This session focused on guidelines that inform about the development of publications. Mark A Bullimore reviewed the importance of good instructions for authors, calling them the “key the orchestra should play in”. He suggested that they should not be long style guides. Instructions for biomedical journals should contain the following minimal ingredients:

- editor’s address
- scope of journal
- language
- number of copies
- contents of cover page
- reference format
- cost to authors
- institutional review board approval requirements
- copyright assignment
- conflict-of-interest statement
- reference to “Uniform Requirements”

Even with excellent instructions, authors often make errors attributable to either ignorance or sloth, Bullimore said. Some common submission errors are, in increasing order of frequency, 4) No conflict-of-interest statement.

2) No electronic copy.
1) References in wrong format, duplicated, or just plain wrong.

Bullimore concluded by praising the newer tools that have improved journal submissions, including electronic appendices, electronic submission and review, new style guides, and reference managers.

Mary D Scheetz, author of the US Office of Research Integrity (ORI) guidance document Managing Allegations of Scientific Misconduct, presented results of a recent study. She surveyed the instructions for authors in the 41 scientific journals that had made corrections after Public Health Service findings of scientific misconduct during 1992-1999. She hypothesized that journals’ instructions might be deficient in communicating their requirements to authors, and she reviewed instructions for the following nine themes:

- authorship
- financial disclosure
- publishing practices
- peer review
- reference practices
- animal and human-subject research
- copyright practices
- issues of concern (scientific misconduct)
- correcting the literature

Her content analysis revealed that of 44 issues surveyed in relation to those themes, only copyright transfer was addressed in over 50% of the surveyed journals. Scheetz reported that only 15% of journals addressed scientific misconduct in their instructions; only 5% indicated that such misconduct would be reported to an authority. Scheetz opined that publication of fraudulent data could be reduced only with good preventive policies that are clearly communicated to authors, including the steps to be taken when misconduct is alleged and the wording of resulting corrections or retractions.

Scheetz concluded that instructions for authors offer journals their opportunity to explain how they will do business. If journals augment their instructions regarding the above nine themes, they will avoid a host of potential problems. Discussion about the usefulness of uniform instructions for authors ensued.

John Tumas, publication manager at AstraZeneca, shared a new policy document, Good Publication Practice: Guidelines for Pharmaceutical Companies (GPP), that was developed by representatives of five companies—AstraZeneca, Aventis, Eli Lilly, Glaxo Wellcome, and Merck (the Working Group)—after a 1998 CBE Airlie House retreat attended by academics, journal editors, and industry. One retreat concern was industry involvement in publication of clinical-trial results, and AstraZeneca’s internal policy was reviewed as an example. The Working Group developed similar guidelines for the pharmaceutical industry that describe common publication standards. GPP recommends following the requirements for authorship issued by the International Committee of Medical Journal Editors and the specific journal where the report will be published, if any. The guidelines also describe avoidance of duplicate publication and the use of unique trial identifiers within a publication. GPP recognizes that when professional medical writers are employed to assist scientists who lack time, expertise, or language skills, authors should determine content, retain responsibility, consult with the writers during drafting, approve the final version, submit the manuscript, and acknowledge the writers’ contribution in the publication. GPP also endorses the need for agreements with clinical-trial investigators about future publication, coordination of multicenter-trial publication, authors’ access to supporting data, and resolution of data interpretation through scientific debate.

The Working Group secured endorsement from its members’ companies, distributed GPP to all major companies for endorsement, and plans to submit the guidelines for publication in a biomedical journal this year. Companies are basing new internal policies on GPP.