Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

CE Mark Certification: Compile a CE Marking Technical File (or Design Dossier for Class III) containing evidence of compliance to the Medical Devices Directive (or the IVD/AIMD Directives) - Impact of the MDR for Europe

Zurich, Switzerland

November 29th & 30th, 2018

9:00 AM to 5:00 PM

Price

Price: **$1,895.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **$5,685.00** You Save: $3,790.0 (40%)*

~~$9,475.00~~

Register for 10 attendees

Price: **$10,422.00** You Save: $8,528.0 (45%)*

~~$18,950.00~~

ENROLL

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

David R. Dills

Global Regulatory Affairs & Compliance Consultant and President, NovaQual

David R. Dills, Global Regulatory Affairs & Compliance Consultant, Interim President, currently provides global regulatory affairs, compliance and quality consultative services for early-stage and established Class I/II/III medical device, including combination products, In Vitro Diagnostics, nutraceuticals/supplements, cosmetics and biopharmaceutical manufacturers in multiple medical specialties and therapeutic areas on the global landscape, and has an accomplished record with more than 26 years of experience in the areas of Regulatory Affairs, Compliance and Quality Systems. He has been previously employed, with increasing responsibilities, by medical device manufacturers and consultancies, including a globally recognized CRO, and has worked directly with manufacturers engaged in compliance remediation activities and services involving consent decrees, CIA's, warning letters,483 observations, and customer generated compliance events.

Why you should attend

- Introductions and Overview of the EU Directives
- Identify the EU Directives and standards applicable to your product
- Comply with the implementation details and requirements of the EU MDR & IVDR
- Design a new product, or evaluate an existing product, for conformity with these Directives and standards
- Conduct and document a detailed Hazard Identification and Risk Assessment of your product
- Complete the necessary Technical File and documentation required to meet EU legal requirements
- Understand the relationship between CE Marking requirements
- Determine exactly which materials need to be compiled
- Completely review all existing documentation in support of meeting the applicable Essential Requirements of the Directive(s)
- Evaluate and identify gaps or deficiencies in your documentation

Agenda:

Day One

Lecture 1: Technical File/Design Dossier/CE Mark

- Introduction and Overview
- Impact of the new MDR
- Directive 90/385/EEC covering active implantable medical devices
- Directive 93/42/EEC covering medical devices
- Directive 98/79/EEC covering in vitro diagnostic medical devices
- Introduction to the "Players:" The Medical Device Manufacturer, Competent Authority, Notified Body and the Authorized Representative
- Identify applicable legislation and requirements
- Confirm Medical Device Status and Class
- Identify and Meet Essential Requirements
- Technical Documentation
- Identify the appropriate route to conformity
- Assess for conformity
- Create and compile a Technical File and Design Dossier
- Declare conformity and CE Marking/Declaration of Conformity
- The EU "New Approach" Directives, and manufacturer's responsibilities
- CE Assessment Process: Overview
- CE Assessment Process: Detailed Compliance
- Identification of applicable Directives
- Identification of applicable Standards
- EU standards and the "presumption of conformity"
- Preparation of Technical File and Design Dossier
- Product markings, instructions, labels, warnings and languages
- Declaration of Conformity and the CE Mark

Who will benefit:

Personnel who want to know all aspects of the CE Mark, Technical File and Design Dossier and the impact from the new MDR for EU. Medical device professionals in areas of quality and regulatory affairs, design, risk management, postmarket activities, R&D, and manufacturing, who work for manufacturers that market devices in the EU. Employees and personnel who will benefit include:

- All levels of management and departmental representatives any anyone who desire a better understanding or a "refresh" overview of MDD/AIMDD/IVDD and compiling the documentation

Day Two

Lecture 2: Technical File/Design Dossier/CE Mark

- Confirm the technical documentation requirements as specified in the Directive
- Interpret the general requirements of the Directive using relevant and harmonized standards together with various European & GHTF guidance documents for specific products
- Define the process enabling the creation and maintenance of compliant technical files and design dossiers
- Explain the Notified Body certification process and level of response required to questions and nonconformities raised
- Technical File requirements for CE marking to the current Medical Device Directives and the key changes with the new MDR Clinical Evaluation
- Updated requirements for content
- Risk Assessment
- Not all reviews are the same
- Changes affecting Technical files in the new Medical Device Regulation
- How to incorporate the new EU requirements with existing STED format
- Structure, layout and contents of Technical File including MDR requirements
- Gap Assessment for Technical Files and Design Dossier
- Review Technical Files and Dossier Dossiers
- New MDR (Medical Device Regulations) and impact for In Vitro Diagnostics and Medical Devices
- References and Guidance
- Industry Trends

Lecture 3: Consulting Case Study Practice

- Participants role play consulting with instructor on CER examples
- Ensure continuing compliance throughout device lifecycle

Lecture 4: Case Study Practice

- Practice on a project relevant to participants' organization

Best Practices and Trends

Lecture 5: Interactive Exercises and Discussions

- Case studies
- Examples
- FAQ's
- Q&A

Questions and Summary

Recap of Day 2

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
3. PO: Please drop an email to support@globalcompliancepanel.com or call the our toll free +1-800-447-9407 for the invoice and you may fax the PO to 302 288 6884
4. Wire Transfer: Please drop an email to support@globalcompliancepanel.com or call our toll free +1-800-447-9407 for the wire transfer information

What You will get

1. Learning Objectives
2. Participation certificates
3. Interactive sessions with the US expert
4. Post event email assistance to your queries.
5. Special price on future purchase of web based trainings.
6. Special price on future consulting or expertise services.
7. Special price on future seminars by GlobalCompliancePanel.
8. Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
9. Networking with industry's top notch professionals

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

GlobalCompliancePanel