to fulfil their research role now and in the future. It may be considered best practice to ensure that, at least in part, training is illustrated with ‘real life’, practical examples of how to ensure compliance.

Authoritative
It is vital that all regulatory training is authoritative. This can be ensured by involving Regulators directly in the development of training and/or ensuring informed input is provided by a wide and appropriate consultative group. The course developer should have appropriate background and expertise.

Specific
Regulatory training should have clearly defined learning outcomes which specify the level of learning proposed (e.g. understand versus be aware of etc). Any proposed assessments must measure learning against these outcomes. It is important that learning outcomes mirror what is required by the law.

When commissioning regulatory training, organisations should ensure that the proposed learning outcomes are appropriate and, where appropriate, reflect specific sponsor’s standard procedures and any relevant employer’s policies.

Evaluated / assessed
All regulatory training should be evaluated and this feedback be used to inform future development of training. Evaluations may include measures of appropriateness, level of learning, perceived quality, and may support reflective learning (i.e. asking trainees to identify how they intend to change their practice following training).

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It is considered best practice to assess learning by conducting a quiz or short test. Such assessments should measure learning against the defined learning outcomes. Assessment may be made compulsory for some regulatory training (e.g. GCP or Sponsor SOPs for trialists). Assessment should always be used to inform trainers of areas of difficulty which require clarification.

**Responsive**
The regulatory environment is subject to change, it is therefore vital that all regulatory training is responsive to the changing needs of research staff and their sponsors and employers. All regulatory training must be up to date and should flag areas that are known to be subject to change (if appropriate).

**Provide appropriate sign posting**
Trainers should provide information on where to find help in the future, including details of local support arrangement where appropriate. Sponsors and employers should ensure that details of local arrangements promoting and supporting compliance are flagged, whenever this is appropriate.

**Supporting training materials**
Training should be supported by the provision of appropriate and authoritative training materials, provided as handouts and/or pre-training reading. Any pre-course preparation required must be made explicit to attendees and should be as succinct as possible.

**Well planned**
Trainers should provide clear delivery plans identifying: how long the training will last; how it will be provided (distance learning, presentations, workshops etc); the learning outcomes; the specific target audience; all training materials provided; details of assessment and/or evaluation; and details of any pre-course reading or preparation required.

When commissioning regulatory training, sponsors and employing organisations should ensure that appropriate plans are in place, and that the facilities provided for training are appropriate and fit for purpose.

**Well promoted**
Without appropriate promotion, regulatory training is likely to be poorly attended. Good quality regulatory training should be accompanied with a robust advertising strategy. Employing organisations and sponsors should indicate the importance they place on attendance at relevant regulatory training in supporting compliance with regulatory requirements. In some instances, organisations may decide to make specific regulatory training compulsory for staff engaged in specific research activities.
Organisations must ensure that research staff are able to access appropriate regulatory training. This includes releasing staff from clinical or other duties, and / or providing staff with access to appropriate IT systems which support distance learning.

**Well managed**
Research organisations should be aware of the regulatory training needs of individual members of staff, and should maintain managerial oversight of all regulatory training completed by staff.

In many circumstances repeated attendance may be required to ensure that staff are both kept up to date and are reminded of specific regulatory responsibilities they may have. Regulatory training should be considered as part of Continuing Professional Development (CPD) for all research staff.

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1. **UKCRC Training Coordination Group**
This Group is composed of a small core of individuals drawn from organisations providing regulatory and governance training. The Group’s remit is to explore and identify opportunities for a joined up approach to training, in order to bring together, for mutual benefit, diverse audiences involved in research regulation and governance. The premise will be on sharing information, coordinating activities, driving programmes forward and identifying further areas for collaboration.

In particular the Group:
- Shares information on existing/planned initiatives and activities
- Facilitates coordination of initiatives and activities
- Identifies areas where new training programmes are required
- Sets objectives for training and identifying what should be taught in certain courses
- Devises ways of assessing courses

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