Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

MHRA GCP Forum Demo

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Aim

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Background

Due to a number of reasons the MHRA strove to look for new ways to engage GCP stakeholders:

- Request from the community (both commercial and non-commerical including NHS)
- Requirement from government
- Response to the Academy of Medical Sciences Report 2011 for regulation and governance of health research

Some of the new engagements were:

- GCP guide
- NHS floorshows, training and workshops
- **Plus the GCP Forum – which went live in October 2011**

Benefits of the GCP Forum

- An area for all those involved in GCP to use (e.g. ask questions and get/give examples of how to implement processes to ensure compliance with the regulations)
- Registration can be anonymous, so users can ask questions without worrying about a potential inspection
- As all posts are moderated by the MHRA:
  - There are no posts approved that are non-compliant with the regulations
  - The MHRA can add comments or proviso's to comments as the moderator
- Used by the MHRA to post (as sticky post-it) FAQs

NHS Example of Benefit

Implementation of the Clinical Trials Directive 2001/20/EC in 2004 and GCP Directive 2005/28/EC in 2005 meant the principles of GCP became a legal requirement for everyone in the European Union involved in the conduct of a clinical trial with a medicinal product (both commercial and **non-commerical**).

Despite having a degree of flexibility in how the principles of GCP are applied, many NHS organisations had concerns about not meeting all of the statutory requirements for the conduct of clinical trials. Resulting in some NHS organisations:

- Becoming reluctant to participate in clinical trials
- Taking a risk-averse approach, requiring additional processes increasing the cost and complexity of clinical trials unduly

NHS Example of Benefit (cont.)

In 2011 the Risk Adaptive Approach was published (collaboration between the MHRA, DH, MRC and NHS stakeholders).

The **GCP forum** is **key** to the MHRA and NHS communities as a mechanism to **publishing** key **messages**, **expectations** and **NHS examples** of risk adaptive assessments, so **all** the NHS (and commercial) communities can gain an understanding of how to apply this approach to their trials and create compliant procedures within their own organisations.

Management & Moderating

The GCP forum is:

- Set up and managed by the MHRA on independent servers
- There is an introduction and rules page that all users must follow
- All posts and attachments are moderated by the MHRA:
  - SOPs and a moderators guide for the GCP inspectors to follow when moderating
  - GCP inspectors are allocated to moderate forum via a rota (so its not too time consuming)
  - All posts are moderated within 72 hrs of submission (to allow for holidays, usually moderated within 24 hrs)
  - There is full IT support for registration problems and spam management

Management & Moderating (cont.)

- For use by the community only, so they can work together by:
  - raising and answering questions
  - posting best practice or examples

  (as the GCP inspectorate has their own separate procedure for answering questions via the clinical trial helpline mailbox)
- Can provide the MHRA with identification of specific areas that can target FAQs or topics for any symposia, consultative committee meetings or inspector blogs etc.

Information & Demo

The GCP forum:

- 2316 members
- 199 threads
- 549 posts
- FAQs by the MHRA
- All approved posts and attachments can be view by anyone
- Only registered users can post on the forum
- MHRA moderators all posts and attachments

Link:

http://forums.mhra.gov.uk/forumdisplay.php?1-Good-Clinical-Practice-(GCP)