

# **FDC Guideline for Manuscript Submission**

Establishment of the Regulations for Manuscript Submission on July 1, 2006

Revised on June 1, 2009

Revised on November 5, 2015

## **Chapter 1 General Provision**

### **Article 1 (Purpose)**

The purpose of this regulation is to set forth overall matters and requirements for the Editorial Board responsible for the publication affairs of the academic journal, 'FDC Regulatory Sciences' (hereinafter referred as the Journal) being published by the Korean Society of Food, Drug and Cosmetics Regulatory Sciences, and for submission and deliberation methods of manuscript to be published in the Journal as well as for the actual publishing of the Journal.

### **Article 2 (Scope and Prohibition of Duplicate Publication)**

The manuscript to be published in the Journal should be related to pharmaceuticals, cosmetics, medical devices and health functional foods. And it should not be posted in duplicate study that has been previously published in other journal or it should not be under consideration for submission or publication elsewhere at the point of submission.

### **Article 3 (Author Qualifications)**

In principle, the author qualification (When there are several authors, to be referred as 1 or more author) is limited to members of the Society, and even if the author is not a member but if the Editorial Board acknowledges the qualification, such a non-member author can submit a study manuscript.

**Article 4 (Copyright)** The Society holds the copyright of a published manuscript.

### **Article 5 (Compliance to the Research Ethics)**

All authors to submit human and animal subject study manuscripts (including a questionnaire survey related manuscript) (including manuscripts related surveys) should obtain the mandatory approval from the Institutional Review Board (IRB) of their affiliations. In addition, a copy of the IRB approval letter should be attached when submitting the manuscript or the IRB approval numbers and related information should be recorded directly in the article.

### **Article 6 (Types and Form of Manuscript)**

The classified types of manuscripts are as follows and they should be prepared in compliance

with the regulations for writing of the Society. The types of a manuscript are as follows;

- 1. Original Articles:** Original articles are the manuscript that contains new knowledge gained in the study with creativity of the author. These articles do not have a required page limit and it is written in the order of Introduction, Methodology, Results and Discussion, Conclusion, and References in order.
- 2. Review Articles:** Review articles summarize many different national or international articles in a comprehensive manner that exhibit the study data and the measurement data
- 3. Short Communications:** Short communications include those summaries subject to prompt presentations by important creativity even before the original article is prepared, or such as academic information and new book reviews.
- 4. Others:** A special article and a special issue editorial are published by the request of the Society, and it does not have to follow the format of research manuscript.

## **Chapter 2 Editorial Board of the Journal**

### **Article 7 (Function of Editorial Board)**

The Editorial Board of the Journal (hereinafter referred as “the Board”) is responsible for invitation to the reviewers who review the article for publishing in the Journal. It is also responsible for publication of the Journal and its distribution.

### **Article 8 (Configuration of the Editorial Board)**

The Board should consist as follows:

1. The Board has each 1 person as Editor-in-Chief and as Managing Editor who will be appointed by the Chief Executive Officer, respectively. Managing Editor or an editing assistant will perform the duties when the Editorial-in-Chief cannot perform given duties due to unavoidable reason,
2. About ten editing assistants should be appointed, and the appointment of the editing assistant as well as the managing editors should be in consultation with the Chief Executive Officer and the Chair of the Board.

## **Chapter 3 Manuscript Submission**

### **Article 9 (Submitting Manuscript)**

Together with the manuscript file intended to submit to the Journal of the Society, a cover letter should be submitted as well. The cover letter should summarize the content and the significance of the manuscript typically limited to 1 page. The submission is to be done via an electronic mail (E-mail: kfdc@hanmail.net), in principle. If the volume of manuscript is

too large to send via E-mail, it should be saved in a CD and can be posted to the Secretariat Office of the Society.

#### **Article 10 (Receipt)**

The Editorial Board should issue a receipt for submitted manuscript by setting the date that the manuscript is arrived as the date of receipt, and should send the receipt by post or via e-mail .

### **Chapter 4 Manuscript Review**

#### **Article 11 (Reviewers)**

The Editorial Board should appoint the reviewers, and the review should be conducted by 2 or more responsible reviewers. However, it should be noted that the reviewer should not review his/her own manuscript and is responsible for complying with the confidentiality in respect to every matters concerning the review.

#### **Article 12 (Adoption of the Manuscript)**

Upon the receipt of manuscript subject to review, the reviewer(s) should perform the review without any delay. And the reviewer(s) should prepare a manuscript review report and send it to the editorial secretary. The Editorial Board should make a decision about adoption of the manuscript taking into account the opinions of the reviewers.

The criteria for manuscript review are follows:

1. Accept: When the content and format of a manuscript do not need to make revision
2. Accept with minor revisions: When the content and format of a manuscript need minor revisions
3. Accept after re-review: When it is determined as the content and format of a manuscript require major revisions
4. Reject: If the content of a manuscript does not comply with the matters prescribed by this regulations or if it is determined as acceptance with minor revisions is impossible or meaningless

#### **Article 13 (Special Contributions)**

Special feature paper or special contribution of a study conducted upon the request of the Society can be exempted from the review.

#### **Article 14 (Publication Confirmation)**

When the entire process of manuscript review is completed and acceptance for publication is once confirmed, the editorial secretary may issue a Certificate of Publication Confirmation to the author. For rejected manuscript, the result should be notified to the

author by specifying the reason for rejection. The author should recognize that there is no conflict caused by the inter-authors interests as well as between the author and the Society, and must sign and submit the Statement of Copyright Transfer. (Attachment Form 1)

#### **Article 15 (Re-submission)**

The time limit of making revisions to the manuscript returned for revisions after being reviewed should be set as 2 months, and if this due time is passed, the returned manuscript should be considered as a new one and should go through re-review.

#### **Article 16 (Rectification)**

The author should be responsible for rectification of the manuscript and should conduct the primarily rectification. In principle, the manuscript for which the review is completed should not be revised or added with new content. When the revision or the addition is unavoidable, it should be reviewed again by the Editorial Board and any cost rising due to such process should be paid by the author. When the rectification is delayed beyond the designated due date, it may be printed by the regulations of the Editorial Board or the publication may be postponed.

### **Chapter 5 Publication of the Journal**

#### **Article 17 (Publication of the Journal)**

The Journal should be published on the basis of publication for twice a year and it should be published on June 30 and on December 31 every year, in principle.

#### **Article 18 (Publication of the Festschrift)**

The Journal can publish as a 'festschrift' that is a collection of writings published in honor of member of outstanding merit by the resolution of the Board of Directors.

#### **Article 19 (Printing of Manuscript)**

The publication of manuscript should be done in the order of submission, in principle. If necessary, the Editorial Board can adjust the order.

#### **Article 20 (Error Correction)**

When the author has found any error after the manuscript is published by the Journal, the author may submit an errata notice within one month. The errata will be published in the next issue for corrections.

### **Chapter 6 Distribution of the Journal**

## **Article 21 (Publication and Submission fee)**

A person who submitted a paper that has been published has to pay a certain amount of publication fee per printed page. The society will distribute 30 copies of pull-out to the corresponding author who has paid the publication fee. Any member who needs more than 30 copies should inform the editorial secretary of the required number of copies and should pay for additional costs involved with the publication. One(1) copy of the Journal should be distributed to every member of the Society as well as to the corresponding authors.

## **Supplementary Provisions**

1. This regulation should be effective from July 1, 2006
2. This regulation should be effective from June 1, 2009
3. This regulation should be effective from January 1, 2016. However, the regulation specified in Article 5 should be effective after July 1, 2016
4. These regulations for manuscript submission may be revised by the Editorial Board.

## **Regulations for Manuscript Preparation**

### **Article 1 (Form of Manuscript)**

A manuscript of an article should be written in the order of Introduction, Methodology, Results and Discussion, Conclusions, Acknowledgements and References, if possible.

### **Article 2 (Title, Author, Affiliation)**

On the cover page of the manuscript, Study title, author and affiliation should be written in the order of Korean and English and placed before the main text, but if the manuscript is written in English, it does not need the Korean Title. The title should be written as simple as possible, and if there are 2 or more authors, the mark “†” should be on the name of corresponding author in respect to the paper.

Safety and Quality Evaluation of DNA Vaccines

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### **Article 3 (Abstract)**

The abstract both in Korean and English in an orderly manner should be attached following the title, author, affiliation and address, but if the manuscript is written in English, it does not need the Korean abstract. Abstract should be limited to one(1) page with summarized points of the study's objective, results, etc. The key words should be written by a word for no more than 5 key words as many as possible.

### **Article 4 (Introduction, Methodology Results and Discussion, Conclusions, Acknowledgements)**

The main text of a manuscript will be prepared according to the following editing format as possible.

I. II. III. Main Text (Large)

1. 2. 3. Main Text (Medium)

1.1 1.2 1.3 Main Text (Small)

1.1.1 1.1.2 ... Main Text (Smallest in Small) (Font: Sinmyeongjo, Size: 10.5)

### **Article 5 (Notes)**

Any description other than the references should be listed as notes.

1. Footnote: Letter (Font: Sinmyeongjo, Size: 9), Paragraph (Line Spacing: 140)

2. The number of footnotes in the text should be indicated in the form of a), b) and c), and the text of footnote should start after having a space. And it should be aligned vertically.

### **Article 6 (References)**

The literatures quoted in the manuscript should be numbered in serial in the order of appearance in the main text. Arabic numerals should be marked on the right upper side and bracket should be closed. When quoting the same literature for 2 or more times, it should use the initial number. The papers in progress of submission and non-presented paper can be listed in the references. 'In press' should be marked behind the author and the paper title. The indication of the literatures should be written in the order of the author name, paper title, name of magazine (in *Italic* Font), volume (Gothic Font), the first page-the last page

and the year. Citations of references in the text should be expressed in superscript Arabic numerals described in the reference list.

#### 1. Citations of a book

Author, title of book, place of publication, publisher, the first page -the last page (Year)

e.g. 1) Hong GD, Environmental law, Seoul, Joongang Publishing Company, pp. 126-135 (2002)

e.g.) B.W. Barry, *Dermatological Formulations*, New York, USA, Marcel Dekker, pp. 55-80 (1993)

#### 2. Citation of papers in an edited book

Author(s), Title, Title of the Edited Book, Ed, Name of Editing Author, Place of Publication, Publisher, pp.~ ( or S,~) (year).

※ The names of a dissertation book and an edited book should be written in *italic*

e.g. 1) C.G Pitt and A. Shindler, *Biodegradation of polymers: In Controlled Drug Delivery*, Vol. 1, S.E. Bruck (Ed.), Florida, U.S.A., CRC Press, pp. 55-80 (1993)

#### 3. Citation of Periodicals

Journal Articles: author name, title. journal name (in *italic* Font), volume(issue) number: the first page number-the last page number. (year of publication).

※ Volume(issue) number should be written in Bold Font

e.g. 1) Jeong-Ja Lee, Myeong-Gyu Lee, Comparison of Domestic and International Regulatory Status on Cosmetics, *Journal of the Korean Society of Pharmaceutical Regulatory Science*, 3(1-2), pp. 57-70 (2008)

2) C-K. Shim, B.-H. Jung, Noncontribution of enterohepatic recycling to multiple plasma peaks of acetaminolben in rats, *Int. J. Pharm.*, 83, pp. 257-252 (1992).

#### 4. Abstract and proceeding

e.g. 1) Y.J. Yang and I.K Chun, Stability of [D-ala2]-methionine enkephalinamide in aqueous solution, Abstracts, 21st Annual Academic Convention, Korean Society of Pharmaceutics, pp. 43 (1991).

2) S. Keramidas, Global trends and future challenges in the biopharmaceutical sector: The critical role of the regulatory profession, Proceeding of the 2009 International Conference on Innovative Strategy on the Improvement and Globalization of Pharmaceutical, Seoul, Korea, The Korean Society of Pharmaceutical Regulatory Sciences, pp. 65-93 (2009)

#### 5. Citation of Dissertations or theses

Author name. title. Dissertation for Ph. D. OO University, (year) ~ page

e.g. 1) H.-K. Tan, Studies on sustained release of ranitidine hydrochloride matrix tablets, M.S. Thesis for Pharmacy, Sungkyunkwan University (1989).

6. Footnote for case citation should be in compliance with the method of "Law Reports " issued by the court administration office (Supreme Court. 1997.11.8 Decision 97 Da 118) and "Supreme Court Reports" (Dapan 1997.11.8 Decision 97 Da 118) issued by the court administration office.

#### 7. Paper under printing

e.g.) K.D. Park, S.Y. Jeoung and Y.H. Kim, Hydrogels for drug delivery system: Colon-specific delivery, J. Kor. Pharm. Sci., In press.

8. Paper submitted but not determined for acceptability of publication officially yet.

e.g.) S.-C. Chi, submitted for publication in J. Kor. Pharm. Sci.

9. Unpublished paper

e.g.) K. H. Park “unpublished results”

#### **Article 7 (Tables)**

Tables should be prepared separately or inserted in the text. Each table should be marked with serial number as Table 1, 2 and 3. The title should be written in English or in Korean. Necessary description should be added under the transverse line at the bottom. Any longitudinal lines should not be used as much as possible

#### **Article 8 (Figure, Flow Chart and Structured Equation)**

Figures are numbered consecutively using odd numbers as possible. Figures may be prepared in separate files, or may be embedded in the main text of the manuscript

Figure 1, 2, 3 · Picture 1, 2, 3 · Scheme I. II. III.

#### **Article 9 (Specifying the Source Data)**

When citing tables and figures from other literatures or other data, the source should be specified.

#### **Article 10 (Others)**

When the main text is written consecutively, the material of the aforementioned text will be described as the footnote of the title of table. Description of matters other than the literatures will be based on footnotes. The others should follow the system of the latest issues of the Journal.

### **Supplementary Provisions**

1. This regulation should be effective from July 1, 2006
2. This regulation should be effective from June 1, 2009
3. This regulation should be effective from January 1, 2016.
4. These regulations for manuscript submission may be revised by the Editorial Board.

**(Attachment Form 1)**

**Statement Copyright Transfer**

Herewith, the authors listed below agree to the transfer of copyrights in every form to the Korean Society of Food, Drug and Cosmetic Regulatory Sciences when the following manuscript submitted is published.

**Date:**

**Title of Manuscript** (To be prepared both in Korean and English. But if the manuscript is written in English, it does not need the Korean abstract)

Korean:

English:

**Signature of Author** (Names of all authors should be written both in Korean and English and to be signed respectively)

Name in Korean	Name in English	Signature
The 1 <sup>st</sup> Author		
The 2 <sup>nd</sup> Author		
The 3 <sup>rd</sup> Author		
The 4 <sup>th</sup> Author		
The 5 <sup>th</sup> Author		
The 6 <sup>th</sup> Author		
The 7 <sup>th</sup> Author		
The 8 <sup>th</sup> Author		
The 9 <sup>th</sup> Author		
The 10 <sup>th</sup> Author		

If there are more co-authors, add them to the list