BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

21 CFR 211 (WORK-015)

OVERVIEW:

Manufacturers must establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. The quality systems for FDA-regulated products (food, drugs, biologics, and medical devices) are known as current good manufacturing practices (CGMP's). The 21 CFR Part 211 contain the minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a finished pharmaceutical product to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess. In this workshop, all parts of the regulations set forth in the 21 CFR 211 will be reviewed and discussed in detail.

TARGET GROUP FOR THE TRAINING:

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

LEARNING OBJECTIVES:

Upon completing this workshop, participants will be able to:

- Identify the most up-to-date information and interpretation on the 21 CFR 211 regulation, and how compliance with the regulation is determined
- Improve confidence in preparing for, and hosting of an FDA inspection

MATERIALS:

Each participant will receive:

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

TRAINING DURATION:

7 contact hours

ACCREDITED IACET PROVIDER

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

COURSE INSTRUCTOR:

Pepe Rodríguez is founder and President of Business Excellence Consulting Inc., a leading Puerto Rican training and consulting organization. From 2009-11 he served as a Science Advisor for the FDA San Juan District. He has served as instructor of courses on quality and continuous improvement in several countries with thousands of professionals trained in topics such as Quality Engineering, Six-Sigma, Effective CAPA and Root Cause Analysis, HACCP and Quality Management. Pepe holds a bachelor's degree in biology and PhD in immunology, both from the University of Granada, Spain. He served as a senior member of the American Society of Quality and President of the Puerto Rico (ASQ 1500) section during the period 2003-05. He was secretary from 2005-2012. He is also a member of the Regulatory Affairs Professional Society (RAPS), ISPE, AAMI, and the Parenteral Drug Association (PDA). Pepe is also the author of the best-selling books "CAPA for the FDA-Regulated Industry", "Quality Risk Management in the FDA-Regulated Industry", and "The FDA & Worldwide Current Good Manufacturing Practices and Quality System Requirements Guidebook for Finished Pharmaceuticals", published by the American Society for Quality.

Gloryvee Maldonado Pérez is a training consultant within the FDA-regulated industries with more than 10 years of pharmaceutical and medical devices industry experience, in the areas of quality assurance, quality control, regulatory, validation, manufacturing, and packaging. She has a Bachelor Degree in Chemistry from the University of Puerto Rico at Rio Piedras Campus. She also has a Master of Science in Manufacturing Competitiveness, with a specialization in pharmaceutical products, from the Polytechnic University of Puerto Rico in Hato Rey, P.R. Since year 2012, she is fully devoted to consulting under Business Excellence Consulting Inc, focusing on training on related Quality sectors. She is an ASQ Certified Six Sigma Black Belt, and Certified Quality Engineer. She is also a CAPA System Expert Investigator and ISO 13485 Lead Auditor.

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.

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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 – 9:45	**U.S. FDA Overview** • FDA Laws and Regulations • FDA Guides and Guidances
9:45 – 10:15	**21 CFR Part 211** **Subpart A--General Provisions** o § 211.1 - Scope. **Subpart B--Organization and Personnel** o § 211.22 - Responsibilities of quality control unit. o § 211.25 - Personnel qualifications. o § 211.28 - Personnel responsibilities. o § 211.34 - Consultants.
10:15 – 10:30	**Break**
10:30 – 11:15	**Subpart C--Buildings and Facilities** o § 211.42 - Design and construction features. o § 211.44 - Lighting. o § 211.46 - Ventilation, air filtration, air heating and cooling. o § 211.48 - Plumbing o § 211.50 - Sewage and refuse o § 211.52 - Washing and toilet facilities o § 211.56 - Sanitation o § 211.58 - Maintenance
11:15 – 12:00	**Subpart D--Equipment** o § 211.63 - Equipment design, size, and location. o § 211.65 - Equipment construction. o § 211.67 - Equipment cleaning and maintenance. o § 211.68 - Automatic, mechanical, and electronic equipment. o § 211.72 - Filters.

12:00 – 13:00	**Lunch**
13:00 – 14:00	**Subpart E--Control of Components and Drug Product Containers and Closures** o § 211.80 - General requirements. o § 211.82 - Receipt and storage of untested components, drug product containers, and closures. o § 211.84 - Testing and approval or rejection of components, drug product containers, and closures. o § 211.86 - Use of approved components, drug product containers, and closures. o § 211.87 - Retesting of approved components, drug product containers, and closures. o § 211.89 - Rejected components, drug product containers, and closures. o § 211.94 - Drug product containers and closures. **Subpart F--Production and Process Controls** o § 211.100 - Written procedures; deviations. o § 211.101 - Charge-in of components. o § 211.103 - Calculation of yield. o § 211.105 - Equipment identification. o § 211.110 - Sampling and testing of in-process materials and drug products. o § 211.111 - Time limitations on production. o § 211.113 - Control of microbiological contamination. o § 211.115 - Reprocessing. **Subpart G--Packaging and Labeling Control** o § 211.122 - Materials examination and usage criteria. o § 211.125 - Labeling issuance. o § 211.130 - Packaging and labeling operations. o § 211.132 - Tamper-evident packaging requirements for over-the-counter (OTC) human drug products. o § 211.134 - Drug product inspection. o § 211.137 - Expiration dating.
14:00 – 15:00	**Subpart H--Holding and Distribution** o § 211.142 - Warehousing procedures. o § 211.150 - Distribution procedures. **Subpart I--Laboratory Controls** o § 211.160 - General requirements. o § 211.165 - Testing and release for distribution. o § 211.166 - Stability testing. o § 211.167 - Special testing requirements. o § 211.170 - Reserve samples. o § 211.173 - Laboratory animals. o § 211.176 - Penicillin contamination.

15:00 – 15:15	**Break**
15:15 – 17:00	**Subpart J--Records and Reports** o § 211.180 - General requirements. o § 211.182 - Equipment cleaning and use log. o § 211.184 - Component, drug product container, closure, and labeling records. o § 211.186 - Master production and control records. o § 211.188 - Batch production and control records. o § 211.192 - Production record review. o § 211.194 - Laboratory records. o § 211.196 - Distribution records. o § 211.198 - Complaint files. **Subpart K--Returned and Salvaged Drug Products** o § 211.204 - Returned drug products. o § 211.208 - Drug product salvaging.