

2-day In-person Seminar:

SOP Writing, Training and Compliance in the Pharmaceutical Industry

-  Washington, DC
-  October 22nd & 23rd, 2018
-  8:30 AM to 4:30 PM



Michael Esposito

*Principal, TrainReach Consulting,
LLC & Life Science Training Institute*

Michael Esposito has over 30 years experience in the pharmaceutical industry and 17 years experience in GMP training and document management. He has worked for Wyeth Pharmaceuticals, Pfizer and Johnson & Johnson's Consumer Healthcare Division in a variety of areas including Packaging, project administration, Quality Assurance, Government Contracts, translations, systems training, and international operations. He collaborated in the development and implementation of the training portion of the Consent Decree workplan for Johnson & Johnson Consumer Healthcare and revised their introductory GMP course. He is a member of the training organizations GMP Training Educators Association and Association for GXP Excellence, and is fully fluent in Spanish.

Overview :

Standard Operating Procedures (SOPs) are the basis for a large part of the day-to-day training that most pharmaceutical employees are required to perform, and are a vital component of ensuring compliance with regulatory agency requirements for pharmaceutical manufacturing.

Pharmaceutical employees often do not realize that by putting their processes in writing, they are making commitments to regulatory agencies. To achieve the goal of an SOP that has adequate but not excessive detail, the course will define the parameters of an effective SOP and provide a solid foundation that will have a positive impact on training and job performance. Conversely, the negative impact of poorly written procedures on production and compliance will also be explored. To achieve these ends, the course will explain the use of process excellence tools, as well as interaction with the SOP process owner and/or author to create a robust process and procedure. In addition, the course will demonstrate how to avoid common pitfalls in revising existing procedures.

Price

Price: \$1,295.00

(Seminar for One Delegate)

Register now and save \$200. (Early Bird)

Register for 5 attendees

Price: \$3,885.00 You Save: \$2,590.0 (40%)*

~~\$6,475.00~~

Register for 10 attendees

Price: \$7,122.00 You Save: \$5,828.0 (45%)*

~~\$12,950.00~~

ENROLL

***Please note the registration will be closed 2 days
(48 Hours) prior to the date of the seminar.*

Agenda:

Day One

Registration Process - (8:30am - 9:00am)

Session will begin by - (9:00am)

8:30-8:59 Registration, Meet & Greet.

9:00 - 10:00

Lecture 1:

- Seminar objectives review, expectations and scope.
- Interview attendees re their specific responsibilities and needs
- Agreement on focus

10:00 - 11:00

Lecture 2:

- Regulatory requirements for SOPs
- What commitments you make when you put your process in writing
- Consequences of noncompliance
- Review or knowledge check

12:00 - 1:00 Lunch

1:00 - 2:00

Lecture 4:

- Using process excellence tools to create a robust process and procedure
- Brief process excellence exercise using areas of expertise in room

2:00 - 3:00

Lecture 5:

- Pulling out the process from process owners and subject matter experts
- Simulation of interview with stakeholders
- Revision of procedures - avoiding pitfalls
- Brief exercise to revise a process

3:00 - 4:00

Lecture 6:

- Keeping training in mind while writing procedures
- Simulation of a discussion between training and documentation
- Attendee practice

4:00 - 4:30

Lecture 7:

- Knowledge check for day

Day Two

8:30-8:59 Registration, Meet & Greet.

9:00 - 10:00

Lecture 1:

- Seminar objectives review, expectations and scope.
- Review of Day 1 topics, feedback and conclusions

10:00 - 11:00

Lecture 2:

- Relationship between SOPs and training curricula
- Basics of training curricula
- Structuring courses and modules
- Demo of creating a curriculum with existing SOPs

11:00 - 12:00

Lecture 3:

- Exercise in creating training curricula with existing SOPs - breakout groups and flip charts
- Group review

12:00 - 1:00 Lunch

1:00 - 2:00

Lecture 4:

- Curriculum completion and qualification to perform tasks
- Special circumstances of systems training roles and curricula
- Demo and practice of evaluating qualification

2:00 - 3:00

Lecture 5:

- Measurement of SOP and training effectiveness (e.g. knowledge assessment questions)
- Tools in Learning Management Systems (LMSs)
- How you as an SOP writer can access these tools
- Exercise in evaluating training data

3:00 - 4:00

Lecture 6:

- Course review
- Questions and feedback

4:00 - 4:30

Lecture 7:

- Knowledge assessment

Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

- 1 Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
- 2 Check: Kindly make the check payable to NetZealous DBA GlobalCompliancePanel and mailed to 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
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What You will get

- 1 Learning Objectives
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Contact Information: Event Coordinator

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

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