Chapter 1: Background, outline and structure of the thesis


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1 INTRODUCTION

1.1 Overview

This research is a study of trainers, drawn mainly from the commercial sector of the field of clinical research, journeying towards becoming a community of practice (CoP). The focus of the study is the concept of practice among this community, formed within the professional body of the Institute of Clinical Research (ICR). Its scope is limited to discussing emergent features of the community, known as the Trainers Forum (TF), in terms of the ‘ecology’ of the commercial sector. This reflects the ICR’s history as a professional association whose members were drawn mainly from the pharmaceutical industry or its associated service industries (recruiters, freelancers, contract research organisations). Observation, questionnaires and interviews further established that members of the Forum were a heterogeneous community of full-time and part-time trainers whose identities ranged from: clinical research trainers, training managers; clinical research managers, clinical research associates; compliance managers and auditors.

As a member of this community, which meets at least three times a year, a contradiction was observed between how community members share ideas, experiences and training methods and how these were frequently talked about. Initial observations suggested that community discourse confused two contrasting pedagogic models, using each of their distinctly defined approaches and associated methods interchangeably. That is, at community meetings, trainer-centred pedagogic strategies routinely used in the act of ‘sharing and discussing’ topical training issues were referred to as ‘learner-centred’.

In this study, pedagogy encompasses not only approaches to the Teaching & Learning (T&L) process, and the associated strategies or methods regarding curriculum content, but also the communicative content of ‘classroom’ talk in terms of its culture, as an element of pedagogy (Alexander, 2005). Hence, for the purposes of this study, in a pedagogic model of learner centred enquiry, the approach is defined as learner centred, the process is one of enquiry, and the methods involve collaborative dialogue (sharing and building on ideas). Whereas, in a
trainer-centred transmission model, the approach is defined as trainer-centred, the process is one of information transfer, and the methods involve didactic monologue (sharing through delivering information). Consequently, observations suggested that the contradiction is between a practice that emphasises content and transmission, and a discourse that emphasizes process and enquiry, which raised the following questions:-

- Why is a content-driven approach to training, evident in the field of clinical research, dominant in an emergent Community of Practice (CoP)?
- Why do trainers talk about learner-centred approaches but predominantly tend to use trainer-centred methods in this community?

Therefore, this study is based on analysing the ways in which shared understandings of practice are developed within this community. The intention was to explore the concepts, methodology and experiences in the TF in relation to its object of activity. Insights were drawn from observations related to practice in this community, which are explored further via questionnaires and interviews in order understand what goes on around here and its implications for how we do things and why within a community that, due to its distributed nature, may have wider implications across the field of practice.

1.1.1 Problem background

Training is a fundamental issue that affects the entire field of clinical research (from academia to commercially sponsored research), since the goal of appropriate training in this highly regulated field is ultimately to protect the public from unscientific research that is not conducted to ethical standards. In particular, a quality standard known as Good Clinical Practice (GCP) governs the conduct of clinical research and affects everyone involved in it: subjects, investigators, and sponsors. Protection of subjects' rights, safety and well-being is at the heart of this ethical and scientific quality standard.

Ongoing regulation in this field means that regulatory inspectors are turning their attention to how organisations sponsoring clinical research demonstrate the effectiveness of their GCP training programmes that support the practice of GCP among investigators as well as their
own clinical research staff. Such organisations include those in the private commercial sector, ranging from pharmaceutical companies to contract research companies, as well as those in the public healthcare sector (e.g. the NHS) affiliated to academic institutions\(^1\). Accordingly, as shared at various Trainers’ Forum meetings\(^2\), and in articles published in the ICR magazine\(^3\), inspection of training records during mandatory GCP inspections by regulators is becoming more of a regular feature.

However, it remains to be seen how trainers or organisations may respond or change their practices as a consequence of inspectors drilling down into training records to find out what is going on in the training process. Generally, it seems that inspectors’ focus on training records is limited to concerns about the frequency of GCP training rather than the quality of GCP training (Bringslimark, 2004). However, as reported at the TF, there have been some instances where inspectors have requested to see lesson plans\(^4\).

An inevitable consequence of this scrutiny has been that organisations concerned about inspectors’ expectations with training records have shared their experiences of inspections more widely through publication in order to establish best practices for dealing with inspections generally (Chief Scientist Office, 2005).

Currently, the main implication of these regulatory inspection practices for organisations is the need to be able to demonstrate that not only have employees been trained, but that their training was appropriate and effective. Yet, if regulatory authorities increase pressure on companies to ‘practice’ accountability with regard to demonstrating the effectiveness of their training programmes, this could challenge under-resourced training departments, especially when training is not necessarily the issue. In particular, in those companies without an evaluative framework it would be difficult to demonstrate that deficiencies in manufacturing

\(^{1}\) i.e. University teaching hospitals within the NHS
\(^{2}\) TF_FN_6/E_09-05; TF_FN_9/G_05-07.
\(^{3}\) Hepworth-Jones, 2005
\(^{4}\) TF May 2007: When an inspector comes calling
or clinical research and development processes are addressed effectively through training (Vesper, 2001).

Moreover, if deficiencies are addressed through increasing the frequency of training without paying heed to the quality of that training, then little is accomplished. Therefore, more crucially, success in mediating an effective training process depends on knowing when and how to evaluate different stages and elements of the training process. Otherwise, the status quo is likely to remain unchanged: deficiencies that are not due to lack of training continue to be addressed inappropriately with training; or, deficiencies are addressed with inadequate training. In either case, deficiencies are not remedied. In effect, the potential for GCP non-compliance remains.

Meanwhile, there is no agreement or guidelines about training standards within this field concerning how organisations should demonstrate that their training programmes are effective in assuring regulatory compliance to GCP. At present this is a matter of judgement for individual organisations involved in conducting clinical research. Debate is ongoing in the field regarding the specifics of how organisations might train their employees as well as what they should learn about the processes involved in clinical research in order to demonstrate compliance with GCP (Zimmerman, 2000a). As a consequence, the need to define training standards is as critical now as when Zimmerman (2000b), an independent trainer, first highlighted this issue:

“...although the global clinical research community agrees upon basic GCP standards, it has not settled on training standards. At the dawn of the 21st century, GCP training can best be described as a hodgepodge of serendipitous activities of arguable quality. Until the global community identifies and harmonises core GCP knowledge, skill, and behavioural competencies for every position in clinical research, we will all – including the patients whom we strive to help-painfully endure the consequences of GCP non-compliance. And the research community will continue to misuse the minimal funds that management allots for training clinical research personnel.”

Inevitably, some organisations will excel in the development, delivery and evaluation of their training programmes, whereas others may invest minimal resources in training. Yet, if regulators become involved in defining standards of training, then paradoxically, these may lower quality standards rather than having the desired effect of raising them.
In his time at the Office for Human Research Protections (OHRP)\(^5\) in the USA, Dr Greg Koski recognised the dilemma arising with legislating for quality standards. That is, paradoxically such a legally mandated regime creates the opportunity for competing cultures to develop. Some organisations will do no more than the minimum necessary to adhere to the standards regime (i.e. regulations), thereby creating a *culture of compliance* (Koski, 2001a; Whalen, 2003). Whereas, striving for a *culture of conscience* means standards are driven by a desire to excel in the activities inherent to practice, with full appreciation of the historical context that commands the need for such standards of practice (Koski, 2002:1).

Under Koski’s leadership, the OHRP attempted to move from a reactive compliance-focused system of oversight and sanctions in the system of patient protection to a proactive system focused on prevention of harm to subjects—a system in which performance excellence is achieved through education, support and quality improvement. In collaboration with the Food and Drug Administration (FDA)\(^iv\), the National Institutes of Health and other federal agencies, his office worked “… to identify new opportunities to make the US system for protection of human subjects more efficient and more effective” (Aungst, 2003). Because Koski was acutely aware of the paradox created by more regulations, he was an advocate of proactive training, especially since training is an essential component of quality (Bringslimark, op.cit.). As he recalled in an interview about his time as Head of the OHRP in the USA:

> “…I never believed that more regulation was the way to go. A "culture of compliance" was not what we wanted. We wanted to build a "culture of conscience" where people didn’t do the right thing because it was required by the law, but because of their own sense of moral responsibility and personal integrity – because it was the right thing to do. We emphasized proactive approaches to prevent injury, rather than reactive approaches that would punish someone when something bad happened. Obviously, the goal was, and is, to prevent harm, not to react after harm occurs." (Goldfarb, 2007)

Similarly, since the introduction of the Clinical Trials Directive (Directive 2001/20/EC) in the European system of clinical research governance, a culturally advanced motive has also been

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\(^5\) The OHRP protects the rights, welfare, and well-being of subjects involved in research conducted or supported by the Department of Health and Human Services (HHS) and helps ensure that such research is carried out in accordance with the regulations described at 45 CFR part 46 of the Code of Federal Regulations, the legislative framework, for the USA.
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superseded by a less advanced motive. Compliance with GCP standards is therefore enforced with regulations (through mandatory inspections in order to protect clinical research participants) versus monitored through voluntary inspections (where organisations were trusted to operate from a sense of “doing the right thing, for the right reasons”). Thus, in the attempt to transform the conduct of clinical researchers, the activity of governance has itself been transformed, through the move from voluntary to mandatory inspections. The main outcome of this transformation is reinforcement of a culture of compliance rather than the intended culture of conscience.

In turn, due to its legitimation in a legal framework, this cultural shift then permeates all clinical research activity operating as a pitfall or double-bind in the struggle to achieve balance in clinical research between quality, time and costs\(^6\). Conflict then manifests as contradiction whether in the field, the workplace or among training professionals in their community of practice. Hence, in developing a legal framework to enable statutory inspections that uphold and maintain high standards of practice, regulators’ unintentionally may have created the opposite effect through shifting clinical research culture from one of conscience to one of compliance. As Koski states:

“...We have gotten to where we are through our own actions. We are going to have to work together now to get back to a place where reason prevails, and we are doing things for the right reasons rather than doing them because we have to.” (Koski 2001b:197)

Therefore, in the field of clinical research, training is pivotal to helping people do “the right thing, the right way” in the clinical research process, which in the long run satisfies regulatory requirements. Therefore, creating the opportunity for learning lessons where reason prevails depends on identifying the contradictions created by the system of research governance in the field of clinical research\(^6\), the workplace and at the level of professional practice. Equally, in time, regulatory demands may mean that trainers require formal certification through external

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\(^6\) According to Armstrong and Kaul (2004:191), industry cannot achieve its objectives of providing quicker, better-quality clinical evidence, for regulatory submission, at a lower cost without compromising on cost, quality or time. That is, experience has shown that only 2 of these 3 objectives (described as the 3 sides of an iron triangle) can be achieved simultaneously: “Evidence that is quick and cheap is likely to compromise quality; high-quality research at lower costs is likely to take longer; and quality research in a shorter time is likely to come at a higher price tag.”
qualifications, which has resource implications for both trainers and their organisations, in terms of organisational support for the financial investment and time needed to achieve certification.

Finally, as explained in this outline of issues surrounding training in the field of clinical research, mitigating the risk of regulatory imposition concerning training standards in this field, involves striving to do right things for the right reasons through the pursuit of excellence. Such an endeavour also signals organisations’ voluntary commitment to upholding standards in a culture of conscience rather than a culture of compliance. Moreover, for industry, such pro-activity signals that training is seen as something it ‘wants to do’ rather than something it ‘has to do’ (Zimmerman 2000c; 2000d).

In conclusion, the issues can be summarised as follows: -

- Risk of further regulatory imposition if training standards fail to be proactively developed in the field of clinical research
- A standards regime arising from regulatory imposition creates the possibility of standards that are driven by the need to satisfy the regulatory agenda, rather than standards that are driven by a desire to excel
- The need to satisfy an imposed standards regime creates a culture of compliance, which paradoxically may lead only to adherence to minimum standards.

This research therefore, concerns how those working as trainers in the field of clinical research endeavour to uphold standards through developing their shared understandings of practice as part of their continuing professional development (CPD).

1.1.2 Problem statement

Issues:

- Lack of agreement among organisations in the field of clinical research about the standards/knowledge of training practice e.g. is training mostly about: content or process? Which methods are most helpful: trainer-centred or learner centred?
Role of the Trainers Forum in supporting development of training practice/standards:
is there congruence in our theory-in-action (Argyris & Schön, 1978) i.e. does our espoused theory (what we say we do) match our theory-in-use (what we do in actual practice)?

The challenge for the training community is to convince players in the field (i.e. employers - NHS, pharma and CROs) of the need to pro-actively ‘raise our game’ to avoid future regulatory imposition of training standards, which because they are imposed, further reinforces a culture of compliance. Thus, developing knowledge of training process (particularly in evaluation) enables effective demonstration to regulators that personnel are adequately and appropriately trained in GCP. Endeavouring to develop the internal goods of practice founded on the virtues of justice, courage and honesty (MacIntyre, 1985), enables a culture of conscience to flourish (Koski, 2002).

Since 2003, within the Institute of Clinical Research (ICR)\(^7\), a community of trainers has worked in a group known as the Trainers Forum (TF), with the expressed aims of sharing best practice and discussing topical training issues. This community represented an opportunity to develop training standards through sharing concepts of practice rooted in a culture of conscience in the field of clinical research. However, two issues were apparent that could affect efforts to find or provide effective solutions to this cultural challenge. That is, a contradiction was observed in the Trainers’ Forum concerning training practice:

- While the discourse emphasised learner-centred training (espoused theory: our training approach & training methods are learner-centred), the practice of training was about transmitting subject matter, since a content-focus was favoured above the process of learning (theory-in-use: our approach & training methods are trainer-centred).

\(^7\) The ICR is a professional body representing clinical research professionals primarily in the UK, but also in Europe and India.
Training appeared to be driven by a culture of compliance, rather than a culture of conscience in which trainers strive for excellence in the improvement of their practice.

These contradictions were considered as sources of tension driving the community in its learning activities (sharing best practice (BP), discussing topical training & technology issues). In particular, tensions were observed between the desire to excel in practice (operating as a fundamental value providing motivation) and a basic need to ensure standards conform to regulations through delivering content.

1.2 Outline of the study

1.2.1 Purpose

The Trainers Forum represented an opportunity to explore conditions giving rise to the contradiction between discourse and practice amongst trainers (i.e. between espoused theory (learner-centred learning approach) and theory-in-use (trainer-centred delivery methods)).

It also provided an opportunity to explore, share and develop awareness of reasons for this contradiction. Moreover, since the mission statement of the TF expressed its aims as sharing best practice and discussing training topical issues, the aim of this research was to establish how we are doing this. Therefore, the purpose was:

- To study how the community of trainers, focusing on the Trainers Forum, were developing their professional training practice in response to the implementation of state regulation (e.g. mandatory inspections) beginning by exploring what was meant by training within this community.

- Given the apparent contradictions between discourse and practice amongst trainers, to study to what extent, and how, have they been able to transform themselves into a community of practice (CoP).
To explore the activity system – of communication and decision-making – and its social influences that have helped or hindered the development of a community of practice.

To contribute to practice theory through a critical analysis of the relationship between practice theory and activity theory.

1.2.2 Aims

1. To examine how a group of professional trainers journey towards becoming a community of practice by studying the characteristics of this emergent professional community and the conditions that create and sustain this kind of CoP.

2. To describe conditions governing practice, which explain the relationship between a compliance culture and the prevalence of a transmissive pedagogy of training within the Trainers’ Forum.

1.2.3 Objectives

To explore the workings of the Trainers Forum in order to understand:

1. How trainers develop their discourse on pedagogy through exploring: the values, purpose and practice of training; the standards of training to be achieved

2. The internal tensions and contradictions between the discourse and practice

3. The social structure of the Trainers Forum: who trainers are; their backgrounds; why they differ in their principal affiliation (to their employers, or to their profession); why they are attached to a particular pedagogy and why they have particular cultural orientations (of training) to regulation (compliance or conscience).

4. The activity system of the TF, in terms of: its division of labour, rules, power and decision-making; its practices of communication (that help or hinder development as a CoP); its practices of agreement making.

If most communities of practice tend to be those that are distributed across organisations where community members are employed, this kind of professional CoP differs in that its members are distributed across a professional institution to which they subscribe, rather than through which they share employment.
1.2.4 Research questions

Seeking answers to these research questions involved de-constructing:

- The object of study (the concept of practice in clinical research training) and
- The object of activity within the Trainers Forum (CPD of trainers with practice issues) based on the premise that activity at the TF is guided by its explicitly expressed aims.

The following key and associated questions sharpened the issues to be investigated.

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<tr>
<th>Research Question 1</th>
<th>Why is the discourse on pedagogy in the Trainers Forum marked by internal contradictions?</th>
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<td>Why is a content-driven approach to sharing and discussing practice and training issues dominant in an emergent Community of Practice (CoP)?</td>
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<td>Why are some trainers committed to a transmission model?</td>
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<td>Is there a relationship between the transmissive pedagogy and the compliance regime? If it exists, how do we explain this relationship?</td>
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<td>How are trainers working within the Trainers Forum to establish shared understandings about practice/training issues?</td>
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**Research Question 2:**

What activities help the Trainers’ Forum develop towards becoming a community of practice (and conversely which activities act as a barrier to becoming a CoP)?

- What are the characteristics of activity in the TF? What does practice look like?
- Why do trainers talk about learner-centred approaches but predominantly tend to use trainer-centred methods in this community?
- What social processes are moulding the TF (i.e. processes involved in its structuration) e.g. how does the TF run: how is it organised (planning & administration; decision-making; consultation etc.)? Who makes decisions and how

**Research Question 3:**

How can the Trainers’ Forum realise its potential as a CoP to provide guidance about training standards generally, and evaluation practices in particular, in order to transform training culture from one of compliance to one of conscience?

Consequently, to gain an insight into the nature of training practices, an understanding of the operational definition of *practice* within this emergent community of practice, spanning this specialised field of clinical research training, needed to be developed. The notion of *best practice* promulgated by this emergent community of practice could then be examined.

Therefore, because the TF represented a developing community of practice within the social setting of a professional society or institution, where trainers met socially and discussed issues of common interest, it provided an opportunity to find answers to the research questions posed in this study.
1.2.5 Hypotheses
As a consequence of initial observations, hypotheses or propositions that will be examined in this thesis are that:

- If trainers feel divided in their commitments (between their profession, and their employer), then they may speak a language (of process pedagogy) to satisfy their professional peers, but feel forced to deliver cost-constrained training that will satisfy their executive employers.

- If the activities of communicative action (dialogue, and giving and taking of reasons to develop dialectical understanding of training) are emphasized within the Forum, then trainers may be more likely to become a community of practice reaching shared understanding about an enquiry-led pedagogy and a culture of conscience in relation to training and ultimately, regulation.

1.3 Structure of the thesis
In this section, the outline of the thesis is provided, which is structured in four parts and split into ten chapters:

PART 1 INTRODUCTION
- Background, outline and structure of the thesis (Chapter 1)
- Review of Literature (Chapter 2)
- Analytical framework (Chapter 3)

PART 2 METHODOLOGIES
- Research Methodology (Chapter 4)
- Research Design (Chapter 5)
- Research Methods (Chapter 6)

PART 3 RESEARCH FINDINGS AND DISCUSSION
- The Subjects: Trainers (Chapter 7)
- Community, Rules & Division of Labour: The Forum (Chapter 8)
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- Object & Tools: Purpose & pedagogy of the Trainers’ Forum (Chapter 9)

PART 4 CONCLUSIONS & RECOMMENDATIONS

- Outcome: Towards a culture of conscience in a developing community of practice?
  (Chapter 10).
- References
- Appendices.

The background to this research study is provided in Chapter 1. The focus is presented concerning the ways in which shared understandings of practice are developed within a community of practice and why regulatory developments in the field of clinical research may make training problematic.

The literature is reviewed in Chapter 2, exploring where a contribution to knowledge may be situated. This chapter begins by considering the concept and meanings of practice from a number of philosophical, sociological, and educational perspectives to derive an operational definition of practice and to define a conceptual-analytical framework applicable to this object of study. This chapter includes considering reflexivity as fundamental to the analysis of any and all practices, including that of research.

In chapter 3, it is explained how the conceptual framework allows the concept of practice to be viewed as a whole within the Community of Practice (CoP). In turn, the CoP can then be delineated as an activity system with its own rules, community and division of labour. An explanation then follows of how activity can be analysed in terms of the concepts, methodology and experience of training as a practice within the CoP.

Next, the concept of practice is considered in terms of those cognitive and cooperative elements of activity that constitute its objective regularities. This analytical framework is used to analyse observational data, and data obtained from interviews.

The complex nature of activity in the CoP is further distinguished using contrasting epistemological frames of discourse (EFsD) observed within the CoP (i.e. in terms of saying-
writing-doing and being-valuing-believing discourse combinations). These EFsD represent different ways of knowing (received or constructed).

In Chapter 4, Methodology, the pragmatic approach to this research and its ontological structure is described and explained. This provides the background to the research design (Chapter 5) and methods (Chapter 6) that were used to explore elements of practice. These constitutive elements acknowledge the recursive nature of practice, and its institutional arrangement. Methods used to analyse conditions shaping training practices in the field of clinical research within the commercial sector are also outlined in Chapters 3 and 6.

The main analyses are presented in Chapters 7, 8 and 9. To begin, findings are analysed using Wenger’s dimensions of community, domain and practice to describe the structure of the Community of Practice, based on individual sessions observed within the Trainers’ Forum. Interviews and findings were then analysed using Engeström’s activity system model, to explore the social influences of communication and decision making that work to help or hinder the development of the Trainers’ Forum as a Community of Practice.

Finally, in Chapter 10, the implications of using activity theory in this study are summarised, concluding with recommendations for future studies of CPD within this field, and other contexts.

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i The specialised field of clinical research is subject to complexity and constant challenge. Not least of these challenges, in Europe at least, is the need to comply with an increasing amount of European Regulations and Directives issued by the European Parliament and Council on behalf of Member States of the European Community (EC) (Hooper, 2005; Sweetman, 2003:5).

ii The ethical origins of GCP can be traced through the Declaration of Helsinki back to the Nuremberg Code. The Declaration is a code of research conduct binding members of the medical profession to practice ethical principles with regard to the medical care of research subjects. The Declaration grew from the Nuremberg Code, the first internationally recognised code of research ethics established by the Nazi War Crimes Tribunal in 1947 (The Nuremberg Code, 1949), which established the principle of informed consent, whereby participants in research are made aware of the risks as well as the benefits to which they may be exposed by their informed choice of participating in a clinical study.

iii GCP was first implemented as a Guideline in the European Community (EC) in 1997. However, individual Member States had their own approach to regulations governing the implementation of GCP in the conduct of clinical trials on medicinal products for human use. So, although it was largely adhered to within the EC, GCP’s adoption was neither complete nor uniform, since it was not consistently incorporated into national legislation. In practical terms, regulators’ legal powers to seek evidence of GCP compliance through the inspection of relevant sites varied across Europe, ranging from mandatory schemes in the Netherlands and Denmark but voluntary schemes elsewhere (Wilshe, 2002). By contrast, the regulatory authorities in the USA,
namely the FDA, had been conducting mandatory inspections for many years, in Europe such inspections were performed under a voluntary inspection scheme.

Nevertheless, because of past lessons learnt in Europe, including the thalidomide tragedy in the late 1950s and early 1960s, the ethical and moral requirement to demonstrate that patients were protected from participation in ill conceived or inadequately designed studies - indicative of ‘poor science’ – constituted a basic regulatory obligation despite having no uniform legal framework for adoption. Thus, basic patient protection was achieved through independent review of proposed research protocols by ethics committees, and by obtaining participants’ informed consent prior to their participation in a clinical study (van Dongen, 2001). The publication of this legislation as Directive 2001/20/EC in the Official Journal of the European Communities on 1 May 2001 (Fontaine N. and Rosengren B., 2001) has since provided a common legal framework across Member States in the EC for monitoring and enforcing GCP standards applicable to clinical research implementation (Wilson, 2003).

The Food and Drug Administration (FDA) is an agency of the Federal Government in the United States (US) and part of the US Department of Health and Human Services (DHHS). It became firmly established as a government agency in 1937, to ensure that products with claimed medicinal properties were registered and evaluated for safety, quality and efficacy before licensing. Its firm establishment was triggered by the deaths of one hundred and seven people in 1937 from ingesting a liquid presentation of a drug. The drug, sulfanilamide, had been used without incident in tablet and powder form to treat streptococcal infections. However, following demand for a liquid presentation, the drug was found to dissolve in diethylene glycol, and was developed into a solution, accordingly. The toxicity of this ingredient (which is now used in antifreeze) was overlooked despite warnings in the published scientific literature of the time about its potential to cause kidney damage or failure. Thereafter, toxicity became a prime concern. Appropriate regulations were enacted the following year, in 1938 (Ballentine, 1981).

Government agencies or regulators are charged with the responsibility of reviewing GCP compliance, with a legal mandate to ensure compliance with GCP standards (Wilson, op.cit.). Since 2004, legislation throughout Member States of the European Union (Directive 2001/20/EC) mandates the monitoring of compliance by regulators through conducting inspections of documentation and procedures at the sites of sponsors, investigators and the Independent Ethics Committees (IECs) involved in reviewing the ethical nature of proposed research (van Dongen, op.cit.). Whereas in the USA mandatory inspections had been conducted for many years, in Europe such inspections were performed under a voluntary inspection scheme prior to the introduction of the Directive. However, directives have to be transposed into national law in each Member State within three years of their publication. Consequently, scope exists for differing interpretations of the intended regulatory requirements such that the goal of harmonisation in terms of approach to clinical research or to standards of GCP is not necessarily achieved (Pinder, 2005).