Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

Quality System Regulations for Drugs, Devices,and Tablets and How to generate your DMF

Jerry Dalfors

April 2nd & 3rd, 2015

Seattle, WA

9 AM to 6 PM

Course "**Quality System Regulations for Drugs, Devices, and Tablets and How to generate your DMF**" has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.



SPEAKER

Jerry Dalfors Principal, JD Technologies and Coaching

Mr. Jerry Dalfors has extensive (40+ years) of business administration, consultative, technical and managerial experience in the development and manufacture of highly regulated biopharmaceutical products including injectables, biologics, medical devices and oral dosages. He has held permanent employee, temporary employee and company representative management positions with a multitude of the major pharmaceutical and biotechnology companies in the US. He has worked with or assisted more than two dozen companies with the establishment of controlled document/quality systems.

OVERVIEW

Primary Student Objectives - General High Level Topics where we will move down to very specific discussion and details to generate a much higher comprehension for quality individuals even though during this course you will not have to take a final exam! Upon completing this course participants will gain a much better Quality Systems comprehension, based on the instructor's decades of experience helping generate quality system regulations, working with the FDA, fixing FDA findings and generating a synergistic discussion with the attendees to help us all make sure we understand that there is rarely ever on "one" way to do things or "right and wrong".

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AGENDA

DAY ONE

Lecture 1: Job Functions

Lecture 2: Quality Systems

Lecture 3: Quality Compliance

Lecture 4: Method Development and related activities associated with Technology Transfer - Quality Testing as well as Production

Lecture 5: Validation, Verification and on-going Cost Savings programs to generate Continuous Quality Improvement

Lecture 6: How to ensure an inspector is impressed while doing his/her inspection based on what the instructor helped with generating the quality systems inspector training - each student will get a copy of the workbook to be able to get their company in quick compliance.

DAY TWO

Lecture 1: Continued portion of 6 to ensure Quality Assessments are occurring in compliance with QSIT (statistics, incident tracking, 6 Sigma, audits, lab tests, inspections, document control, etc.)

Lecture 2: Quality Agreement regulatory requirements and vendor inspections

Lecture 3: Ensuring that all the above topics generate the proper "legal documents" that must be in compliance with the company's specific GDP requirements

Lecture 4: Regulatory requirements for setting up Procedures and BPRs / DHRs including the Master Records to make sure we are minimizing operator error and making the Document Review process more effective and cheaper prior to Product Release

Lecture 5: Using all the above to make adjustments to the company's regulatory submissions and the related DMF when applicable.

WHO WILL BENEFIT:

- Senior Quality Managers
- Quality Professionals
- Regulatory Professionals
- Compliance Professionals
- Production Supervisors
- New FDA Inspectors
- Manufacturing Engineers
- Production Engineers
- Design Engineers
- Process Owners
- Quality Engineers
- Quality Auditors
- Document Control Specialists
- Record Retention Specialists

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Pricing List

Price for One Delegate pass Price: $1,295.00

Register now and save(Early Bird) **$200.**(Early Bird) Price

Register Now

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

Group participations

Get fabulous discounts by participating in groups of two or more.

No	Attendees	Discount
1	2 Attendees	10% off
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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 Team
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