

# Getting ready for GPP2: the Caudex Medical experience

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## Abstract

**Background:** Caudex Medical, a full-service medical communications agency with a strong heritage in publication planning, had responded to the earlier version of Good Publication Practice (GPP) by developing a written acknowledgments policy.<sup>1</sup> Development of the updated GPP2 meant that an overhaul of processes, including the acknowledgments policy, was required.

**Purpose and objective:** To ensure that the processes necessary to implement GPP2 were in place.

**Methods:** A working group including representatives from medical writing, editing, and account management was convened to discuss the implications of draft GPP2 provisions presented in 2009.<sup>2</sup> The draft guidance was discussed on a topic-by-topic basis and responses agreed. As soon as possible after publication of GPP2, a final meeting was held to review and amend the initial responses against published guidance.

**Results:** Detailed advice, including draft documentation and process instructions, was devised to cover publication responsibilities, disclosures, acknowledgments, and review papers. New working practices were set up for freelance writers and editors, and rigorous standards introduced for documentation. It became apparent that there was a need for training on GPP2 within our own organization and for our clients. The working group responded with a series of internal briefings and by acting as internal 'GPP2 champions'; a training workshop and a consultancy service are available for our clients.

**Conclusion:** Through a systematic approach, we achieved our objective of being ready to implement GPP2. The level of training required was higher than anticipated.

1. van Bueren J, Drake T, Loder P, Marchington J, Deakin C. Taking an Ethical Standpoint: Developing the Caudex Medical Authorship and Acknowledgements Policy. *International Society for Medical Publication Professionals Annual Meeting*, 23–27 April 2007, Philadelphia, USA.
2. Graf C. Good Publication Practice for Communicating Research Sponsored by Pharmaceutical, Medical Device and Biotechnology Companies (GPP2). *International Society for Medical Publication Professionals Annual Meeting*, 20–22 April 2009, Philadelphia, USA.

## Introduction

Following the publication in 2003 of the original guidelines for Good Publication Practice (GPP),<sup>1</sup> Caudex Medical recognized the concerns voiced in the medical and lay press over perceptions of ghostwriting in publications related to the pharmaceutical industry, and responded by developing a written policy to acknowledge the contributions made by the medical communications agency.<sup>2</sup> The policy included two versions of standard wording to be included in peer-reviewed publications for which Caudex Medical had provided assistance (**Box 1**). A presentation of the policy at the 2007 ISMP annual meeting attracted great interest. Although other agencies had devised similar internal policies, putting the acknowledgments policy in writing and employing standardized wording may have enhanced the authority of the Caudex policy and resulted in more ready acceptance of the policy by clients and, consequently, a higher level of adherence.

Early in 2009, Caudex Medical took part in the consultation exercise of the first draft of GPP2, and in April, the draft requirements were presented at the 2009 ISMP annual meeting.<sup>3</sup> Having been made aware of the broad scope of the planned update, it was apparent that revision of the Caudex Medical standard operating procedures (SOPs) was required and that many Caudex clients would also need to update their working practices. We therefore assembled an internal working group to examine the expected requirements of GPP2 and to prepare our responses.

## Methods

The Working Group consisted of the Medical Director (TK), three members of the writing team (AP, HW, PF) a medical editor (LB), and an account manager (SJ). They were subsequently joined by an additional medical writer (JF). The group systematically compared all current Caudex working practices with the draft guidance and subsequently revised procedures. If appropriate, draft documentation was also prepared to help clients to meet the new requirements.

*The authors take full responsibility for the content of the paper but thank Caudex Medical (supported by <sponsor name>) for their assistance in preparing the initial draft of the manuscript and collating the comments of authors and other named contributors.*

OR if acknowledgement of the writer is required

*The authors take full responsibility for the content of the paper but thank <name plus qualifications> (Caudex Medical; \* supported by <sponsor name>) for his/her assistance in preparing the initial draft of the manuscript and collating the comments of authors and other named contributors.*

\*Delete if necessary; †adapt role of writer if necessary.

**Box 1: Acknowledgment statements in existing Caudex policy?**

It became apparent that clients would also need to be aware of the requirements of GPP2 and that many would need to update their standard procedures. We identified a role for Caudex in helping companies to prepare for GPP2 and considered what form this should take.

On publication of the final GPP2 guidelines in November 2009,<sup>4</sup> we reviewed the Working Group outputs against the final guidance and updated as necessary.

## Results

We identified seven areas in the draft guidance for which action would be required (**Box 2**). Each topic was considered separately and reviewed against current practice.

- Publication agreements
- Access to data
- Publication steering committee
- Acknowledgment of contributors
- Conflicts of interest
- Review articles
- Documentation

**Box 2: Areas initially considered by the Working Group**

## Publication agreements

The guidance states that the roles and responsibilities of the author, sponsor, and medical writer should be set out before work commences. We looked at each step in the pathway for manuscript production and identified which party should be responsible for each stage. Draft documentation was created that could serve as a template for our clients to use.

## Access to data

The GPP2 guidelines state that authors and other contributors must be provided with full access to study data, including study protocols, statistical reports, data tables, clinical study reports, and results for posting on clinical trial websites before the manuscript writing process begins. If required, access to raw data or the study database should be provided.<sup>4</sup>

It is not uncommon for agencies to be asked to start writing a manuscript or abstract before the full study report is available. We determined that it could be acceptable for the introduction and methods section to be written from the study protocol without sight of the final data. It may sometimes also be acceptable for a first draft of the results and discussion section to be written on the basis of non-final data tables; however, in this case the text must be cross-checked against and revised using the final data before the manuscript is finalized.

All protocol-determined study endpoints should be made available to authors before review and approval of the final text, normally in the form of the final clinical study report, and any additional data requested by the authors should be provided to them as soon as reasonably possible.

## Publication steering committees

We recommend that steering committees should be limited to no more than eight members, in the interests of efficient decision-making and timely publication. Membership should include a maximum of four investigators, representatives from the sponsor's Clinical department, the publications manager, and a statistician, as well as a designated agency medical writer. For each planned publication, the steering committee would consider the data to be presented, additional analyses that may be used, potential authors, the order and ideal timing of publications, target journals and congresses, and the process for publication delivery. The steering committee would also periodically review the progress of the publication program against its objectives. Membership would be flexible to ensure that the most relevant individuals are involved for each publication.

## Acknowledgments

We determined that the existing Caudex acknowledgment statements would be inadequate to meet the requirements of GPP2. Many people may come into contact with a manuscript during the course of its preparation and we felt it appropriate to distinguish between those who contributed to the content of the manuscript and those who merely acted on the

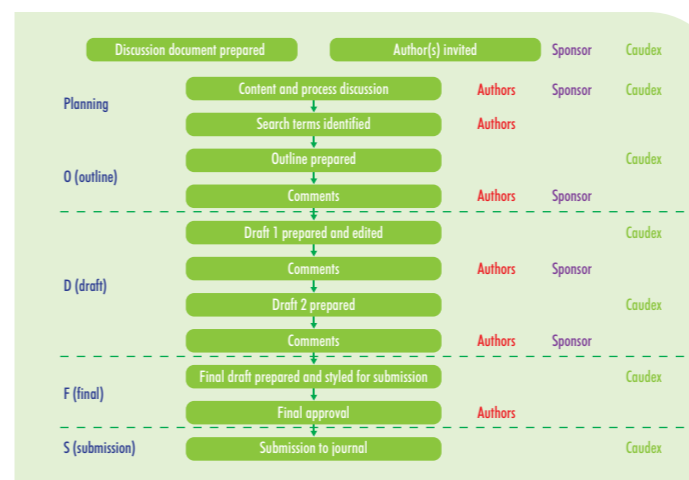


Figure 1: Caudex standard operating procedure for review papers

instructions of another. Freelance medical writers or editors who have contributed to manuscript development should be appropriately acknowledged; the Caudex freelancer policy was updated to ensure that all freelancers are aware in advance of starting work on a project that their name will appear in the final publication and to request details of any conflicts of interest (Col). We also openly advise our clients of the freelance status of any contributors to their projects. For maximum efficiency, we have adapted our SOP to ensure that information on contributors is collected during the course of manuscript production, rather than immediately prior to submission.

## Conflicts of interest

GPP2 recommends full and complete disclosure of both financial and non-financial Col for all publications submitted to journals, abstracts submitted to congresses (at the time of submission if space allows), and posters and oral presentations at the time of presentation, even when such information is not specifically requested. Having reviewed available disclosure forms, we determined that the International Committee of Medical Journal Editors (ICMJE) standard form<sup>5,6</sup> was comprehensive and would be acceptable for most journals and congresses, although if organizations have their own Col forms these would be preferred.

A further advantage of using the ICMJE form was that it would carry greater authority than one without the endorsement of a recognized external body. This is expected to drive greater acceptance by authors unaccustomed to providing extensive Col disclosures.

## Reviews

GPP2 includes provisions for review papers, particularly with respect to selection of data and authorships of reviews. To ensure transparency, we have adapted our SOP to include mandatory consultation with authors regarding literature searches and data selection (**Figure 1**). Although in some cases authors may suggest suitable papers on which to base the review, we recommend an additional literature search to ensure that no important data have been accidentally omitted. Search and selection criteria must be fully documented.

Nevertheless, authors and journal editors have occasionally requested that the medical writer is named as an author rather than a contributor. Such requests are accommodated, provided that the writer feels able to take public responsibility for the content of the manuscript.

## Documentation

The underlying principles of GPP2 include integrity, completeness, and transparency, and full documentation is required to prove that these standards are being followed. Although retention and archiving of project documentation was already standard company procedure, the advent of GPP2 promoted a more systematic approach.

Proprietary publication planning software packages can provide a record of early drafts and reviewer comments, but these are often incomplete and we have therefore devised additional processes for saving all documentation, including e-mails and meeting minutes as well as interim drafts. We also record all reviewer comments received throughout the course of manuscript development and details of how these were addressed.

On project completion, all files are archived electronically and saved for 10 years, or longer on client request.

## Training

Communicating new documentation and processes to internal and external audiences was recognized as central to successful implementation of GPP2. To this end, a series of GPP2 briefings were organized for Caudex staff and the members of the Working Group were identified as 'GPP2 champions' to answer specific queries.

We also devised a training workshop for clients. The majority of clients felt that they had already addressed the requirements of GPP2 in their internal processes, but some have shown interest in a formal training session. The number of formal requests for advice or training has been relatively small (approximately 10 to date), but, on a regular and frequent basis, we have provided unsolicited guidance on aspects of GPP2 to clients who may have otherwise embarked on non-compliant processes. Such informal communications have shown that uncertainty about GPP2 is widespread among our clients, particularly with regard to some of the unstated implications of the guidance. Indeed, we have already accumulated substantial evidence that Caudex expertise in GPP2 has provided a valuable service for clients.

Our experience of working with authors varies. Many academic institutions appear to have been proactive in putting GPP-compliant publication policies in place, and the majority of authors understand their role and the responsibilities it confers. However, some authors are less aware of the guidelines and the requirements for authorship and acknowledgments, and we have needed to advise accordingly.

## Conclusions

By taking a proactive and systematic approach, we have been able to respond rapidly to the published GPP2 guidance and to implement the requirements with minimal delay. The process of discussing the guidance in detail and developing a considered response meant that the Working Group developed a high level of expertise and members are able to advise and guide colleagues, clients, and authors. Caudex clients have a high level of awareness of GPP2 and want to comply with guidelines. However, our experience has shown that many clients remain unclear about the full implications of GPP2 and rely on guidance from their communications agency. Responses to such guidance have been positive.

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## Disclosure

The authors are employed by Caudex Medical Ltd, a medical communications company working with major pharmaceutical companies. The abstract and poster describe Caudex's internal procedures and were produced without reference to or influence by any external company.