BUSINESS EXCELLENCE CONSULTING Inc.

*Passion for Quality*

## TRAINING TITLE:

How to Write Effective Regulatory Documents (WORK-007)

## OVERVIEW:

There have been several Form 483's and Warning Letters being issued to companies by the FDA as it relates to various regulatory documents because of confusing or incomplete information in such documents. All regulatory documents must be clear, concise, coherent, self-explanatory, and grammatically correct, among other characteristics. The purpose of this workshop is to help authors and reviewers of regulatory documents to improve the quality of those documents. It will benefit any personnel who write or approve regulatory documents, such as SOPs, work instructions, policies, validation protocols, batch records, DMRs, annual product reviews, and so on. Effective writing of those documents will avoid situations that could end up in opening CAPA investigations or any other regulatory action.

## TARGET GROUP FOR THE TRAINING:

This workshop will benefit manufacturers of FDA-regulated products in documenting their regulatory documents in order to avoid FDA or other regulatory bodies' inspection findings in such documents. It will be a great resource to Quality Assurance, Manufacturing, Regulatory Affairs, Supplier Quality and Quality Control personnel and management within the Pharmaceutical, Biotechnology and Medical Device companies.

## LEARNING OBJECTIVES:

Upon completing this workshop, participants will be able to:

- Compose an effective regulatory document to optimize understanding and clarity
- Avoid writing errors

## MATERIALS:

Each participant will receive:

- MS PowerPoint presentations
- Certificate of Attendance
- Final Exam (70% minimum score required to approve the course

## TRAINING DURATION:

14 contact hours

ACCREDITED IACET PROVIDER

BEC is authorized by IACET to offer
1.4 CEUs for this program.
FULL attendance to the learning event
is mandatory to receive CEUs.

## COURSE INSTRUCTOR:

**Manuel E. Peña-Rodríguez** is a process improvement and training consultant within the textiles, electronics, and FDA-regulated industries with more than 20 years of experience in those fields. Since January 2006, he is fully devoted to consulting under Business Excellence Consulting Inc, focusing on training and implementation of Lean Six Sigma initiatives and CAPA / Root Cause Analysis workshops. He also serves as professor in the graduate program in biochemistry at the University of Puerto Rico, Medical Sciences Campus, in San Juan. Manuel received his J.D. degree from the Pontifical Catholic University of Puerto Rico and his master's of engineering in Engineering Management from Cornell University in Ithaca NY. He is also a licensed Professional Engineer registered in Puerto Rico. Manuel is an ASQ Certified Six Sigma Black Belt, Manager of Quality & Organizational Excellence, Quality Engineer, Quality Auditor, Biomedical Auditor, and HACCP Auditor. He is also a Senior member of ASQ and former Chair of the Puerto Rico ASQ Section. He is the author of the book "*Statistical Process Control for the FDA-Regulated Industry*", published by ASQ Quality Press in April 2013 and co-author (with José Rodríguez-Pérez) of the article "*Fail-Safe FMEA*" published in the January 2012 edition of the ASQ Quality Progress magazine.

**Arlene Delgado Velázquez** is a training consultant within the FDA-regulated industries and educational sectors with over 20 years of experience. She has a Bachelor Degree in Industrial Microbiology from the University of Puerto Rico, at Humacao Campus. She also has a Master Degree in Industrial Engineering in Manufacturing Competitiveness and Quality Management from the Polytechnic University of Puerto Rico, in Hato Rey, P.R. Since year 2013, she is fully devoted to consulting under Business Excellence Consulting Inc, focusing on training on related Quality sectors. She also serves as professor in the Humacao Community College for Biology, Biotechnology, Microbiology and Validation, and GMP courses. She is an ASQ Certified Six Sigma Green Belt, Manager of Quality & Organizational Excellence and Certified Quality Auditor.

**Solmarie Vélez Rivera** is a training consultant within the FDA-regulated industries with over 20 years of experience. She has a Bachelor Degree in Industrial Engineering from the University of Puerto Rico at Mayaguez Campus. She also has a Master Degree in Business Adminitration from University of Phoenix, Puerto Rico Site. Since year 2013, she is fully devoted to consulting under Business Excellence Consulting Inc, focusing on training on ASQ Certified Quality Auditor Academia, Internal Audits Program, Quality Systems Regulations (21CFR820), CAPA, Root Cause Analysis, Technical Writing, and other topics. She is an ASQ Certified Quality Auditor, Manager of Quality & Organizational Excellence, Biomedical Auditor, and HACCP Auditor.

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**Title:** How to Write Effective Regulatory Documents (Day 1)

**Lunch** from 12:00 – 13:00.

**Coffee break**: 15 min. each during morning and afternoon session. Time schedule are rough estimates and may vary consequently.

| **Agenda** | |
|---|---|
| 8:30 – 9:00 | **Opening Remarks** |
| 9:00 – 10:15 | **Measures of Excellence**<br>• Documentation Style Manual<br>o Abbreviations<br>o Numbers and Numerals<br>o Dates and Times<br>o Symbols |
| 10:15 – 10:30 | **Break** |
| 10:30 – 12:00 | **Measures of Excellence (cont.)**<br>• Documentation Style Manual<br>o Punctuation<br>o Capitalization<br>o Bold and Italics<br>o Lists<br>o Grammar and Usage<br>o Correct and Preferred Usage of Words |
| 12:00 – 13:00 | **Lunch** |
| 13:00 – 14:00 | **Sentence Construction**<br>• Imperative Sentences<br>• Active vs. Passive Sentences<br>• Subject-Verb Agreement<br>• Transition Words |
| 14:00 – 15:00 | **Writing Basics**<br>• Writing for Clarity<br>o Avoiding the Passive Voice<br>o Being Positive<br>o Removing Gender Bias |
| 15:00 – 15:15 | **Break** |
| 15:15 – 17:00 | **Writing Basics (cont.)**<br>• Writing for Economy<br>o Cutting Who, Which, and That<br>o Cutting Redundancy |

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**Title:** How to Write Effective Regulatory Documents (Day 2)

**Lunch** from 12:00 – 13:00.

**Coffee break**: 15 min. each during morning and afternoon session. Time schedule are rough estimates and may vary consequently.

| **Agenda** | |
|---|---|
| 8:30 – 10:15 | **Writing Basics (cont.)**<br>• Writing for Readability<br>o Replacing Long Words<br>o Breaking Long Sentences |
| 10:15 – 10:30 | **Break** |
| 10:30 – 12:00 | **Writing Effective Documents**<br>• Writing Styles<br>• Executive Summary<br>• The Writing Process<br>• Things to Avoid |
| 12:00 – 13:00 | **Lunch** |
| 13:00 – 15:00 | Hands-on Practice With Participant's Documents |
| 15:00 – 15:15 | **Break** |
| 15:15 – 17:00 | Hands-on Practice With Participant's Documents |